9500 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Magnetic resonance guided focused ultrasound surgery for palliation of painful bone metastasis: Results of a multicenter phase III trial.

Mark Hurwitz, Joshua E. Meyer, Dimitri Iozeffi, Pejman Ghanouni, David Gianfelice, Fiona M. Fennessy, Abraham Kuten, Suzanne LeBlang, Anne C. Roberts, Junsung Choi, Alessandro Napoli, Vladimir Turkevich, Clare M. Tempany, Yael Inbar, Raphael M. Pfeffer, James Mitchell Larner, Sergy Kanaev; Thomas Jefferson University and Hospitals, Philadelphia, PA; Fox Chase Cancer Center, Philadelphia, PA; Rostov Scientific Research Institute of Oncology, Rostov-on-Don, Russia; Stanford University, School of Medicine, Stanford, CA; University Health Network, Toronto, ON, Canada; Dana-Farber Cancer Institute/Brigham and Women's Hospital/Harvard Medical School, Boston, MA; Rambam Health Care Campus, Haifa, Israel; University MRI, Boca Raton, FL; University of California, San Diego, San Diego, CA; H. Lee Moffitt Cancer Center & Research Institute, Tampa, FL; University of Rome, Rome, Italy; N. N. Petrov Research Institute of Oncology, St. Petersburg, Russia; Chaim Sheba Medical Center, Ramat Gan, Israel; Chaim Sheba Medical Center, Ramat-Gan, Israel; University of Virginia, Charlottesville, VA

Background: Pain due to bone metastases is a common cause of cancer-related morbidity. Magnetic resonance guided focused ultrasound surgery (MRgFUS) is a non-invasive approach to thermal tissue ablation. This multi-center phase III trial assessed efficacy of MRgFUS compared with sham treatment to alleviate pain due to bone metastases. **Methods:** Subjects with a painful bone metastasis amenable to MRgFUS treatment for whom radiation therapy was ineffective or contraindicated were randomized 3:1 to MRgFUS or sham treatment in a single blind design. Un-blinding of sham subjects who did not experience significant pain relief within 2 weeks was permitted with crossover allowed to salvage MRgFUS treatment. Pain response and impact on quality of life (QOL) were assessed using the numerical rating scale (NRS) and Brief Pain Inventory-Quality of Life (BPI-QOL). Safety was also assessed. **Results:** 142 randomized subjects were included in an intent-to-treat analysis. 67% (95%CI: 57.5-76.0%) of 107 subjects in the MRgFUS arm experienced clinically significant pain relief, equating with an anchor descriptor of "much improved" or better at 3 months compared to 20% of 35 sham arm subjects ($p<0.0001$). Median baseline and 3 month NRS scores were 7.0 and 2.0 for the MRgFUS arm vs. 7.0 and 6.0 for the sham arm. A clinically significant improvement at 3 months in BPI-QOL score for MRgFUS but not sham treatment was noted [average change: 2.4 vs. 0.2 respectively, ($p<0.0001$)]. MRgFUS treatment was well tolerated. **Conclusions:** MRgFUS, as demonstrated by this phase III trial, results in excellent rates of pain relief and improvement in QOL for patients with oncologic related bone pain who are not candidates for radiation therapy. Given these excellent results coupled with a favorable side effect profile, MRgFUS should be considered a primary choice for this patient population. Clinical trial information: NCT00656305.

9501 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Outcomes and toxicity for hypofractionated and single-fraction image-guided stereotactic radiosurgery for sarcoma metastatic to the spine.

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Background: Conventional radiation treatment (20-40 Gy total dose, 5-20 fractions, 2-5 Gy per fraction) for sarcoma metastatic to the spine provides subtherapeutic doses and results in poor local control (58-77% at 1 year). Hypofractionated (HF) and/or single-fraction (SF) image-guided stereotactic radiosurgery (IG-SRS) may provide a more effective means of control and salvage for these lesions. **Methods:** Patients with pathologically-proven high-grade sarcoma metastatic to the spine treated with HF and SF IG-SRS were included. Local control (LC) and overall survival (OS) were analyzed using Kaplan-Meier statistics; univariate/multivariate analyses were performed using Cox regression. Toxicities were assessed according to CTCAE v4.0 criteria. **Results:** From 5/2005 and 11/2012, 88 patients with 120 discrete metastases were treated with HF (3-6 fractions, median dose 28.5 Gy; n=52, 43.3%) or SF IG-SRS (median dose 24 Gy, n=68, 56.7%). Median followup was 12.3 months. LC at 12 months was 87.9% (95% CI 81.3-94.5%). OS at 12 months was 60.6% (95% CI 49.6-71.6%) with a median survival of 16.9 months. SF IG-SRS demonstrated superior LC to HF IG-SRS (P=.007) (Table). SF IG-SRS retained its significance in terms of improved LC on multivariate analysis, HR 0.304 (95% CI: 0.117-0.790); variables tested included prior radiation therapy, histology, IG-SRS fractionation, surgery, and chemotherapy. Treatment was well-tolerated with 1% acute Grade 3 toxicity and 4.5% chronic Grade 3 toxicity observed; there were no > Grade 3 toxicities. **Conclusions:** In the largest series of metastatic sarcoma to the spine to date, image-guided stereotactic radiosurgery provides excellent local control in the setting of an aggressive disease with low radiation sensitivity and poor prognosis. Single-fraction image-guided stereotactic radiosurgery demonstrates the highest rates of local control with minimal toxicity.

Oncologic outcomes with IG-SRS.

	12 months	24 months
LC	% (95% CI)	% (95% CI)
All patients	87.9% (81.3-94.5%)	77.4% (67.4-87.4%)
HF	84.1% (72.9-95.3%)	65.7% (46.7-84.7%)
SF	90.8% (83-98.6%)	85.2% (74.6-95.8%)
OS		
All patients	60.6% (49.6-71.6%)	39% (27.6-50.4%)

9502 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

A randomized trial of single versus multiple fractions (Fx) for re-irradiation (RE-RT) of painful bone metastases (PBM): NCIC CTG SC.20.

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Background: The optimal RE-RT dose and fractionation schedule for PBM is uncertain. **Methods:** Patients (pts) with PBM after previous radiation (RT) to the same site were stratified by previous Fx schedule and pain response and randomized to 8 Gy in 1 Fx or 20 Gy in 5 Fx (8 Fx if previous RT was to spine/whole pelvis in multiple Fx). The primary endpoint was overall response rate (RR) at 2 months using the International Consensus schema (Chow 2002) which combines Brief Pain Inventory worst pain score and opioid analgesic use. We tested if 8Gy was non-inferior (NI), analyzed by intention to treat (ITT) and a per-protocol (PP) sensitivity analysis excluding those who were ineligible, inevaluable or received non-allocated therapy. Sample size was calculated using an expected RR of 70% with 20Gy and a NI margin of 10% (i.e. upper boundary of 1-sided 95% CI for the RR difference). Pts reported adverse events (AEs) by questionnaire on Day 14. Quality of life (QoL) was assessed using the EORTC QLQ C30. **Results:** Between 01/2004 and 06/2012, we enrolled 850 pts from 9 countries. Most common cancers were prostate (27%), breast (26%) and lung (22%). Before the 2 month assessment, 98 (11%) pts died. By ITT, the 2-month RR was available in 66% (557/850) and was 119/425 (28%) with 8Gy and 136/425 (32%) with 20Gy (P=0.2); the upper boundary of the 95% CI for RR difference = 9.2% and is less than the pre-specified NI margin. By PP analysis, 2-month RR was available in 521 and was 117/258 (45.3%) with 8Gy and 135/263 (51.3%) with 20Gy (P=0.17); the upper boundary of the 95% CI for RR difference = 13.2%, which exceeds 10% non-inferiority boundary. Day 14 AEs differing by treatment were: lack of appetite (P=0.01), vomiting (P= 0.001), diarrhea (P=0.02) and skin reddening (P=0.002); all were worse with 20Gy. There were 30 vs 20 pathological fractures and 7 vs 2 spinal cord compressions with 8Gy and 20Gy, respectively (P=NS). No difference in QoL existed between arms. **Conclusions:** In pts with PBM receiving RE-RT, the 2-month RR obtained with 8Gy is non-inferior to 20 Gy when assessed by ITT but findings were not robust to a PP sensitivity analysis. When choosing between options tested, trade-offs exist between pain response and acute toxicity. Clinical trial information: NCT00080912.

9503 Oral Abstract Session, Sun, 8:00 AM-11:00 AM

A multicenter, randomized, double-blinded, placebo-controlled trial of modafinil for lung cancer-related fatigue: Dose response and patient satisfaction data.

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Background: Fatigue is a very common, disabling symptom in cancer, and particularly severe in lung cancer. Modafinil is a novel central nervous system stimulant, which, along with methylphenidate, is cautiously recommended by the 2013 National Comprehensive Cancer Network Guidelines for fatigue. In this phase IV randomized placebo-controlled trial, we assessed the efficacy of modafinil for managing fatigue in lung cancer. **Methods:** Adults with locally advanced or metastatic non small cell lung cancer (stages III and IV), ECOG performance status (PS) 0-2 and suffering from fatigue (score 5/10 or greater) were randomised 1:1 to modafinil or matched placebo, 100mg daily for 14 days and 200mg daily for a further 14 days. The primary outcome measure was change in the Functional Assessment of Chronic Illness Therapy fatigue subscale (FACIT-fatigue) at 28 days. The trial was powered to detect a 5-point difference with 80% power and 5% significance allowing for 25% attrition. Dose-response, patient satisfaction and safety were also evaluated. **Results:** 208 patients were recruited from 24 UK centres. Baseline characteristics were well-balanced. 160 patients completed both baseline and 28 day questionnaires and were included in the modified-ITT analysis. FACIT-fatigue mean change from baseline was modafinil=5.28, placebo=5.11, difference=0.17, (95%CI -4.17, 3.82). Adjustment for baseline fatigue and PS had no impact on outcome. No dose response was seen; the majority of improvement on all scales was seen at 14 days and sustained to 28 days. 47% of the modafinil group and 23% of the placebo group stated the study treatment was not helpful (p=0.132). Adverse events were equal. **Conclusions:** Both modafinil and placebo led to a clinically significant 5-point improvement in FACIT-fatigue score, but there was no significant difference between the two groups. This well-powered study suggests that there is a large placebo effect and NCCN guidelines should be reviewed. Clinical trial information: NCT00829322.

FACIT-F score	Modafinil (mean, [SD] N)	Placebo (mean, [SD] N)
Baseline	24.64 [10.58] 104	24.98 [10.83] 103
Day 14	30.58 [12.17] 88	29.43 [11.57] 90
Day 28	31.28 [13.66] 75	30.66 [13.85] 85

9504 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Losing sleep over cancer: Relationships with negative affect, blood pressure, and disease-free interval among women with metastatic breast cancer.

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Background: Few studies have examined how polysomnographic (PSG) measured sleep disturbance is associated with negative affect and markers of health status among women with metastatic breast cancer (MBC). **Methods:** 91 women with MBC (aged 57.9 ± 7.3 yrs) and Karnofsky ratings of at least 70 were recruited. We used latent profile analysis to identify distinct patterns of in-lab sleep disturbance. These profiles were used to predict affect (measured by PANAS), blood pressure, and disease progression (disease free months before metastases). **Results:** Two classes of women emerged and were distinguished as "severely disturbed sleepers" (n = 24) or "mildly disturbed sleepers" (n = 67). Severely disturbed sleepers had worse quality of sleep (e.g., sleep efficiency=54% vs. 69%) and spent significantly and less time in slow wave and REM sleep. One-way ANOVA revealed that severely disturbed sleepers reported significantly more negative affect ($p < .05$). Specifically, they reported greater negative affect in the afternoon (2-3pm) and evening (6:30-7pm) prior to lab-sleep, and the morning (9:30-10:30am) and afternoon (12:30pm and 2pm) following lab-sleep. In addition, severely disturbed sleepers had higher systolic blood pressure (M=140 vs. M=124, $p = .001$) measured the afternoon prior to lab-sleep. Strikingly, women with severely disturbed sleep had significantly shorter disease free intervals (49 months vs. 80 months, $p < .05$), and worse Karnofsky ratings ($p < .05$) indicating worse medical prognosis than mildly disturbed sleepers. **Conclusions:** Women with MBC and severely disturbed sleep experienced more negative affect prior to and following a poor night's sleep. In addition, they exhibited hypertension and accelerated cancer progression relative to women with mild sleep disruption. These detrimental changes may be an indication of the effects of chronic sleep disruption. Understanding the role of daily negative affect in conjunction with physiological markers of disease progression may inform better treatment methods for women with MBC experiencing severe sleep disruption.

9505 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Phase II double-blind placebo-controlled study of armodafinil for brain radiation induced fatigue.

Edward G. Shaw, Doug Case, David Bryant, David Grisell, Glenn Lesser, Drew C. Monitto, Michelle Joy Naughton, Stephen R. Rapp, Steven R. Savona, Sunjay Shah, Michael D Chan; Wake Forest University, School of Medicine, Winston Salem, NC; Via Christi Cancer Center, Wichita, KS; Greenville CCOP, Greenville, SC; Spartanburg Reg Healthcare Syst, Spartanburg, SC; Wake Forest University, School of Medicine, Winston-Salem, NC; Hofstra North Shore-LIJ School of Medicine, New Hyde Park, NY; Christiana Care CCOP, Hockessin, DE

Background: Armodafinil (ARM), the R-enantiomer of modafinil, is FDA approved for narcolepsy, shift work disorder, and treated sleep-apnea, and has also been shown to reduce fatigue/improve cognitive function in cancer patients. This phase II study estimated the efficacy and toxicity of ARM in primary brain tumor (PBT) patients receiving brain radiation therapy (RT) to determine whether a larger phase III study would be warranted. **Methods:** Eligibility criteria – adult, PBT, total RT dose >45Gy, KPS>60, no severe headaches, and concurrent chemotherapy allowed. Patients were assessed at baseline, end of RT, then 4 weeks after end RT with the Brief Fatigue Inventory (BFI), Epworth Sleep Scale (ESS), FACT, and FACT brain and FACIT fatigue subscales. Patients were randomized to receive ARM 150mg/day during RT and for 4 weeks after RT or placebo (PLAC). **Results:** 54 patients enrolled between 9/10-12/12; 26 to ARM, 28 to placebo PLAC. Median age 59; 59% female; 95% White; 41% KPS 90-100, 59% KPS 60-80; 74% malignant glioma, 26% low-grade glioma/benign histology. 83% patients had concurrent chemotherapy. For all randomized patients, there were no statistically significant differences in outcome between ARM and PLAC groups at end-RT vs. baseline or 4 weeks post RT vs. baseline. For patients who had more baseline fatigue (fatigue subscale score <median), ARM-treated patients had significantly/suggestively better outcomes at end-RT vs. baseline compared to PLAC-treated patients: less fatigue (BFI $p=0.056$, fatigue subscale $p=0.0295$), less sleepiness (ESS $p=0.1034$), and better QOL (FACT $p=0.0001$). Incidence of grade 2/3 toxicities was the same between the two treatment groups: 7% anxiety, 7% nausea, 18% headaches, and 20% insomnia. There were no grade 4 or 5 toxicities. **Conclusions:** In irradiated PBT patients, fatigue, sleepiness, and reduced QOL occurring at the end of brain RT was less with ARM in those patients who were more fatigued at baseline. Toxicity was minimal. These data support conducting a larger phase III study. Analysis of cognitive function data is ongoing. Support - NIH/NCI grant 2U10 CA 81851 and Teva Pharmaceuticals. Clinical trial information: 95709.

9506 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Association of pro-inflammatory biomarkers and post-chemotherapy cognitive changes in Asian breast cancer patients: A prospective cohort study.

Yin Ting Cheung, Maung Shwe Ham Guo, Yuan Chuan Kee, Wai Keung Chui, Han Kiat Ho, Gilbert Fan, Wei Sean Yong, Preetha Madhukumar, Wei Seong Ooi, Wen Yee Chay, Rebecca Alexandra Dent, Soo Fan Ang, Soo Kien Lo, Yoon Sim Yap, Raymond C.H. Ng, Alexandre Chan; National University of Singapore, Singapore, Singapore; National Cancer Centre Singapore, Singapore, Singapore

Background: Although existing evidence suggests that cytokines play an intermediary role in the development of post-chemotherapy cognitive changes, specific cytokines associated with this neurotoxic sequela of chemotherapy are still unknown. This study was designed to identify pro-inflammatory biomarkers that are associated with memory and attention impairment in Asian patients receiving chemotherapy. **Methods:** This is a prospective, cohort study conducted at the National Cancer Centre Singapore. Early-stage Asian breast cancer patients (Stage I to III), who received anthracycline and/or taxane-based chemotherapy were recruited. Computerized neuropsychological assessments (Headminder) were administered to evaluate patients' memory and attention performances and a panel of pro-inflammatory plasma cytokines (IL-1β, IL-2, IL-4, IL-6, IL-8, IL-10, GM-CSF, IFN-γ and TNF-α) was evaluated using multiplex immunoassay at three time points: prior to chemotherapy (*T1*), at midpoint (*T2*), and end of chemotherapy (*T3*). Memory and attention impairment were defined as a $>$2.5 reduction of the *Z*score from baseline, as calculated by the reliable change index for repeated cognitive measurements. **Results:** Thirty-six patients were included (mean age 49.7$\pm$9.0 years; 80.6% Chinese). Comparing to *T1*, 50.0% and 36.1% of the patients suffered memory and attention impairment at *T3*, respectively. Comparing patients with intact memory to those who suffered impairment from *T2* to *T3*, they had higher levels of circulating IL-1β [median (IQR): 0.44 (0.1-0.5) vs 0.56 (0.4-0.7) pg/ml, *p=0.069*], IL-4 [0.41 (0.0-0.8) vs 0.85 (0.2-1.5) pg/ml, *p=0.067*) and TNF-α [1.78 (1.3-2.2) vs 3.01 (1.3-3.5) pg/ml, *p=0.069*]. At *T3*, reduction of attention scores were associated with higher levels of IL-1β (r_s= -0.37, *p=0.023*) and IL-6 (r_s= -0.33, *p=0.045*). No significant associations were identified with IL-2, IL-8, IL-10, GM-CSF and IFN-γ. **Conclusions:** These findings suggest that an increase in the post-chemotherapy levels of TNF-α, IL-1β, IL-4 and IL-6 may have an association with the manifestations of memory and attention impairment in Asian breast cancer patients.

9507 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

The course of depression, inflammation in the serum and tumor microenvironment, and survival in the context of advanced cancer.

Jennifer Lynne Steel, Kevin H Kim, T. Clark Gamblin, Danyelle Fraser, Michelle Biala, Alexandra Savkova, Lisa Butterfield, David A. Geller, J. Wallis Marsh, Allan Tsung; University of Pittsburgh School of Medicine, Pittsburgh, PA; University of Pittsburgh, Pittsburgh, PA; Medical College of Wisconsin, Milwaukee, WI; University of Pittsburgh Cancer Institute, Pittsburgh, PA; NSABP and the University of Pittsburgh Medical Center Liver Cancer Center, Pittsburgh, PA; University of Pittsburgh Medical Center, Pittsburgh, PA; Comprehensive Liver Cancer Center, University of Pittsburgh Medical Center, Pittsburgh, PA

Background: The aims of the present study were to study the course of depression in patients diagnosed with cancer and the link with biomarkers of inflammation in the serum or tumor microenvironment and survival. **Methods:** A total of 474 patients diagnosed with advanced cancer were administered the Center for Epidemiological Studies-Depression (CES-D) scale every 2-months and blood samples were drawn to assess biomarkers of inflammation in the serum and tumor microenvironment. The course of depression was estimated using a semi-parametric trajectory analyses and cross-lagged panel analyses were performed to assess the link between depression and biomarkers of inflammation. Cox regression analysis was use to test the link between depression and survival while adjusting for demographic and disease specific factors. **Results:** A three-class solution was chosen based on Bayesian information criterion and theory. The first class, "not depressed," with a mean CES-D score of 6.7 at baseline contained 32% of patients and no significant change in depression scores across time. The second class, "mildly depressed" (53% of sample) had a significant increase in the mean CES-D from 14.5 at baseline to 18.0 at 12 months and 20.0 at 16 months [B = .35, z = 3.12, p = .002]. The third class, "severely depressed," with a mean of 31.5 at baseline (15% of patients) and no significant change win depression over 24 months. Depression predicted serum levels of Tumor Necrosis Factor (TNF)-alpha and Interleukin-1alpha at subsequent time points and was associated with High Mobility Group Box 1 in the tumor microenvironment. Trajectory group assignment significantly predicted survival after demographic and disease specific factors were adjusted (p=0.04). The non-depressed trajectory group had a median survival of 13 months (95%CI=8.9-17.1), the mildly depressed group median survival was 10 months (95% CI 7.1-12.9) and the severely depressed group median survival was 6 months (95% CI=7.6-12.4). **Conclusions:** These findings may facilitate the targeting of psychosocial and biological interventions to reduce depression symptoms, improve quality of life, and potentially slow disease progression.

9508 **Oral Abstract Session, Sun, 8:00 AM-11:00 AM**

Biomarker prediction of chemotherapy-related amenorrhea.

Kathryn Jean Ruddy, Anne M. O'Neill, Kathy Miller, Bryan P. Schneider, Emily Baker, Joseph A. Sparano, Chau T. Dang, Donald W. Northfelt, George W. Sledge; Dana-Farber Cancer Institute, Boston, MA; Indiana University Melvin and Bren Simon Cancer Center, Indianapolis, IN; Montefiore Medical Center, Bronx, NY; Memorial Sloan-Kettering Cancer Center, New York, NY; Mayo Clinic, Scottsdale, AZ; Stanford University, Stanford, CA

Background: Chemotherapy-related amenorrhea (CRA) is associated with infertility and may impact treatment decision-making. We investigated whether anti-mullerian hormone (AMH) levels before chemotherapy predict likelihood of CRA. **Methods:** 591 patients enrolled on the quality of life substudy of ECOG5103, which randomized breast cancer patients to doxorubicin-cyclophosphamide followed by paclitaxel: 1) alone; 2) with concurrent bevacizumab; or 3) with prolonged bevacizumab. 144 of the 195 women who reported a period <12 months before enrollment consented to serum collection prior to chemotherapy. AMH was measured in 143 with available serum. Participants self-reported menstrual frequency at 12 and 18 months after enrollment. 12-month CRA was defined as no menses for 6 months before the 12-month survey, and 18-month CRA as no menses for 6 months before the 18-month survey. Fisher's exact test was used to identify associations with CRA. **Results:** Of the 143, 16 were excluded due to bilateral oophorectomy or initiation of ovarian function suppression within 12 months, and 2 due to missing data at 12 months. In the remaining 125, median age at enrollment was 45 (range 25-55). 103 (82%) had CRA at 12 months, including 68% of patients </= 45 (43/63) and 97% of patients >45 (60/62). Median pre-chemotherapy AMH was 0.11 (range 0.01-8.63). 12-month CRA was more likely in women who received bevacizumab ($p<0.01$), were >45 ($p<0.01$), and had AMH </=0.11 ($p<0.01$) pre-treatment. Hormonal tx was not associated with 12-month CRA ($p=0.63$). 100 patients were eligible for 18-month CRA analysis: 81 (81%) had CRA, including 63% of patients </= 45 (33/52) and 100% (48/48) of patients >45. 18-month CRA was more likely in women >45 ($p<0.01$) and with AMH </=0.11 ($p<0.01$) pre-treatment. Bevacizumab ($p=0.15$) and hormonal tx ($p=0.07$) were not statistically significant predictors of 18-month CRA. **Conclusions:** Pre-chemotherapy AMH predicts risk of CRA at 12 and 18 months, and is a promising biomarker of ovarian reserve in young breast cancer survivors. Longer studies will be needed to ascertain whether lower pre-treatment AMH is associated with increased risk of later infertility. Clinical trial information: NCT00433511.

9509 **Clinical Science Symposium, Mon, 1:15 PM-2:45 PM**

Do elderly patients benefit from enrollment in phase I clinical trials?

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Background: Despite the significant burden of cancer in the older population, their outcomes in the context of phase I studies have been poorly studied. We evaluated the clinical characteristics and outcomes of elderly pts enrolled in phase 1 clinical trials in our centre and evaluate the performance of Royal Marsden Hospital (RMH) prognostic score (albumin, LDH, no of met sites) in this pt population. **Methods:** 296 consecutive pts who were treated in 20 phase 1 trials from 2005-2012 in our unit were analysed. Clinical characteristics and outcomes between young pts (<65, $n=202$) and older pts (≥ 65, $n=94$) were compared. **Results:** The median age of the older pts was 69 (65-84), 71% were males. 51% of the pts received chemotherapy based treatment with or w/out biological agents. 61% of the pts had lung cancers and 32% had gastrointestinal cancers. 52% of pts had ≥ 2 co-morbidities. After median follow up of 7.5 mths (0.36-50.6 mths), the median progression free survival (PFS) and overall survival (OS) were 5.8 and 8.8 mths respectively. Although elderly pts had more co-morbidities and lower albumin levels at baseline, there was no significant difference in survival (8.8 vs 9.9 mths), $p=0.68$) compared to younger pts. The prognostic factors for OS identified in multivariate analysis were prior lines of chemotherapy (0-2 vs ≥ 3), baseline sodium levels (≥ 135 vs <135mmol/L) and platelet levels (≤ 400 vs $>400\times10^9$). We developed a risk nomogram based on the factors identified prognostic of OS with concordance(c)-index of 0.65. RMH score (2-3 vs 0-1) predicted for OS with hazard ratio of 2.1, $p=0.03$ and c- index of 0.63. 26% of elderly pts experienced grade 3/4 toxicities in the first cycle of treatment. Common grade 3/4 toxicities were dermatological (25%), haematological (17%) and gastrointestinal (13%). Both age of pts ($p=0.70$) and dose levels ($p=0.18$) did not have any bearing on occurrence of grade 3/4 toxicities. **Conclusions:** Elderly pts (≥ 65) enrolled into phase 1 clinical trials had similar survival outcomes and toxicity profiles compared to younger pts. Risk scoring models to aid patient selection need further clarification in this population.

9510 **Clinical Science Symposium, Mon, 1:15 PM-2:45 PM**

Baseline cognitive functions among elderly patients with localized breast cancer.

Florence Joly, Marie Lange, Natacha Heutte, Aurélie Daireaux, Chantal Rieux, Johan Le Fel, Olivier Rigal, Vincent Roy, Jean-Emmanuel Kurtz, Benedicte Clarisse, Benedicte Giffard, Francis Eustache, Sabine Noal; GINECO/Centre François Baclesse, Caen, France; Centre Hospitalier Universitaire de Caen, U1077, Caen, France; Unité de Recherche Clinique, Centre François Baclesse, Caen, France; Centre François Baclesse, Caen, France; Université de Rouen, EA4306, Rouen, France; Department of Medical Oncology, Centre Henri Becquerel, Rouen, France; EA4306, Mont-Saint-Aignan, France; Hôpitaux Universitaires de Strasbourg, Strasbourg, France

Background: Cognitive deficits (CD) were reported among patients receiving chemotherapy (CT) for cancer, but could also be observed before treatment. Elderly patients were poorly studied although they are more prone to present age-related CD and CD onset or enhancement during CT. This study assessed baseline cognitive functions among elderly localized breast cancer (LBC) patients before adjuvant treatment therapy. **Methods:** Episodic memory, working memory, executive functions and information processing speed were assessed with neuropsychological tests. Validated questionnaires were used to assess subjective CD, anxiety, depression and fatigue before adjuvant treatment. Geriatric assessment was also realized. Objective CD were defined as a score less than 1.5 standard deviation (SD) of normative data on >2 tests, or less than two SDs on >1 test. Significant subjective CD (evaluated by the FACT-Cog) were defined when the 4 subscales below the first tercile distribution. **Results:** Results concern 123 elderly LBC (71 ± 4 years): planned treatment included CT and radiotherapy (RT) for 61 patients and RT only for 62 patients. Characteristics are as follows: mastectomy (28%), stage (I: 60%, II: 27%, III: 13%), positive hormonal receptor (88%) and positive Her2 (17%). Before any adjuvant treatment, objective CD were observed in 40% of patients (46% in CT group, episodic memory mainly impaired and 37% in RT group, executive functions and information processing speed mainly impaired). No relation was observed between cancer stage, geriatric frailty and objective CD. Twenty nine percents of patients presented fatigue, 6% anxiety and 10% depression. These variables were not related to objective CD but they were related to subjective CD. **Conclusions:** More than 40% of elderly LBC patients presented objective CD before any adjuvant therapy that is higher than observed among younger patients. It is important to take account in the decision making of adjuvant treatment in elderly patients. Clinical trial information: NCT01333735.

9511 **Clinical Science Symposium, Mon, 1:15 PM-2:45 PM**

Predictive factors for chemotherapy feasibility in elderly patients with solid tumor: Results of GERCOR old prospective multicenter study.

Elisabeth Carola, Benoist Chibaudel, Stephanie Trager, Leïla Bengrine-Lefèvre, Joelle Chuzel, Jean Francois Seitz, Patrick Dion, Pascal Artru, Nasredine Aissat, Emmanuelle Sarlon, Florence Woerth, Mélanie Gauthier, Franck Bonnetain, Aimery de Gramont, GERCOR; Groupe Hospitalier Public Sud Oise, Senlis, France; Hôpital Saint-Antoine, Paris, France; Hôpital Saint Antoine, Paris, France; Hôpital de Mougins, Mougins, France; La Timone University Hospital, Marseille, France; Centre Hospitalier Aubenas, Aubenas, France; Hôpital Privé Jean Mermoz, Lyon, France; GERCOR, Paris, France; Biostatistic Unit, Georges-François Leclerc Cancer Center, Dijon, France; Methodology and Quality of Life in Oncology Unit (EA 3181) & Quality of Life and Cancer Clinical Research Plateform, Besancon, France; Hopital Saint Antoine, Paris, France

Background: One quarter of patients with cancer are 75 year old and over. Previous studies suggested that geriatric parameters improved survival in elderly patients with solid advanced cancer and chemotherapy severe toxicity. A simplified scale would be helpful for oncologist to predict chemotherapy feasibility. The aim was to identify geriatric predictors of chemotherapy feasibility in chemo-naïve elderly patients. **Methods:** We conducted a prospective multicenter cohort study (NCT00664911). Inclusion criteria were: $\geq$ 75 years, solid tumor, able to receive at least 2/3 of the standard dose at the first course of treatment. Ten geriatric parameters were recorded at baseline by the oncologist: 1-three words test, 2-date and address for cognitive function, 3-Instrumental Activities of Daily Living (IADL), 4- monopodal stand-up test, 5-hospitalization during the previous year, 6-number of medicines taken for comorbidities, 7-creatinine clearance, 8-albumin serum level, 9-self-rated depressive mood question and 10-presence of a caregiver. The main outcome was chemotherapy feasibility defined by the ability to receive at least 3 months of the planned therapy. Multivariate logistic regression was used. **Results:** 576 patients were included in 49 centers from 2008 to 2012, 516 (89.6%) were eligible for analysis. Mean age was 81 years, 50.6% had colorectal cancer, 69.5% advanced stage and 83.6% had performance status 0-1. Chemotherapy feasibility was observed in 298 (57.8%) patients. Grade 3-4 toxicity was observed in 26.2% of patients. In multivariate analysis albuminemia $<$ 30g/l (adjusted OR $=$2.34 CI95% [1.43-3.83]) and depressive mood (adjusted OR$=$1.55 CI95% [1.02-2.35]) were significantly associated with chemotherapy unfeasibility whereas others geriatrics parameters were not. **Conclusions:** Albuminemia and self rated depressive mood status were independently predictive for chemotherapy feasibility in elderly patients with solid tumor. Unexpectedly others geriatrics parameters were not independent predictors. Clinical trial information: NCT00664911.

9512 **Poster Discussion Session (Board #1), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM**

Efficacy of NEPA, a novel combination of netupitant (NETU) and palonosetron (PALO), for prevention of chemotherapy-induced nausea and vomiting (CINV) following highly emetogenic chemotherapy (HEC).

Paul Joseph Hesketh, Giorgia Rossi, Giada Rizzi, Marco Palmas, Anna Alyasova, Igor Drobner, Richard J. Gralla; Lahey Hospital & Medical Center, Burlington, MA; Helsinn Healthcare S.A., Lugano, Switzerland; Federal State Institution, Privolzhsky District Medical Center, under the Federal Medical-Biological Agency of Russia, Nizhny Novgorod, Russia; Regional Oncology Center, Khmelnytsky, Ukraine; Albert Einstein College of Medicine, Bronx, NY

Background: Further progress in preventing CINV will require the introduction of novel agents providing maximal convenience and with efficacy for nausea as well as vomiting. NEPA is a single dose combination of NETU, a novel NK_1 receptor antagonist (RA) and PALO, a pharmacologically distinct 5-HT_3RA. This study was designed to determine the proper dose of NETU to combine with PALO. **Methods:** This was a randomized, double-blind, parallel group study in chemotherapy-naïve patients (pts) undergoing cisplatin-based HEC. Four study arms compared 3 oral doses of NEPA (NETU 100, 200, 300mg + PALO 0.50 mg) with oral PALO 0.50 mg, all given on day 1. All pts received oral dexamethasone (DEX) days 1-4. An exploratory aprepitant (APREP) + ondansetron/DEX arm was included. The primary endpoint was complete response (CR: no emesis, no rescue) in the overall (0-120h) phase. **Results:** 694 pts were enrolled with comparable characteristics across groups: males (57%), median age 55. Common cancers: lung (27%), head and neck (21%). Median cisplatin dose: 75 mg/m^2. All NEPA groups showed superior CR rates compared with PALO during the overall and delayed phases, with $NEPA_{300}$also superior to PALO during the acute phase. $NEPA_{300}$was also superior to PALO during all phases for no emesis, no significant nausea and complete protection with incremental benefits over lower NEPA doses. AEs were comparable across groups with no dose-response. The % of pts developing ECG changes was comparable across groups. **Conclusions:** Each NEPA dose resulted in superior CR rates compared with PALO. $NEPA_{300}$was the best dose studied, with an advantage over lower doses for all efficacy endpoints (including nausea). NEPA doses were well tolerated with similar safety profiles to PALO and APREP. NEPA combined with DEX is superior to PALO plus DEX in prevention of CINV following HEC.

CR rates (% pts) p value*	PALO (N=136)	$NEPA_{100}$ (N=135)	$NEPA_{200}$ (N=137)	$NEPA_{300}$ (N=135)
Overall (0-120h)	76.5	87.4	87.6	89.6
		0.018	0.017	0.004
Acute (0-24h)	89.7	93.3	92.7	98.5
		0.278	0.383	0.007
Delayed (25-120h)	80.1	90.4	91.2	90.4
		0.018	0.010	0.018

* p value: logistic regression adjusted for gender.

9513 Poster Discussion Session (Board #2), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Does gabapentin prevent delayed chemotherapy-induced nausea and vomiting (N/V)? Results of a randomized placebo controlled trial, NCCTG N08C3 (Alliance).

Debra L. Barton, Jeff A. Sloan, Paul J Novotny, Jyotsna Fuloria, Lisa A. Kottschade, Alan P. Lyss, Anthony John Jaslowski, Miroslaw Mazurczak, Scott Cameron Blair, Shelby A. Terstriep, Charles L. Loprinzi; Mayo Clinic, Rochester, MN; Ochsner Clinic Foundation, New Orleans, LA; Missouri Baptist Cancer Center, St. Louis, MO; Green Bay Oncology, Green Bay, WI; Sanford Cancer Center, Sioux Falls, SD; Columbus Onc Assoc Inc, Columbus, OH; MeritCare-Roger Maris Cancer Center, Fargo, ND

Background: The need for more research in N/V control is exemplified by agents that are costly, interfere with cytochrome P450 metabolism, and inadequately address delayed N/V. Based on pilot data, there was justification for evaluating whether gabapentin could improve the prevention of delayed N/V from highly emetogenic chemotherapy (HEC). **Methods:** Patients (pts) about to receive HEC were randomized to prophylactic treatment with 20 mg of dexamethasone (dex) and a 5HT3 receptor antagonist (RA) on the day of chemotherapy, followed by either gabapentin (gaba) 300 mg BID and dex or placebo (plac) and dex. Gaba/plac was started the evening of the day of chemotherapy and continued through day 5 of the first chemotherapy cycle. Dex was given at 8 mg BID days 2-3, then 4 mg BID for day 4, in both arms. The primary endpoint was complete response (CR), defined as no emesis and no rescue medications day 2-6, using a nausea and vomiting diary. The percent of CR were compared in each group by Fisher's exact test. Secondary outcomes included the Functional Living Index-Emesis (FLIE), satisfaction, and a side effect questionnaire. **Results:** 430 pts were enrolled in this study between 5/2009 and 2/2011. 47% of pts in the gaba arm and 41% in the plac arm had a CR (p=.23). At some time during days 2-6, 30% in the gaba and plac arms experienced emesis, and 45% and 53% in the gaba and plac arms, respectively, took rescue medication. Mean diary nausea scores over days 2-6 ranged from 0.9 – 1.2 (gaba arm) and 1.0-1.3 (plac arm)(7 = the worst); mean number of diary emetic episodes ranged from 0.1 -0.3 (gaba arm) and 0.1-0.2 (plac arm). The FLIE was not significantly different between arms. Mean vomiting satisfaction was 9.1 in both arms and for nausea was 8.3 for gaba, 8.1 for plac (10= totally satisfied). There were no significant differences in toxicities by CTCAE provider grading or by self-report. **Conclusions:** In this study, gaba did not improve delayed N/V. Overall, there was little emesis and nausea severity was low. Patients were satisfied with the control of their N/V, irrespective of arm. The use of standard prophylactic guidelines that include a 5HT3RA and dex provided good control of N/V for most patients. Clinical trial information: NCT00880191.

LBA9514 **Poster Discussion Session (Board #3), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM**

Phase III study of NEPA, a fixed-dose combination of netupitant (NETU) and palonosetron (PALO), versus PALO for prevention of chemotherapy-induced nausea and vomiting (CINV) following moderately emetogenic chemotherapy (MEC).

Matti S. Aapro, Giorgia Rossi, Giada Rizzi, Marco Palmas, Steven Grunberg; Clinique de Genolier, Genolier, Switzerland; Helsinn Healthcare S.A., Lugano, Switzerland; Fletcher Allen Health Care, Burlington, VT

The full, final text of this abstract will be available at abstract.asco.org at 7:30 AM (EDT) on Saturday, June, 1, 2013, and in the *Annual Meeting Proceedings* online supplement to the June 20, 2013, issue of *Journal of Clinical Oncology*. Onsite at the Meeting, this abstract will be printed in the Saturday edition of *ASCO Daily News*.

9515 Poster Discussion Session (Board #4), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Effect of renal function (RF) on outcomes in the adjuvant treatment of older women with breast cancer (>65 years): CALGB/CTSU 49907 (CC) ancillary data study.

Stuart M. Lichtman, Constance Cirrincione, Arti Hurria, Aminah Jatoi, Maria Theodoulou, Antonio C. Wolff, Julie Gralow, Daniel Morganstern, Gustav Magrinat, Harvey Jay Cohen, Hyman Muss, The Alliance for Clinical Trials in Oncology; Memorial Sloan-Kettering Cancer Center, New York, NY; Alliance Statistical Center, Duke University, Durham, NC; City of Hope, Duarte, CA; Mayo Clinic, Rochester, MN; The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, Baltimore, MD; Seattle Cancer Care Alliance, Seattle, WA; Dana-Farber Cancer Institute, Boston, MA; Cone Health Cancer Center, Greensboro, NC; Duke University Medical Center, Durham, NC; University of North Carolina Lineberger Comprehensive Cancer Center, Chapel Hill, NC

Background: CC 49907 showed superiority of standard therapy (cyclophosphamide/doxorubicin [AC] or cyclophosphamide/methotrexate/5-fluorouracil [CMF]) over capecitabine[C]. Dose adjustments made for renal insufficiency (RI) for methotrexate and C; ideal body weight used. Purpose was to analyze the relationship between RF at baseline and 5 endpoints: toxicity, dose modification, therapy completion, relapse-free survival [RFS] and overall survival [OS]. **Methods:** Pre-treatment RF was calculated (Cockcroft-Gault). Endpoints assessed by regimen. RF was tested as a dichotomous and continuous variable of stages 1,2 vs. 3,4 kidney disease (National Kidney Foundation). Logistic regression modeled the relationship between renal stage and the first three endpoints of toxicity, dose modification and therapy completion. Toxicity divided by hematologic or not. The relationship of RFS and OS with RF was assessed with the logrank test and as a continuous variable with Wald chi square. **Results:** 619 patients; incidence of stage 3/4 RI(<60 ml/min) was: CMF=72%; AC=64%; C=75%. With AC the incidence of toxicity differed by renal function. 31% of patients with poorer function >grade 3 non-hematologic toxicity vs. 14% with better function($p=0.011$). There was a suggestion of effect of RF on OS and RFS for C-treated patients. RF was **not** associated with dose modification, premature therapy termination, RFS or OS for the CMF-treated patients. **Conclusions:** 1) AC: declining RF was associated with increased non-hematologic toxicity. 2)Patients with RI who received dose modifications were not at increased risk for complications in comparison to those who did not have renal insufficiency and received full dose. 3)Declining RF did not affect therapy completion. 4)C: suggestion that worse RF was related to poorer RFS or OS. 5)Exclusion of patients from clinical trials with RI based on concern of excessive hematologic toxicity may not be justified with appropriate modification. 6)Results should be considered in the design of clinical trials for older patients.

9516 Poster Discussion Session (Board #5), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Predicting fitness for chemotherapy in older cancer patients.

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Background: The Vulnerable Elders Survey-13 (VES-13) is increasingly used to screen for older patients who can proceed to intensive chemotherapy without further comprehensive assessment. This study compared the VES-13 determination of fitness for treatment with the oncologist's assessments of fitness. **Methods:** Sample: Consecutive series of solid tumour patients ≥65 years (n=175; M=72; range=65-86) from an Australian cancer centre. Patients were screened with the VES-13 before proceeding to usual treatment. Blinded to screening, oncologists concurrently predicted patient fitness for chemotherapy. A sample of 175 can detect, with 90% power, kappa coefficients of agreement between VES-13 & oncologists' assessments >0.90 (″almost perfect agreement″). Separate backward stepwise logistic regression analyses assessed potential predictors of VES-13 & oncologists' ratings of fitness. **Results:** Kappa coefficient for agreement between VES-13 & oncologists' ratings of fitness was 0.41 ($p<0.001$). VES-13 & oncologists' assessments agreed in 71% of ratings. VES-13 sensitivity = 83.3%; specificity = 57%; positive predictive value = 69%; negative predictive value = 75%. Logistic regression modelling indicated that the odds of being vulnerable to chemotherapy (VES-13) increased with increasing depression (OR=1.42; 95% CI: 1.18, 1.71) & decreased with increased functional independence assessed on the Bartel Index (OR=0.82; CI: 0.74, 0.92) & Lawton instrumental activities of daily living (OR=0.44; CI: 0.30, 0.65); RSquare=.65. Similarly, the odds of a patient being vulnerable to chemotherapy, when assessed by physicians, increased with increasing age (OR=1.15; CI: 1.07, 1.23) & depression (OR=1.23; CI: 1.06, 1.43), & decreased with increasing functional independence (OR=0.91; CI: 0.85, 0.98); RSquare=.32. **Conclusions:** Our data indicate moderate agreement between VES-13 & clinician assessments of patients' fitness for chemotherapy. Current 'one-step' screening processes to determine fitness have limits. Nonetheless, screening tools do have the potential for modification & enhanced predictive properties in cancer care by adding relevant items, thus enabling fit patients to be immediately referred for chemotherapy.

9517 **Poster Discussion Session (Board #6), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM**

The role of age on dose-limiting toxicities (DLTs) in phase I dose-escalation trials.

Anita Schwandt, Pamela Jo Harris, Sally Hunsberger, Amélie Deleporte, Gary L Smith, Diana Vulih, Barry Douglas Anderson, S. Percy Ivy; Case Western Reserve University School of Medicine, Cleveland, OH; National Cancer Institute, Bethesda, MD; Institut Jules Bordet, Brussels, Belgium; Cancer Therapeutics Evaluation Program, National Cancer Institute, Bethesda, MD; Theradex Systems, Inc., Princeton, NJ; Theradex, Princeton, NJ; Cancer Therapy Evaluation Program, National Cancer Institute, Bethesda, MD

Background: Elderly oncology patients are not enrolled on phase I trials in proportion to the prevalence of cancer in the age-matched population. They are excluded from these trials based on the perception that these patients will have an increased number of and more severe toxicities, per dose level, than younger patients. We hypothesize that if other patient characteristics are accounted for, then age will not be an independent predictor of dose limiting toxicities (DLTs). **Methods:** We retrospectively reviewed data from 162 single-agent dose-escalation phase I clinical trials performed at the Cancer Therapy Evaluation Program/National Cancer Institute. Several baseline patient characteristics, including age, were collected. Patient dose levels were described as %MTD and an analysis of age, dose and DLTs was performed. **Results:** Data was obtained from 5,401 patients who were divided into five age groups, with 556 pts $<$ 40 years old, 2,438 between 40-59, 1,481 between 60-69, 836 between 70-79 and 90 pts $>$ 79. Proportion of DLT occurring in each age group and %MTD are described in the Table. **Conclusions:** This analysis of DLTs occurring in nearly 1000 patients over 70 years of age on phase I dose-escalation trials is the largest reported. A logistic regression model will be performed to determine if age, by itself, predicts for DLTs and what concurrent patient characteristics contribute to their occurrence.

Proportion of patients with DLT in each dose level of %MTD in each age group.

Dose level as % MTD	Age<40 prop (n)	Age 40-59 prop (n)	Age 60-69 prop (n)	Age 70-79 prop (n)	Age >79 prop (n)	DLT proportion per dose level	Total pts
≤33%	.045 (44)	.026 (265)	.013 (153)	.024 (82)	.011 (8)	.1	552
34-66%	.024 (85)	.053 (356)	.053 (225)	.067 (135)	0 (11)	.15	812
67-100%	.062 (306)	.061(1254)	.079 (793)	.076 (423)	.1 (51)	.52	2,827
>100%	.066 (121)	.122 (563)	.017 (310)	.122 (196)	.011 (20)	.23	1,210
Total n	556	2,438	1,481	836	90	-	5,401

9518 **Poster Discussion Session (Board #7), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM**

Intensity of palliative care and its impact on the aggressiveness of end-of-life care in patients with advanced pancreatic cancer.

Raymond Woo-Jun Jang, Monika K. Krzyzanowska, Camilla Zimmermann, Nathan Taback, Shabbir M.H. Alibhai; University of Toronto, Princess Margaret Hospital, Toronto, ON, Canada; Princess Margaret Hospital, Toronto, ON, Canada; Princess Margaret Hospital, University Health Network, Toronto, ON, Canada; University of Toronto, Toronto, ON, Canada; University Health Network, Toronto, ON, Canada

Background: Quality indicators have been developed to avoid overly aggressive care in patients with advanced cancer. Specialized palliative care (PC) may reduce overly aggressive care in patients with advanced pancreatic cancer. Our objective was to examine the impact of the intensity of specialized PC (defined as a physician consultation focusing on PC needs, lasting at least 40 minutes) on (a) use of chemotherapy within 14 days of death; (b) more than one emergency department (ED) visit; (c) more than one hospitalization; and (d) at least one intensive care unit (ICU) admission, all within 30 days of death. **Methods:** A retrospective population-based cohort study using linked administrative databases in Ontario, Canada was conducted with patients diagnosed with advanced pancreatic cancer from Jan 1 2005 to Dec 31 2010. Multivariable logistic regression analyses were performed with the above quality indicators as the outcomes of interest and the intensity of PC visits as the exposure, adjusting for other variables (age, sex, comorbidity, rurality, and health region). Intensity of PC was defined in both absolute numbers (ie 0, 1, 2, 3+ visits) and rate of visits per month. **Results:** Of 6076 patients with advanced pancreatic cancer, 5381 had died at last followup. 2816 (52%) received a PC consultation, 218 (4%) received chemotherapy near death, 234 (4%) patients went to the ICU near death, 993 (18%) had multiple ED visits near death, and 447 (8%) had multiple hospitalizations near death. 2565 (48%) had 0 PC visits, 513 (10%) had 1, 555 (10%) had 2, and 1748 (32%) had 3 or more. In multivariable analyses, having had one PC consultation was associated with a lower odds of ICU admission near death (odds ratio (OR) 0.25; 95% CI 0.13-0.46), multiple ED visits near death (OR 0.44; 95% CI 0.33-0.58), and multiple hospitalizations near death (OR 0.47; 95% CI 0.33-0.69). Two PC visits were associated with a lower OR for chemotherapy near death (OR 0.26; 95% CI 0.14-0.51). Using the monthly PC visit rate, a higher rate was associated with less aggressive care for each outcome. **Conclusions:** In patients with advanced pancreatic cancer, more intensive PC involvement is associated with less frequent overly aggressive care.

9519 **Poster Discussion Session (Board #8), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM**

Outcomes of prognostic disclosure: Effects on advanced cancer patients' prognostic understanding, mental health, and relationship with their oncologist.

Andrea Catherine Enzinger, Baohui Zhang, Tracy A. Balboni, Deborah Schrag, Holly Gwen Prigerson; Dana-Farber Cancer Institute, Boston, MA; Center for Psychosocial Epidemiology and Outcomes Research, Boston, MA

Background: Many oncologists are reluctant to discuss life expectancy with advanced cancer patients. We examined the frequency of prognostic disclosure and its impact on patients' prognostic understanding, the patient-doctor relationship, and psychological distress. **Methods:** Coping with Cancer was an NCI-funded, multi-site prospective cohort of 726 patients with advanced incurable cancer, enrolled 2002-2008. At baseline, patients were asked if their oncologist had ever discussed prognosis, and if so what estimate was communicated. Patients also estimated their prognosis. The therapeutic alliance scale measured patient-doctor relationship, and the McGill QOL instrument assessed symptoms of depression and anxiety. Multivariable analyses (MVA) assessed relationships between prognostic disclosure and psychological symptoms, controlling for confounds. **Results:** Among this cohort of terminally ill patients (median survival 4mos), most (72%) wanted to be told their life expectancy. Only 19.8% (104/525) of patients had received a prognostic estimate from their oncologist (median estimate 6mos; IQR 6-15mos). When queried about factors informing their prognostic understanding, 85.9% of patients cited personal or religious beliefs; only 11.7% cited a physician's estimate. Of the 299 patients willing to estimate their life expectancy, patients who had been previously informed of their prognosis were substantially more realistic in their own estimate (median 12mos v 48mos, Wilcoxon test $p<0.001$). Moreover, patients' and oncologists' prognostic estimates were significantly correlated ($\rho=0.49$, $p<0.001$). Prognostic disclosure was not associated with poor patient-doctor relationship rating (Fisher's Exact, $p=0.625$), nor was it associated with depressive symptoms (β 0.06, $p=0.242$) or anxiety (β 0.06, $p=0.234$) in MVA. **Conclusions:** Few advanced cancer patients are informed of their life expectancy, although most want this information. Prognostic disclosure is associated with substantial improvement in patients' prognostic understanding, without compromising the patient-doctor relationship or increasing psychological distress.

9520 Poster Discussion Session (Board #9), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Prognostic information (PI), psychological well-being, and quality of life for advanced cancer patients (ACP) in phase I trials and their spousal caregivers (SC).

Fay J. Hlubocky, David Cella, Tamara Sher, Bonnie Yap, Mark J. Ratain, Christopher Daugherty; The University of Chicago Medicine, Chicago, IL; Robert H. Lurie Comprehensive Cancer Center of Northwestern University, Chicago, IL; Northwestern University Family Institute, Chicago, IL; The University of Chicago, Chicago, IL

Background: The impact of the physician's (MD) disclosure of PI on the psychological well-being and quality of life (QoL) of clinical trial subjects with terminal disease on Phase I trials has not been formally evaluated. **Methods:** A prospective cohort of ACP enrolling in phase I trials was assessed at baseline (T1) and one month (T2) utilizing various measures including: state-trait anxiety (STAI-S/T), depression (CES-D), quality of life/QoL (FACIT-Pal), and global health (SF-36). Semi-structured interviews of ACPs also evaluated MD-Pt communication re prognosis and worry about ACP death. **Results:** 100 subjects (50 Phase I ACPs and 50 SC) were separately interviewed at T1 and T2. For the population as a whole: median age 62 (28-78y); 51% male; 100% married; 88% Ca; 68% > HS educ; 56% GI dx; 54% income <$65,000 yr. At T1, 45% of ACPs acknowledged having a discussion re life expectancy with MD; 35% stated the MD gave a prognostic timeframe; and 41% reported worry re death. For SC at T1, 62% recalled a prognosis discussion with the MD; 50% stated MD gave a timeframe; 53% reported PI disclosure was initiated by the MD; 66% reported worry re ACP death. At T2, rates remained consistent for both ACP and SC with the exception of increased reported worry re ACP death at 55% and 70% respectively. At T2, ACP who denied a prognosis was given by the MD had higher STAI-S (35 ± 10 v 29 ± 9, p=0.03) and CES-D scores (16 ± 12 v 7 ± 4, p=0.01); and lower FACT-Pal scores (128 ± 18 v 153 ± 24, p=0.01). SC with acknowledgement of a prognostic timeframe given by the MD had higher STAI-S anxiety (39 ± 16 v 35 ± 14, p=0.04) at T2. Regression analyses revealed that ACP with acknowledgement of a prognostic timeframe given by the MD had poorer FACIT-Pal QoL over time. Also, SC with acknowledgement of a prognostic timeframe at T2 was negatively associated with SF-36 scores. ACP and SC qualitative responses re PI disclosure revealed salient themes: hope for a positive outcome or prolonged survival; stabilization of disease; emotional distress; ambivalence/fear; acceptance. **Conclusions:** Physician disclosure of a prognostic timeframe is negatively associated with QoL among clinical trial subjects and SC in phase I trials.

9521 Poster Discussion Session (Board #10), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Patients' perceptions of caregivers' preference for comfort care at the EOL: Impact on DNR completion.

Kalen Michele Fletcher, Holly Gwen Prigerson, Paul K Maciejewski; Dana-Farber Cancer Institute, Boston, MA; Brigham and Women's Hospital, Boston, MA

Background: Research has shown that informal caregivers provide substantial psychosocial and material support to advanced cancer patients. Few studies have examined how family caregivers influence patients' advance care planning. Here we test whether patients' perceptions of their caregivers' preference for comfort (vs. life-extending) end-of-life (EOL) care is associated with DNR order completion. We also evaluated whether caregivers' *actual* agreement with patients on preference for comfort EOL care was associated with their rates of DNR order completion. **Methods:** Coping with Cancer II is an NCI –funded, multi-site, prospective cohort study of patients with advanced cancer and their informal family caregivers. Patients are interviewed after receiving restaging scan results and asked if they would prefer a plan of EOL care focused on life-extension or one focused on relieving pain. Patients are also asked what type of EOL care they think their family caregivers would prefer for them and whether or not a DNR order has been completed for them. Caregivers are interviewed separately after patients receive restaging scan results and asked what type of EOL care they would want for the patient. **Results:** Based on patient data alone (N=72), patients who preferred comfort care at the EOL and who believe that their family caregiver agrees with them on this were significantly more likely than others to report DNR order completion (OR=3.67, p=0.013). Based on data from both patients and caregivers, patients' *perception of agreement* with their caregivers on desire for comfort EOL care was more strongly associated with patients' reports of DNR completion (r_s=0.51, p=0.004) than was *actual agreement* with their caregivers on desire for comfort EOL care (r_s=0.36, p=0.045). **Conclusions:** Patients who prefer comfort care to life-extending care at the EOL, and who think that their caregivers also want them to pursue comfort care, are more likely to have a DNR order completed. Interestingly, patients' *perception* of this agreement had a stronger influence on DNR completion than the caregivers' *actual* agreement with patients' preference for comfort EOL care. DNR completion is influenced by patients' perceptions of family support.

9522 Poster Discussion Session (Board #11), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Caregivers' perception of advanced cancer patients' quality of death: Impact on caregiver suicidal ideation in bereavement.

Caroline H Abbott, Holly Gwen Prigerson, Paul K Maciejewski; Dana-Farber Cancer Institute, Boston, MA; Brigham and Women's Hospital, Boston, MA

Background: Evidence suggests that patients' quality of life (QOL) at the end of life (EOL), i.e., patients' quality of death, may affect the health and well-being of informal family caregivers. Here we examine the relationship between family caregivers' perception of patients' QOL at the EOL and caregiver suicidal ideation in bereavement. **Methods**: Our analysis was based on data from a sub-sample of family caregivers (N=112) from the Coping with Cancer Study, an NCI-funded multicenter prospective cohort investigation of advanced cancer patients and their caregivers enrolled September 2002 – February 2008. Caregiver baseline suicidal ideation was assessed using the Yale Evaluation of Suicidality (YES) Scale a median of 4.1 months pre-loss; caregivers' perception of patients' overall distress in the last week of life was assessed a median of 1.9 months post-loss; and caregiver suicidal ideation in bereavement was assessed using the YES a median of 6.5 months post-loss. Suicidal ideation was defined as a positive screen on the YES. Multiple logistic regression analysis examined the effect of caregivers' perception of patients' quality of death on bereaved caregiver suicidal ideation, adjusting for caregivers' baseline suicidal ideation and potential demographic confounds. **Results:** Caregivers' perception of patients' overall distress at the EOL was significantly related to caregivers' suicidal ideation post-loss (AOR=1.26, p=0.022) adjusting for caregivers' baseline suicidal ideation, relationship to patient, and years of education. **Conclusions:** The more caregivers' perceive their loved ones' quality of death to be poor, the more they are at risk for suicidal ideation in bereavement. Improving QOL at the EOL will not only benefit patients but also protect caregivers from suicidal ideation.

9523 Poster Discussion Session (Board #12), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

End-of-life care for Medicare beneficiaries with ovarian cancer: Evaluation of intensity and rate of hospitalizations.

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Background: Patients with advanced cancer are receiving increasingly aggressive medical care at the end-of-life (EOL). Population-based studies have not examined the medical care that ovarian cancer patients receive near death. **Methods:** We identified a national cohort of 6,956 Medicare beneficiaries who were living in Surveillance, Epidemiology, and End Results (SEER) areas, were diagnosed with epithelial ovarian cancer between 1996 and 2007, and died from ovarian cancer by December 2007. Using multivariable models, we examined rates of aggressive medical care within 30 days of death over time and examined indications for hospitalizations near death. **Results:** Adjusted rates of intensive care unit (ICU) admissions and emergency department (ED) visits increased significantly between 1996 and 2007 (ICU: 6.4% to 16.6%, $p<0.0001$ and ≥ 2 ED visits: 19.7% to 32.1%, $p<0.0001$). In contrast, late (within 7 days death) or absent hospice referrals decreased (63.1% to 47.8%, $p<0.001$) and chemotherapy use within 30 days of death decreased slightly (8.1% vs. 7.1%; $p=0.04$). Although terminal hospitalizations decreased (28.0% to 19.1%, $p=0.001$), rates of hospitalizations near death increased over time (41.4% vs. 45.3%, $p=0.01$). The most common indications for hospitalization included: bowel obstructions (20.0%), infections (10.4%), fluid or electrolyte abnormalities (9.2%), and malignant effusions (8.1%). **Conclusions:** Despite significant increases in the use of hospice near death, utilization of ICUs, EDs, and acute inpatient care at the EOL rose significantly between 1997 and 2007 for older ovarian cancer patients. Future studies should examine whether this high-intensity health care is avoidable given evidence that high-intensity care is associated with lower patient quality-of-life near death and increased complications in bereaved caregivers.

9524 Poster Discussion Session (Board #13), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Prospective study of vaginal dilator use adherence and efficacy following pelvic and intravaginal radiotherapy.

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Background: Vaginal stenosis (VS) as a late effect of pelvic radiotherapy (RT) and intravaginal brachytherapy (IVB) can impair long-term quality of life. The best care guideline for post-treatment 3x/week vaginal dilator (VD) use is based on limited research. This prospective study aimed to determine adherence and efficacy of VD use as measured by ability to return to pre-RT VD size at 12 months (mos). **Methods:** From 2009-2011, women with rectal (n=28), anal (n=35), endometrial (n= 45) and cervical (n=1) cancers were followed for one-year post-radiation therapy (RT). Clinicians provided structured teaching to use dilators 3x/week, regardless of frequency of sexual intercourse. For 12 mos, patients self-reported dilator size and vaginal symptoms in monthly diaries. At pre-RT, 1, 6 and 12 mos post-RT, clinicians graded VS using CTCAE v3. Adherence was measured as the percentage of times patients used the dilator out of the number of times they were instructed (3x/week X 52 weeks=156). Fisher's exact and Kruskal-Wallis tests were used to assess differences among groups. **Results:** Among 109 participants, aged 28-81 years (median = 58), mean adherence with VD use over a 12 mos period was 42% (sd 34%, 95% CI:36%- 49%). Adherence was highest in the first quarter (58%), but fell to 25% by the fourth quarter. Disease type, treatment sequence and chemotherapy were predictors of adherence (all $p<0.05$). Rectal cancer patients were less likely to adhere to dilator use than anal and endometrial patients. 82% of all patients returned to pre-RT size at 12 mos; of the 49% who reported a decrease in dilator size from pre-RT to 1 month post-RT, 71% were able to return to pre-RT size at 12 mos. Anal cancer patients were most likely to report a decrease in VD size at 1 mo post-RT (77%), but 68% of these patients were able to return to baseline at 12 mos. Disease type and greater adherence to VD use at 6 months were associated with returning to pre-RT size at 12mos (both $p<0.05$). **Conclusions:** Based on this prospective study, VD use is an effective strategy in minimizing VS, but adherence at 12 mos was poor. Future studies are needed to evaluate methods of improving adherence with VD use and to determine the optimal frequency and duration of VD use.

9525 Poster Discussion Session (Board #14), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Preliminary results of RTOG 0831, a randomized, double-blinded, placebo-controlled trial of tadalafil in the prevention of erectile dysfunction in patients treated with radiotherapy for prostate cancer.

Deborah Bruner, Stephanie L. Pugh, Thomas Michael Pisansky, Richard Evan Greenberg, Nadeem Pervez, Daniel R. Reed, Seth A Rosenthal, Rex B. Mowat, Adam Raben, Mark K. Buyyounouski, Lisa A. Kachnic; Nell Hodgson Woodruff School of Nursing, Emory University, Atlanta, GA; Radiation Therapy Oncology Group, Philadelphia, PA; Mayo Clinic, Rochester, MN; Fox Chase Cancer Center, Philadelphia, PA; Cross Cancer Institute, Edmonton, AB, Canada; Arizona Center for Cancer Care, Peoria, AZ; Radiological Associates of Sacramento, Sacramento, CA; Toledo Community Hospital Oncology Program CCOP, Toledo, OH; Helen F. Graham Cancer Center, Wilmington, DE; Boston University Medical Center, Boston, MA

Background: Determine if prophylactic tadalafil maintains spontaneous (off-drug) erectile function (EF) compared to placebo in patients (pts) treated with radiotherapy (RT) for prostate cancer. **Methods:** Double-blind 1:1 randomization to tadalafil 5mg daily for 6 mos vs placebo starting with RT. Primary outcomes measured by International Index of Erectile Function (IIEF). Eligibility included pre-RT IIEF Question [Q] 1 response "sometimes/most times/always" able to get an erection. Ps treated with hormones were excluded. Primary outcome was response to IIEF Q1 at 30 wks (6 wks off drug). Pts were stratified by RT modality (external vs. brachytherapy) and age ($\leq$65 vs. $>$65 years). 182 pts were needed in an intent-to-treat analysis to show a difference from 20% responders with placebo to 40% with tadalafil based on a 2-sided Fishers exact test with α=0.05 and 80% power. **Results:** We report on 155/222 analyzable/eligible pts. Median age was 63 years, white (73%), and external RT (63%). Mean total dose for external RT was 77.23 Gy and 136.74 Gy for brachytherapy with penile bulb D50 of 24.46 Gy and 31.24 Gy respectively. Most pts completed treatment per protocol (84% tadalafil, 70% placebo). Spontaneous EF at 30 wks from drug start was not different (p=0.99) between arms based on IIEF Q1 response, total IIEF score (52.5 drug vs 52.8 placebo), or score change from baseline (-8.0 drug vs -8.8 placebo). No difference in these outcomes was noted at 1 year. Non-responders at 30 wks were likely to be older (age$\geq$65; p=0.432), but there were no significant predictors at 1 year. About 80% of pts maintained spontaneous EF in both arms. **Conclusions:** Low-dose daily tadalafil did not preserve EF within the first year of RT for prostate cancer. If tadalafil positively influences delayed RT-induced vasogenic injury, additional time may be needed to observe a benefit to tadalafil as a preventive agent. Alternatively, tadalafil dose modification or altered dosing schedules may be needed to demonstrate a protective effect of this agent when used with RT. Clinical trial information: NCT00951184.

9526 Poster Discussion Session (Board #15), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Psychosocial outcomes among bereaved and non-bereaved parents of children with cancer.

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Background: Psychosocial outcomes among parents of children with cancer are not well characterized and may affect the well-being of cancer-survivors and other children in the home. In order to examine adverse psychosocial outcomes among bereaved (BR) and non-bereaved (NBR) parents, we conducted a cross-sectional, survey-based study. **Methods:** Enrolled parents completed the "Resilience in Pediatric Cancer Assessment" (RPCA) at least 6 months after their child completed therapy or died from cancer. The RPCA is comprised of validated instruments to assess resilience, emotional distress, social function, health-related quality of life, and financial hardship. Descriptive statistics were used to characterize groups. Differences between groups were assessed with t or Fisher's exact tests. Differences between the combined sample and population norms were assessed with one-sample t or binomial tests. **Results:** 120 (78%) of invited parents completed the RPCA (24 BR; 96 NBR). Compared to the general population, parents had lower levels of self-perceived resilience and higher levels of psychological distress. They were more likely to meet criteria for serious, debilitating psychological distress, or Post-Traumatic Stress Disorder (PTSD). All parents (100%) endorsed at least some PTSD symptoms. Parents also reported less marital satisfaction and family cohesion, and more sleep disturbance and binge drinking than population norms. Conversely, enrolled parents reported higher levels of social support and family adaptability, and were less likely to smoke cigarettes (all $p<0.05$). Compared to parents of survivors, BR parents were less likely to report appreciation for life, an ability to cope, or deal with stress. They had higher levels of psychological distress, more sleep difficulties, and greater financial hardship (all $p<0.05$). There were no differences between BR and NBR parents with respect to marital satisfaction, family function, or perceived general health. **Conclusions:** Parents of children with cancer are at high risk for poor psychosocial outcomes. Compared to parents of survivors, bereaved parents are at additional risk. Interventions aimed at improving resilience and other psychosocial outcomes are needed.

9527 Poster Discussion Session (Board #16), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Screening for depression in community-based radiation oncology settings: Results from RTOG 0841.

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Background: Depression screening is recommended in routine cancer care. Brief tools are needed to identify depressed patients in radiation oncology treatment settings. **Methods:** Patients starting radiotherapy for first diagnosis of any tumor were eligible. Screening measures administered prior to or within the first 2 weeks of radiation therapy included: Hopkins Symptom Checklist (HSCL-25), Patient Health Questionnaire (PHQ-9; PHQ-2), and the National Comprehensive Cancer Network-Distress Thermometer (NCCN-DT). Patients exceeding validated cutoff scores on the HSCL-25, PHQ-9 or PHQ-2, and a systematic sample of patients who screened negative, completed telephone-based administration of the Structured Clinical Interview for DSM-IV (SCID) Mood Disorder modules. **Results**: 463 patients from 35 community-based and 2 academic radiation oncology sites were accrued. The majority were women (n=298, 66%). Participants had breast (45%), GI (11%), lung (10%), gynecologic (6%), or other (27%) cancers. All 454 eligible patients completed the screening questionnaires and 100% of questionnaire items were completed. 75 (16%) screened positive for depressive symptoms. A total of 70 SCID interviews were administered to 37 patients who screened positive and 33 who screened negative. Among those who screened positive, 14 (20%) met SCID criteria for major depression. One participant who screened negative met depression criteria (1.4%). Results indicate the prevalence of depression is 3%. The PHQ-2 demonstrated good psychometric properties for identifying current major depressive episode, using a cut-off score $>$ 3 (ROC area under the curve=0.839). The PHQ-9 $>$ 9 was comparable (AUC=0.837). The NCCN-DT $>$ 4 did not adequately detect depression (AUC=0.64). **Conclusions**: The prevalence of depression was low (3%) among this community-based sample of adults receiving radiotherapy. The PHQ-2 demonstrated excellent psychometric properties to detect depression, which were equivalent to the PHQ-9 and superior to the NCCN-DT. Our findings support using the PHQ-2 to identify patients in need of further assessment and treatment for depression, a low prevalence but clinically significant comorbidity.

9528 Poster Discussion Session (Board #17), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Perceived versus measured functional vaginal capacity in cancer patients with sexual function concerns.

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Background: Actual and perceived loss of vaginal capacity can be a source of distress among female cancer survivors. The objective of this study was to assess perceived (PC) versus measured (MC) functional vaginal capacity in patients presenting with sexual function concerns. **Methods:** This was a cross-sectional registry-based study of women seen at the Program in Integrative Sexual Medicine for Women and Girls with Cancer (PRISM) Clinic. During the visit, patients were presented with graduated vaginal dilators and asked to select the largest dilator they perceived could be inserted without pain (PC) and the dilator representing their desired functional capacity (DC) (for patients with a male partner, this was the size closest to the partner's erect penis). Two models of dilators were offered. Dilators were numbered 1-24 in order of increasing volume. If the patient could accommodate the dilator chosen as PC without pain, she was examined with dilators of gradually increasing size until the patient reported discomfort. The largest dilator tolerated without pain was MC. Differences between PC and MC, and between DC and MC were calculated. The association between penetrative sexual activity in the prior 4 weeks and accuracy of PC was assessed using the Mann-Whitney U test. **Results:** Mean patient age was 46 years (range 21-80, N=69). Most patients had breast (60%) or a gynecologic cancer (23%). Nearly half reported two or more sexual concerns; painful intercourse (81%), vaginal complaints (21%), and loss of libido (19%) were most common. Mean PC was 16.9 (SD 5.2, range 3-24), mean MC was 20.8 (SD 3.4, range 10-24), and mean DC was 21.8 (SD 3.4, range 6-24). PC equaled MC in 22%. PC was less than MC in 75% and less than DC in 81% of patients. Of patients with PC less than DC, 41% had MC equal to or larger than DC. PC was closer to MC in patients reporting penetrative sexual activity in the prior 4 weeks ($p=0.03$). **Conclusions:** In this single-site study, many cancer survivors seeking care for sexual concerns underestimate their functional vaginal capacity. Further study is needed to determine whether correcting patient perception of capacity lessens distress and improves function.

9529 Poster Discussion Session (Board #18), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Prevalence and predictors of suicidal ideation in long-term prostate cancer survivors.

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Background: Prostate cancer (PC) is associated with an increased risk of suicide, even a decade after diagnosis. Prior research has relied largely on registry data collected at diagnosis, so little is known about the role of post-treatment functioning on the development of suicidal ideation (SI) in long-term prostate cancer survivors (PCS). To address this, our study examined the prevalence of SI, and the association with cancer therapy and post-treatment physical and emotional health in a cohort of long-term PCS. **Methods:** 695 PCS (5-10 years post-diagnosis) completed a mailed survey on physical and psychological functioning, including the SF-12, EPIC-26, a depression rating scale and 8 items about SI in the prior year. **Results:** 12% endorsed having SI and 2% reported serious SI, plans or urges. Serious SI was more common in PCS compared to age and gender-adjusted normative data. SI was not associated with demographic variables (age, ethnicity, marital status, education, income). SI was not associated with prostate cancer stage, treatments or progression. In univariate analyses, SI was significantly associated with prostate-specific symptoms, poor physical and emotional function, a higher frequency of significant pain, and clinically significant depression ($p<.01$). In an adjusted logistic model, depression and frequent pain remained associated with SI. Of note, 61% of PCS with SI denied a prior depression diagnosis, and 47% denied elevated current depressive symptoms. The majority of PCS with SI (97%) had a recent physician visit, and reported significant interest in receiving mental health information. **Conclusions:** A significant proportion of PCS report recent SI, which is associated with physical and psychological dysfunction, but not PC treatments. Depression and frequent pain, rather than PC-specific symptoms, are most important in the development of SI. While depression is strongly associated with SI, many PCS with SI have no prior or current depression, underscoring the need to evaluate SI independently. PCS with SI reported receiving regular medical care and interest in information about mental health. This emphasizes the critical role that physicians can play in identifying PCS at high risk for suicide.

9530 Poster Discussion Session (Board #19), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Long-term symptom burden and orodental health of oropharyngeal cancer (OPC) survivors following treatment with chemoradiotherapy (CRT) or sequential therapy (ST).

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Background: OPC treatment is associated with significant long-term toxicity. Very little is known about the long-term symptom burden and orodental health in OPC survivors >2 yrs from treatment. **Methods:** Survivors treated for OPC with CRT/ST (involving definitive RT) at Dana Farber Cancer Institute between 2002-2011 and >2 yrs from treatment completion, were identified by chart review and asked to complete the Vanderbilt Head and Neck Symptom Survey version 2 (VHNSS v2), National Health And Nutrition Examination Survey for Oral Health Questionnaire, health care availability survey. **Results:** 200 survivors were contacted, 127 responded (RR: 64%). Median age at diagnosis was 54 yrs; 85% males; 85% stage IVA/B, 13% stage III; 56% CRT, 43% ST. HPV status: 47% (+), 10% (-), 43% unknown. Median time from treatment completion: 50 mths (24-135 mths). Residual moderate to severe toxicities reported in VHNSS v2: 71% dry mouth; 59% difficulty chewing/swallowing food; 53% feeling of food becoming stuck in the throat; 53% prolonged time to eat; 31% thick mucus, 6% had difficulty sleeping secondary to this; 16% trouble speaking, 27% trouble hearing;30% limitation of neck/shoulder movement; altered taste/smell - 45%/23%; sensitivity to spicy food and dryness-57%/62%; 30% decreased desire to eat, 11% had moderate weight loss. Orodental health assessment: 13% thermal sensitivity, 21% teeth cracking and chipping, 20% loose teeth, 33% had treatment for gum disease, 42% had lost bone around teeth. 98% survivors had health insurance; only 66% had dental insurance. No statistically significant difference was noted with respect to symptoms between CRT or ST. ST did not affect long-term toxicity compared to CRT alone. **Conclusions:** OPC is known to correlate with HPV positivity, early age at diagnosis and high rates of long-term survival after appropriate therapy. Our study documents that the OPC survivors have substantial residual long-term head and neck and orodental symptoms directly related to the treatment that significantly impacts their quality of life. A substantial number of patients lack dental health coverage, which likely further impacts symptom burden and QOL.

9531 Poster Discussion Session (Board #20), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Effect of YOCAS yoga on insomnia and sleep medication usage among breast cancer patients receiving hormone therapy: A URCC CCOP randomized, controlled clinical trial.

Luke Joseph Peppone, Michelle Christine Janelsins, Anita Roselyn Peoples, Charles Stewart Kamen, Jeffrey J. Kirshner, Rakesh Gaur, James Atkins, Pavan S. Reddy, Karen Michelle Mustian; University of Rochester Medical Center, Rochester, NY; Hematology-Oncology Associates of Central New York, East Syracuse, NY; NSABP; Kansas City CCOP, Kansas City, MO; Southeastern Medical Oncology Center, Goldsboro, NC; Cancer Center of Kansas, Wichita, KS

Background: Insomnia (INS) is a highly prevalent side effect of hormonal therapy for breast cancer. Patients often turn to Rx sleep meds, which may lead to negative interactions with cancer therapeutics, dependency, rebound impairment, and do not cure INS. We conducted a secondary data analysis of a multi-site, phase III RCT examining the efficacy of yoga for improving INS and decreasing sleep medication usage among breast cancer patients currently receiving hormone therapy through the University of Rochester Cancer Center Community Clinical Oncology Program (CCOP). **Methods:** The original RCT randomized patients with any type of non-metastatic cancer without previous yoga participation into 2 arms: 1) standard care monitoring [controls] or 2) 4-week yoga intervention (2x/wk; 75 min/session) plus standard care. The yoga intervention utilized the UR Yoga for Cancer Survivors (YOCAS) program consisting of breathing exercises, 18 Hatha and Restorative yoga postures, and meditation. Only breast cancer patients currently receiving aromatase inhibitors (N = 95) or tamoxifen (N = 72) were included in this analysis. Changes in INS and sleep meds between the groups were assessed using ANCOVA with baseline values as covariates. **Results:** Despite using Rx sleep meds at baseline, INS, assessed by the Insomnia Severity Index, was worse for those women compared to women not taking any Rx sleep meds (Rx = 15.3 vs No Rx = 13.1; $p<0.01$). Yoga participants demonstrated greater improvements in INS compared to controls (CS=change score; Yoga CS = −3.3 vs Control CS = −0.5; $p<0.01$). In addition to improved INS, yoga participants significantly decreased Rx sleep med usage compared to controls (Yoga = −17.6% vs Control = −3.3%; $p=0.04$). There was also a trend toward lower combined Rx/Non-Rx sleep med use for the yoga group compared to controls (Yoga = −14.5% vs Control = −3.1%; $p=0.09$). **Conclusions:** YOCAS yoga is a safe intervention that significantly improves INS while concurrently reducing Rx sleep medication usage among breast cancer patients receiving hormone therapy. Funding: MRSG-13-001-01-CCE, NCI U10CA37420, K07CA120025 and OCCAM supplement. Clinical trial information: NCT00397930.

9532 Poster Discussion Session (Board #21), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Actigraphy measured sleep disruption as a predictor of survival in advanced breast cancer.

Oxana Palesh, Arianna Aldridge Gerry, Jamie M. Zeitzer, Cheryl Koopman, Booil Jo, Eric Neri, Bita Nouriani, David Spiegel; Stanford University, School of Medicine, Stanford, CA; Stanford University, School of Medicine; Veterans Affairs Palo Alto Health Care System, Palo Alto, CA

Background: Sleep disruption, prevalent in cancer patients and survivors, is associated with disrupted hormonal circadian rhythms and poor quality of life. Previous studies in cancer patients and survivors have pointed out the association between poor sleep and faster disease progression. However, until now these studies have been limited by their retrospective or correlational design, providing little resolution of the question of whether sleep disruption accelerates disease progression or whether disease progression dysregulates sleep, or whether a third factor might underlie the association between sleep dysregulation and disease progression. This study aimed to clarify this relationship by using a longitudinal research design to examine whether sleep disruption assessed at baseline predicts survival in women with metastatic breast cancer. **Methods:** We examined sleep quality and duration in 97 women diagnosed with metastatic breast cancer (mean age=54.6, SD=9.8) via wrist-worn actigraphy for 3 days and sleep diaries. Sleep quality was operationalized as poor sleep efficiency (the ratio of total asleep time to total time in bed * 100%). **Results:** As hypothesized, poor sleep efficiency was found to predict shorter survival (Hazard Ratio (HR), 0.96, 95% CI, 0.93 to 0.98, $p<0.001$) over 6 years. This relationship remained significant (HR, 0.94, CI, 0.91 to 0.97, $p<.001$) even after controlling for other known prognostic factors (age, ER status, cancer treatment, metastatic spread, cortisol levels, and depression). **Conclusions:** Our findings show that sleep dysregulation is a clear and significant independent prognostic factor for disease progression in metastatic breast cancer. Further research is needed to determine whether treating sleep disruption with cognitive behavioral therapy or medication can improve survival in metastatic breast cancer. Funded by P01AG018784, R01CA118867, K07CA132916.

9533 Poster Discussion Session (Board #22), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

The impact of positive spousal support on trauma symptoms and sleep disturbance among prostate cancer survivors.

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Background: Receiving a diagnosis of cancer can lead to psychological effects including symptoms of traumatic stress. Trauma symptoms can dysregulate sleep and sleep disturbance has been linked with negative health outcomes. Cancer-related trauma symptoms and sleep disturbance can affect the spouse of the cancer patient and the couple's relationship; conversely, a supportive relationship can improve cancer survivors' mental health. The impact of spousal support on trauma and sleep disturbance among prostate cancer survivors has not yet been examined. **Methods:** 315 prostate cancer survivors (mean age 66, 89% Caucasian), of whom 265 were married and 50 were unmarried (single, widowed, separated or divorced) completed the Impact of Events Scale (IES), Stanford Sleep Questionnaire, and a measure of positive spousal support. Data are self-report. Rates of trauma symptoms and sleep disturbance by marital status were compared using t-tests, and the contribution of marital status and spousal support to variance in these outcomes was evaluated using linear regression. **Results:** 13.4% of survivors reported significant (i.e., >27 point IES cutoff) symptoms of traumatic stress and 23.2% reported moderate or higher rates of sleep disturbance. Trauma symptoms ($t= -2.16$, $p<.01$) and sleep disturbance ($t= -3.14$, $p<.01$) were significantly lower in married than unmarried survivors. Spousal support was negatively associated with trauma symptoms ($r= -.18$, $p<.01$) and sleep disturbance ($r= -.20$, $p<.05$), and inclusion of spousal support as a covariate rendered the linear relationship between marital status and both trauma symptoms and sleep disturbance non-significant ($p>.05$). **Conclusions:** Spousal support is associated with reductions in trauma and sleep disturbance, over and above dichotomous marital status. This area needs further study, given high rates of trauma symptoms and difficulty disclosing health-related concerns among men with prostate cancer. Future research needs to explore mechanisms by which spousal support leads to improvement in trauma symptoms and sleep outcomes. Interventions bolstering spousal support could improve mental health in prostate cancer survivors.

9534 Poster Discussion Session (Board #23), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

Risk perceptions in localized breast cancer (BC).

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Background: Risk perceptions (RP) play an important role in decision making in localized BC. Little is known about RP in the context of adjuvant (adj) therapy decisions. We examined the accuracy of estimate of absolute benefit of adj therapy among patients (pts) with localized BC and sought to identify determinants of accurate RP. **Methods:** A cross-sectional survey was conducted in localized (Stage I-III) BC pts within 3 months after surgery at 4 U.S. cancer centers. Pts completed the Decision Quality Instrument, which includes items on BC knowledge, numerical estimates of benefit of adj therapy, and communication with providers. We analyzed pts with Stage I/II and calculated objective estimates of benefit of adj therapy using Adjuvant! Online. Based on published data, an estimate that was +/- 5% of the calculated risk was considered correct. We used multivariable (MV) regression to identify determinants of accuracy including tumor stage, age, adj treatment, education, total knowledge score, and decision involvement. **Results:** 192/249 (77.1%) pts completed the survey; analyses were limited to 166 pts stage I/II with complete risk estimate data. Mean age was 56.4 years (SD 12.1), 83% of respondents were white, and 58.5% were college graduates. 56.3% had stage I and 43.7% had stage II disease. Most (95.6%) had some type of adj therapy, either endocrine therapy only (43.2%), chemotherapy only (15.3%), or both (32%). On average, pts estimated the absolute benefit of adj therapy to be 31.8% (SD24.9), and this varied by stage (28.4 and 35.9 for stage I and II, $p=0.06$). The overall estimate for this sample from Adjuvant! Online was 11.8% (SD 7.67) and this varied by stage (8.6/16.0 for stage I/II respectively, $p<0.001$). Few pts (18.1%) had accurate estimates and the majority (68.3%) overestimated the benefit. In MV logistic regression analysis, only BC knowledge score was associated with accurate estimate of benefit (OR 1.36 95%CI 1.04, 1.8). No other factors were significantly associated with accuracy. **Conclusions:** Pts with localized BC overestimated the absolute benefit of adj therapy by an average of 20 percentage points. Some pts may be taking on risks of adj therapy without accurate knowledge of the benefits, calling into question whether these decisions are truly informed.

9535 Poster Discussion Session (Board #24), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

From Bayesian modeling to genomic mapping: Biologic validity of predictive single nucleotide polymorphism networks for chemotherapy-related side effects.

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Background: Using proprietary Bayesian network (BN) algorithms, we discovered interacting single nucleotide polymorphism (SNP)-BNs predicting patient-risk for 6 chemotherapy (CT)-induced side effects (SEs): oral mucositis (OM), diarrhea (D), CT-induced nausea and vomiting (CINV), fatigue, cognitive dysfunction (CD) and peripheral neuropathy (PN). To assess biologic validity, SNP-BNs mapped each SE to its gene loci, exploring biologic pathways for those genes. Roles of genes and pathways found in similar phenotypic diseases (e.g., Inflammatory Bowel Disease [IBD] for D, Alzheimer disease [AD] for CD, chronic fatigue syndrome [CFS] for F) were explored. **Methods:** Via an FDA-cleared DNA extraction kit, saliva was collected from 78 women with breast cancer (dose-dense AC+T) and 57 patients with colon cancer (FOLFOX +/- bevacizumab). We assessed 2.5M SNPs/patient (Illumina OmniQuad bead chip assays). SEs were measured via a validated tool (Patient Care Monitor). Analyzed SNP arrays and SEs discovered SNP-BNs. Final SNP-BNs per SE included gene name, symbol, and loci. Pathways and networks were analyzed for gene function and related genes, querying 6 databases (NLM, NextBio, Weizmann Institute, SPRING, Gene Ontology, AmiGO). **Results:** Mucosal injury-implicated networks and genes were identified, including oxidative stress, NF-κB, pro-inflammatory cytokines IL-1, IL-6, and TNF, MMPs and fibronectin breakdown (SPOCK3). D networks and genes overlapped with IBD (ERG, IER2, CASK). SNP-BNs for CINV overlapped in both CT regimens with genes for neurotransmitters (serotonin, dopamine, substance P) and nerve impulse transmission. B3GAT1, involved with opioid-induced CINV, was identified. F networks involving genes and pathways for cytokines and skeletal muscle overlapped to CFS. CD networks involve genes in AD. PN networks mapped genes involving myelination, demyelination, inflammation, and toxic neuropathy. **Conclusions:** SNP-BNs predicting CT-induced SEs mapped to genes associated with known biology of each SE, sharing central traits with other diseases, and are targets for drug discovery in cancer-related SEs and unmet needs, including AD.

9536 Poster Discussion Session (Board #25), Sat, 1:15 PM-5:15 PM and 4:45 PM-5:45 PM

The role of social exposure to smoking on smoking cessation in adult cancer survivors.

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Background: We previously described a strong inverse relationship between social smoking exposures (at home, spousal and with peers) and smoking cessation in lung cancer, with adjusted odds ratios (aOR) of 3-8 (Eng et al, ASCO 2012, abst 9032). In the current analysis, we evaluated whether these associations hold true in adult cancers in general, particularly cancers not traditionally known to have smoking as a risk factor. **Methods:** 616 cancer survivors across multiple cancer sites were surveyed on their smoking, alcohol, and physical activity habits before and at various times after cancer diagnosis. Social smoking exposures were documented. Multivariate logistic regression models evaluated the association of each variable with change in each habit after diagnosis adjusted for significant socio-demographic and clinico-pathological covariates. **Results:** Median follow-up after diagnosis was 26 months. 15% had breast cancers; 15% gastrointestinal; 20% genitourinary-gynecological; 24% haematological; 36% other. Among current smokers at diagnosis, 56% quit after diagnosis; no ex- or never-smoker restarted. Patients without secondary home smoking exposure were significantly more likely to quit smoking than those with home exposures (aOR=9.5, 95% CI [2.4-37.8]). Similar results were seen in patients with non-smoking spouses versus smoking spouses (aOR=3.7 [1.0-13.4]), and with lack of peer smoke exposure (aOR=3.7 [1.3-10.7]). 63% patients who quit did so in the 1 year period surrounding the diagnosis date (6-months pre or post diagnosis). In comparison, first and second-hand smoking exposures did not affect other modifiable behaviours such as alcohol or physical activity. Patient awareness of quality of life and survival benefits of smoking cessation and receiving smoking cessation counselling were not associated with improved smoking cessation. **Conclusions:** Secondary smoking exposures are associated with lack of smoking cessation in adult cancer survivors, even in cancers not traditionally linked to smoking. Being diagnosed with cancer may be an important ′teachable moment′ to help patients quit, but results are strongly influenced by the surrounding social exposure to smoking. PS and GL contributed equally.

9537 General Poster Session (Board #25A), Mon, 1:15 PM-5:00 PM

Opportunities for improved end-of-life (EOL) care for adult patients with advanced cancer: Results of a longitudinal assessment of care provided by Quality Oncology Practice Initiative (QOPI) participants.

David W. Dougherty, Pamela Kadlubek, Trang Pham, Craig Earle, Jennifer Malin, Larry Breathwaite, Joseph O. Jacobson; University of Rochester Medical Center, Rochester, NY; American Society of Clinical Oncology, Alexandria, VA; Institute for Clinical Evaluative Sciences, Toronto, ON, Canada; WellPoint, Inc., Indianapolis, IN; Dana-Farber Cancer Institute, Boston, MA

Background: End of life care of patients with advanced cancer has received recent attention because of evidence of widespread variation in utilization of aggressive therapies and interventions and possible suboptimal use of palliative care and hospice services. QOPI, the ASCO sponsored quality assessment program, has been available to all United States physician members since January 2006 and has assessed EOL care since its inception. The current analysis explores whether the increased national focus on EOL and increased availability of palliative care and hospice services has resulted in improvements in EOL care as reported by QOPI participants. **Methods:** Data was aggregated across all EOL care quality measures for 9 sequential semi-annual QOPI collection periods from 2008 through 2012. Trends were analyzed among rates of eligible patients related to hospice enrollment and timing of enrollment, palliative care referrals, discussions about hospice and palliative care, and chemotherapy administration at the end of life. The Cochran-Armitage trend test was performed to determine the significance of trends and differences in measure performance over time. **Results:** From Fall 2008 to Fall 2012, the rate of hospice enrollment for appropriate patients improved by 7.4% [51.8% to 59.2%; $p<0.0001$] and the rate of hospice enrollment or palliative care referral improved by 5.6% [63.3% to 68.9%; $p<0.0001$]. Modest improvements were seen in the rates of hospice enrollment more than 3 and 7 days before death [2.8%, 2.6%], discussion of hospice or palliative care with patients not referred for these services within the last 2 months of life [2.7% increase; 19% to 21.7%], and chemotherapy administration within the last 2 weeks of life [2.4% improvement from 13.7% to 11.3%]. **Conclusions:** Despite modest increases in the rate of hospice enrollment and palliative care referrals over time, EOL care for adult patients with cancer associated with QOPI practices remains suboptimal. Opportunities exist to increase more meaningful participation in hospice and palliative care and to reduce exposure to chemotherapy near death.

9538 General Poster Session (Board #25B), Mon, 1:15 PM-5:00 PM

Factors related to end-of-life (EOL) chemotherapy in solid tumor (ST) patients.

Maria Alma Rodriguez, Yvette A DeJesus, Lee Cheng, Aman Buzdar, Thomas W. Burke; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Oncologists will be required to report quality measures for cancer care, including use of chemotherapy in the last two-weeks of life. In this study, we evaluated how use of chemotherapy in ST patients (pts) within 14 days of EOL may be influenced by clinical factors. **Methods:** Adult pts (≥18 years) treated for ST at our institution, deceased December 01, 2010 through May 31, 2012, were retrospectively studied. Data on demographics, chemotherapy (excluded: hormones) within 14 days EOL, comorbidities, and cancer diagnoses were from tumor registry and administrative databases. Logistic regression analysis was performed for association of EOL chemotherapy with age, gender, ethnicity, comorbidities , cancer types, and metastatic status. **Results:** 5,607 pts met study criteria: median age 64 years; 48% female; 76% metastatic disease. EOL chemotherapy frequency was 3.9% overall, 4.6% in metastatic disease versus 1.7% in non-metastatic disease ($p<0.01$). In 23 patients with non-metastatic disease who received chemotherapy, the diagnoses were: brain/other nerve system (34.8%, 8/23) and lung/bronchus (21.7%, 5/23).The top 10 frequencies in chemotherapy use by tumour sites were: melanoma (6.7%), female breast (5.5%), lung & bronchus (4.9%), pancreas (4.2%), brain/other never system (3.9%), head & neck (3.8%), female genital system, excluding ovary (3.4%), ovary (3.2%), liver/intrahepatic bile duct (3.0%), colon & rectum (2.6%). By regression analysis, the factor statistically significantly associated with receiving chemotherapy was metastatic disease (odds ratio [OR], 3.29; 95% CI,1.96-5.54), while factors associated with significantly less treatment were age ≥ 65 (OR, 0.66; 95% CI, 0.49-0.90); and any co-morbid conditions (≥1 versus 0) (OR, 0.58; 95% CI, 0.38-0.89). **Conclusions:** A small portion of ST patients who died received EOL chemotherapy (3.9%). However, metastatic disease and diagnosis category influenced treatment. Melanoma and breast cancer patients had higher frequency of EOL treatment. Older age and comorbidities were associated with less treatment. Variation in EOL treatment of ST patients is thus influenced by several clinical factors, but did not seem influenced by gender or ethnicity factors.

9539 General Poster Session (Board #25C), Mon, 1:15 PM-5:00 PM

Pattern of chemotherapy use at end-of-life (EOL) in patients with solid tumors (ST).

Thomas W. Burke, Yvette A DeJesus, Lee Cheng, Aman Buzdar, Maria Alma Rodriguez; The University of Texas MD Anderson Cancer Center, Houston, TX

Background: Quality performance measures for cancer care, including use of chemotherapy in the last two-weeks of life, will be required for reporting. In this study, we evaluated the pattern and frequency of chemotherapy use for ST patients in the last two-weeks of life, and whether such treatment included standard or investigational drugs. **Methods:** We conducted a retrospective study of 5,607 adult cancer patients (≥18 years) who received their care at The University of Texas MD Anderson Cancer Center and died between December 01, 2010 through May 31, 2012. Data on patients' demographics, and chemotherapy agents dispensed (excluded: hormones) were obtained from the institution's administrative databases. Type of treatment (research versus standard) was obtained from our chemotherapy dispensed database. *Chi*-square test and Fisher's exact test were used to determine the association between categorical variables.All statistically significant levels were determined with P values < 0.05. **Results:** Only 3.9% (216/5,607) of ST patients who died had received chemotherapy within 14 days EOL. For those 216 patients who received chemothapy: median age 64 years; 48% female; 89% metastatic disease. The distribution by chemotherapy treatment route: intravenous (IV) 85%; IV plus oral 6%; oral 6%; other 3%. The distribution of patients by number of chemotherapy agents: one 56%; two 31%, and three or more 13%. Among those who received chemotherapy, 98.6% (213/216) of the chemotherapy administered were standard agents. There were no differences in frequency distribution for chemotherapy treatment route ($p>0.05$), number of chemotherapy agents ($p>0.05$) between patients with metastatic and non-metastatic disease, or between men and women ($p>0.05$). **Conclusions:** Our results indicate EOL chemotherapy use was infrequent in our patients with STs, and most of those treated received standard chemotherapy, with simple one or two drug regimens. We need more research to determine factors that influence chemotherapy use at EOL, and if it palliates physical symptoms and/or emotional distress in advanced stages of disease.

9540 General Poster Session (Board #26A), Mon, 1:15 PM-5:00 PM

End-of-life experience of patients with rare cancers and their caregivers.

Elizabeth Trice Loggers, Holly Gwen Prigerson; Group Health Research Institute and Fred Hutchinson Cancer Research Center, Seattle, WA; Dana-Farber Cancer Institute, Boston, MA

Background: Cancers are defined as rare if fewer than 35,000 cases are diagnosed per year. Rare cancers represented 23% of incident cancer cases and 33% of cancer deaths in 2008. However, little is known about the end-of-life (EOL) experience of patients with rare cancers or their caregivers. **Methods:** From September 2002 to August 2008, 618 advanced cancer patients (195 with rare and 423 with common stage IV cancers following failure of first line chemotherapy) and their caregivers participated in a U.S. multi-site, prospective, interview-based cohort study (Coping with Cancer). Patients were interviewed about EOL preferences, planning, and care at study entry. Interviews with caregivers at baseline assessed caregiver mental and physical health, while post-mortem surveys assessed EOL patient care. Descriptive statistics (t-test, chi-square) were used to characterize the study sample; logistic regression tested the association between cancer type and care received, controlling for confounders. **Results:** Rare cancer participants were more likely to be younger (57.7 vs 60.7 years, p=.01), Hispanic (19% vs 9%, p=.002) and have fewer co-morbidities (Charlson comorbidity index, mean 5.9 vs 6.5, p=.004), than their common-cancer counterparts. Rare cancers patients were four times more likely to be receiving both radiation and chemotherapy at study entry than common cancer patients (10.3% versus 3.3%, OR 4.31, p=0.003), but equally as likely to acknowledge their illness was terminal, have EOL discussions, and participate in advance care planning as common cancer patients. Caregivers of patients with rare cancers were more likely than common cancer caregivers to report declining health during the prior year of care-giving (22.1% versus 15.7%, p=0.05) and marginally more likely to prefer the patient choose treatment focusing on extending life rather than pain relief (22.3% vs 16.5%, p=0.08). **Conclusions:** Patients with advanced-stage, rare cancers may be treated more aggressively following failure of first line chemotherapy than individuals with common cancers. Future research should investigate patterns and quality of care for terminally ill patients with rare cancers and caregiver burden.

9541 General Poster Session (Board #26B), Mon, 1:15 PM-5:00 PM

Palliative sedation (PS) given to patients treated at the Fundación Santa Fe de Bogotá.

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Background: Around 50% of advanced-stage cancer patients have inadequate control of symptoms during the final period of life; palliative sedation (PS) would seem to be appropriate in such scenario. **Methods:** A retrospective cohort analytical study was carried out for determining the effectiveness of PS, evaluating the non-reduction of the number of final days of life in patients suffering advanced-stage cancer. PS therapy consisted of using a continuous infusion of benzodiazepines, opioids, antipsychotics and/or anaesthetics. **Results:** The study included 145 patients recorded between July 2008 and October 2012. Median age was 68 years (24% of the patients being aged over 80). The main motives for considering PS were dyspnoea (30%), uncontrolled pain (25%), delirium (26%) and presenting more than one of these symptoms (19%). The drugs used were opioids (in 87% of the patients), benzodiazepines (54%) and anaesthetics (2%). Using PS led to symptoms becoming controlled in 79% of the cases compared to 53% without it; symptoms became controlled in 85% of the cases in less than 24 hours when PS was used compared to 15% when it was not used ($p<0.001$). Mean overall survival (OS) was 6.8 days for those who received PS and 7.2 for those who did not (RR 0.94, 0.97-1.33 95%CI; $p=0.72$) and final days of life after starting PS was 2.2 days (<1-16 days). Multivariate analysis showed that using PS (HR 1.49, 1.08-2.07 95%CI; $p=2.04$) and the presence of oedema (RR 0.79, 0.61-1.0 95%CI; $p=0.01$) modified the course of controlling symptoms. **Conclusions:** PS improved the time to controlled cancer symptoms in patients suffering terminal illness, and their presentation profile without modifying the OS.

9542 General Poster Session (Board #26C), Mon, 1:15 PM-5:00 PM

Comparison of toxicity experienced by elderly (E) and younger (Y) patients in breast cancer (BC) clinical trials.

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Background: E patients (pts), age 65 and older, form a large percent of BC pts, but are under-represented in trials, due to actual/perceived frail health, or actual/perceived greater potential toxicity from therapy (rx). With ethics approval, we examined whether E pts had more toxicity than Y pts (< 65 years) in clinical trials. **Methods:** All BC phase II and III drug trials open from 1999 to 2012 at British Columbia Cancer Agency Vancouver Center were reviewed, excluding trials with only premenopausal pts. Adverse events (AE) were captured from case report forms and charts. The primary endpoint was meaningful toxicity (MTOX), defined as any grade 3 or 4 AE; any AE with dose delay or reduction; or premature discontinuation of rx. Frequencies of MTOX were compared using chi-square tests, means were compared with T-tests. **Results:** Among 46 trials enrolling 799 pts, rx types were chemotherapy ([CT], 18% of pts), hormone ([HT] 40%), skeletal ([ST] 14%), targeted ([T] 14%]) and CT + T (14%). Pts were 19% E (age range 65-84) and 81% Y (age range 25-64). E pts were more likely to enroll in HT and ST trials; Y pts were evenly distributed among all rx types. Toxicity data (Table) was available for 778 pts (97%). **Conclusions:** In non CT trials, E and Y pts had similar frequency and number of MTOX. Few E (5%) enrolled in CT trials, but with no more MTOX than Y pts. Discontinuation of rx was equal in E and Y, considering all rx types. Appropriate selection of E pts by eligibility criteria, self selection, and/or clinician assessment allows safe participation of E pts in BC trials. Fear of increased MTOX should not exclude fit E pts from trial participation.

Toxicity by age cohort.

	All	Y	E	P value
All trials				
N (%)	778 (100)	631 (81)	147 (19)	
Pts with MTOX (%)	408 (52)	337 (53)	71 (48)	0.26
Average number MTOX per pt	1.0	1.0	0.78	0.01
Pts with AE leading to change in rx (%)	341 (44)	288 (46)	53 (36)	0.035
Pts discontinuing rx due to AE (%)	122 (16)	96 (15)	26 (18)	0.46
Pts discontinuing rx for non AE reason (%)	30 (3.9)	22 (3.5)	8 (5.4)	0.27
CT and CT + T trials				
N	245	232	13	
Pts with MTOX (%)	189 (77)	178 (76)	11 (85)	0.51
Average number MTOX per pt	1.7	1.7	2.5	0.13
HT, ST, T trials				
N	533	399	134	
Pts with MTOX (%)	219 (41)	159 (40)	60 (45)	0.32
Average number MTOX per pt	0.65	0.65	0.62	0.70

9543 General Poster Session (Board #27A), Mon, 1:15 PM-5:00 PM

Health behaviors (HB) and geriatric assessment (GA) in older women with breast cancer (BC).

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Background: Physical inactivity (PI), alcohol (A) and tobacco (T) abuse are associated with poor health outcomes in older adults, however, little is known about the prevalence of these HB and their associations with GA domains in older cancer patients (pts). This study explores the relationship between HB and GA in older BC pts. **Methods:** Between 03/2010-01/2013, 111 pts ≥65 yrs completed a predominantly self-administered GA (Hurria *et al.* Cancer 2005) comprising measures of comorbidity, polypharmacy, cognitive, functional, psychosocial and nutritional status as well as a nine-item HB questionnaire based on the 2006/7 National Health Interview Survey (www.cdc.gov/nchs/nhis.htm) assessing PI, A and T use. Fisher's Exact and Wilcoxon Rank sum test were used to evaluate associations with GA measures. **Results:** Median age was 72 (range 65-94). Most pts were white (89%), married (61%), retired (86%) and at least high school graduates (96%). 51% never smoked while 45% were former and 4% current smokers. Former/current smokers were more likely than never smokers to have slower gait speeds (Timed "up and go" >14 second; 32 vs 14%; p=.04) and took more daily prescription medications (mean 5 vs. 4; p=.04). 52% of pts consumed at least one alcoholic drink per week (median 3.5). Modest alcohol consumption was associated with less activity of daily living (ADL) impairment (p=.03), lower mean BMI (29 vs. 26 kg/m^2 p=.03) and greater non-prescription medication use (p=.04). 48% never performed vigorous activity and these pts were more likely than those exercising to have one or more functionally impairing comorbidities (p=.03); mainly arthritis. PI correlated with more impairment in both ADL (p<.0001) and instrumental ADL (p=.004). HB were not associated with demographic factors, treatment phase, weight loss, falls, sensory impairment, social activity, anxiety or depression in this dataset. **Conclusions:** PI, T and A use were common in this cohort of older BC pts and were associated with significant impairments in several GA domains. These findings reinforce the need for interventions to improve HB in older BC pts. Support: Breast Cancer Research Foundation, New York, NY and Lineberger Comprehensive Cancer Center, Chapel Hill, NC.

9544 General Poster Session (Board #27B), Mon, 1:15 PM-5:00 PM

Outcomes of patients ≥ 65 yrs with advanced cancer treated on phase I clinical trials.

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Background: Older patients with cancer are underrepresented in clinical trials; their disease biology and comorbidities may impact the decision to consider a clinical trial. Here we systematically analyze outcomes of elderly pts treated on phase I clinical trials. **Methods:** The characteristics, toxicity, survival, and response of pts with advanced cancer treated on phase I clinical trials from 1/04 – 12/09 were studied. **Results:** Overall,347 of 1,182 pts (29%) were >65 yrs old. The Table lists pt characteristics by treatment regimen. 251 pts received a targeted agent, of which 241 (96%) received an investigational, non-FDA approved drug. Of 347 pts, 3 (1%) had a CR, 15 (4%) a PR, 127 (37%) SD, of which 43 (12%) had SD ≥ 6mos. Of 347 pts, 194 (56%) had >1 drug-related toxicity, of which 89 (26%) had a Grade 3-4 toxicity, most often hematologic; 72% of toxicities on targeted therapies were Grade 1-2. Six pts had a DLT; there was one death (<0.01%) "possibly" attributed to the study drug. Median OS from 1st phase I Clinic visit was 8.8mos (95% CI, 7.8-10.6). Median TTF on 1st phase I trial was 1.9mos (95% CI, 1.8-2.1). Multivariate analyses demonstrated that ECOG PS 2-3 (vs. 01) ($p < 0.001$) and liver mets (vs. no liver mets) ($p < 0.01$) were independent factors predicting shorter TTF and OS. **Conclusions:** Our results suggest that phase I clinical trials are well tolerated and offer a reasonable therapeutic option for pts > 65 yrs.

Patient characteristics and outcomes by treatment regimen.

	Cytotoxic	Targeted	Cytotoxic + targeted	HAI or IP
N	22	251	55	19
Age, median, yrs	74	70	69	69
Age, range, yrs	65 - 84	65 - 88	65 – 81	65 - 76
Gender: M:F	10:12	150:101	31:24	8:19
ECOG				
0	5	69	18	8
1	14	165	32	10
2	3	16	5	1
3	0	1	0	0
Presence of liver mets: Y:N	8:14	111:140	16:39	17:02
# prior therapies, median (range)	4 (0 - 12)	3 (0 - 16)	4 (0 - 10)	4 (1 - 7)
Median PFS on phase I therapy, mos	2.4	1.8	2.3	3.1
Median OS on phase I therapy, mos	8.9	7.8	12.7	9.9
# pts with therapy-related toxicity (%)	10 (45%)	130 (52%)	41 (75%)	13 (68%)
# of SAEs	22	301	95	45
# of grade 1/2 events (%)	9 (41%)	216 (72%)	59 (62%)	40 (89%)
# of grade 3/4 events (%)	13 (59%)	87 (28%)	36 (38%)	5 (11%)

HAI, hepatic arterial infusion; IP, intraperitoneal; OS, overall survival; PFS, progression-free survival.

9545 General Poster Session (Board #27C), Mon, 1:15 PM-5:00 PM

Measures of polypharmacy and chemotherapy toxicity in older adults with cancer.

Ronald John Maggiore, Tao Feng, William Dale, Cary Philip Gross, William P. Tew, Supriya Gupta Mohile, Cynthia Owusu, Heidi D. Klepin, Stuart M. Lichtman, Ajeet Gajra, June M McKoy, Vani Katheria, Rupal Ramani, Reena Jayani, Jaycen Brown, Arti Hurria; University of Chicago Medical Center, Chicago, IL; City of Hope, Duarte, CA; The University of Chicago Medical Center, Chicago, IL; Yale School of Medicine, New Haven, CT; Memorial Sloan-Kettering Cancer Center, New York, NY; University of Rochester Medical Center, Rochester, NY; Case Western Reserve University, Cleveland, OH; Wake Forest University, School of Medicine, Winston-Salem, NC; Upstate Medical University, Syracuse, NY; Department of Medicine, Robert H. Lurie Comprehensive Cancer Center, Northwestern University Feinberg School of Medicine, Chicago, IL

Background: Polypharmacy is common and associated with adverse clinical outcomes in older adults. Potentially inappropriate medication (PIM) use serves as an adjunctive assessment of polypharmacy. The goals of this study in an outpatient population of older adults with cancer (CA) were: 1) to estimate the prevalence of polypharmacy using multiple measures; and 2) to determine the relationship between polypharmacy and chemotherapy (chemo) toxicity. **Methods:** Medication use was evaluated in 500 patients (pts) age ≥65 years with invasive CA who were starting a new chemo regimen. Polypharmacy was defined by number of daily medications (meds), including non-prescription meds. PIM use was defined by 4 indices: Beers (2003 and 2012 update), Zhan, and HEDIS Drugs to Avoid in the Elderly (DAE) criteria. Prevalence of polypharmacy, PIM, and their association with grade 3-5 chemo toxicity [NCI Common Toxicity Criteria (v. 3.0)] were analyzed using chi square test and unconditional logistic regression. **Results:** All 500 pts were evaluable [mean age, 73 years (range 65-91); 56% female; 61% stage IV]. The mean number of daily meds was 5 (range 0-23); 38% used ≤3 daily meds, 51% used 4-9 meds, and 11% using ≥10 meds. Using 0-3 daily meds as the referent group, no association was found between daily meds and chemo tox: 4-9 meds, OR 1.34 (95% CI: 0.92-1.97); ≥10, OR 0.82 (95% CI: 0.45-1.49). PIM use was identified in 87 (17%), 147 (29%), 54 (11%), and 69 (13%) patients utilizing the 2003 Beers, 2012 Beers, Zhan, and HEDIS DAE criteria, respectively. There was no association between each PIM use index and chemo toxicity ($p>0.10$ for all). **Conclusions:** Polypharmacy and PIM use were common in the geriatric oncology population. Although polypharmacy did not increase the risk of chemotherapy toxicity in this sample, further studies of polypharmacy's impact on additional outcomes, including non-chemotherapy adverse drug events, in older persons with cancer are warranted.

9546 General Poster Session (Board #28A), Mon, 1:15 PM-5:00 PM

Differences in patterns of care and outcomes of elderly versus younger metastatic pancreatic cancer (mPC) patients.

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Background: Despite a median age at diagnosis of 72, elderly pancreatic cancer patients (pts) are poorly represented in clinical trials. We thus compared patterns of care and outcomes of mPC pts $\leq$ and $>$ 65 yrs of age. **Methods:** We retrospectively analyzed medical charts of 277 mPC pts treated at an academic center between 2000 and 2009. Age groups $\leq$ 65 yrs and $>$65 yrs were compared with respect to gender, comorbidities, performance status (PS), tobacco/alcohol use, primary site, stage, histological grade, metastatic sites, treatment modalities, type and number of chemotherapeutic agents received, and survival after diagnosis of mPC (OS). Log-rank tests and Cox proportional hazards models were used to analyze survival endpoints and Fisher's exact test to compare categorical variables. **Results:** 155 pts $\leq$65 yrs with median age of 58 and 122 pts $>$65 yrs with median age of 73.5 were evaluated. The groups were well balanced with respect to sex (majority male), PS (majority $\leq$1), stage (majority 3, 4), and primary site (majority head). Cardiovascular (CV) disease was more prevalent among older pts (OR 1.7, $p=0.04$). Older pts were less likely to receive any chemotherapy for mPC (79% vs 92%; OR 0.33, $p< 0.001$) and if treated were less likely to receive more than one agent (34% vs 52%; OR 0.48, $p=0.003$). Median OS was shorter in older pts (5m vs 6m, $p=0.01$). OS was longer with higher number of agents received (RR: 0.57 for young, 0.51 for old; $p< 0.001$). CV and renal disease negatively impacted OS only in younger pts. The presence of lung metastases was associated with longer survival (10m vs 6m ($p=0.01$)) and liver metastases with decreased survival (5m vs 8m ($p<0.01$)) only among younger pts. **Conclusions:** Elderly mPC pts have shorter OS, are less likely to receive chemotherapy, and if treated receive fewer agents compared to younger pts. These differences cannot be explained solely by PS or disease characteristics and warrant further study.

9547 General Poster Session (Board #28B), Mon, 1:15 PM-5:00 PM

Population-based patterns of palliative systemic therapy use in elderly patients with metastatic colorectal cancer (mCRC).

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Background: Elderly cancer patients are consistently under-represented in clinical trials, which may lead to under-treatment. Our aims were to 1) determine the impact of advanced age on use of palliative systemic therapy in mCRC, 2) examine the reasons for treatment choices and 3) compare adverse events and treatment discontinuations in elderly vs young patients. **Methods:** All patients diagnosed with mCRC from 2006 to 2007 and referred to any 1 of 5 regional cancer centers in British Columbia, Canada were reviewed. Summary statistics were used to describe treatment patterns between elderly patients (EP; >/=70 years) and young patients (YP; <70 years). Cox regression models that adjusted for age and confounders were used to determine the effect of systemic therapy on overall survival (OS). **Results:** We identified 1,013 patients: median age was 67 years (range 23-93); 42% were elderly and 58% were young; 57% were men; and 66% had ECOG 0/1. Compared to YP, fewer EP were offered systemic therapy (46 vs 76%, $p<0.001$). Among those treated, EP were less likely than YP to be given combination chemotherapy (47 vs 81%, $p<0.001$) and bevacizumab (19 vs 47%, $p<0.001$). Most common reasons for no treatment were similar in EP and YP: patient choice (32% for both), poor ECOG (18% of EP and 16% of YP), and significant comorbidities (11% for both). Advanced age alone was also cited as a reason among EP (7%) for not receiving therapy. In the subset that was treated, risk of adverse events (24 vs 14%, $p=0.24$) and early treatment discontinuations (14 vs 13%, $p=0.88$) were comparable between EP and YP, respectively. Receipt of systemic therapy was associated with improved OS in both the elderly (HR for death 0.45, 95% CI 0.37-0.56, $p<0.001$) and the young (HR for death 0.43, 95% CI 0.35-0.53, $p<0.001$), regardless of age (p interaction of age and treatment >0.05). **Conclusions:** In this population-based cohort of mCRC, EP were more likely to receive no treatment, monotherapy rather than combination therapy, or a regimen without bevacizumab. In carefully selected EP, however, it appears that rate of adverse events, frequency of early treatment discontinuations, and magnitude of survival benefit from systemic therapy were comparable to YP.

9548 General Poster Session (Board #28C), Mon, 1:15 PM-5:00 PM

Efficacy and safety data from elderly patients with pretreated advanced melanoma in the Italian cohort of ipilimumab expanded access programme (EAP).

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Background: Ipilimumab was the first agent approved for the treatment of unresectable or metastatic melanoma that showed an overall survival benefit in randomised phase III trials. Here we evaluate the safety and efficacy of ipilimumab treatment outside of clinical trials in elderly (>70 years old) patients (pts) enrolled in the EAP in Italy. **Methods:** Ipilimumab was available upon physician request for pts aged ≥16 years with unresectable stage III/IV melanoma who had either failed systemic therapy or were intolerant to ≥1 systemic treatment and for whom no other therapeutic option was available. Ipilimumab 3 mg/kg was administered intravenously every 3 weeks for 4 doses. Disease evaluation was performed at baseline and after completion of induction therapy using immune-related response criteria. Patients were monitored for adverse events (AEs), including immune-related AEs, using Common Terminology Criteria for Adverse Events v.3.0. **Results:** Out of 855 Italian pts participating in the EAP from June 2010 to January 2012 across 55 centres, 193 (22.6%) were over 70 years old (median 75; 70-88). Of these, 132 pts (68.4%) received all 4 doses of ipilimumab, 24 (12.4%) 3 doses, 17 (8.8%) 2 doses and 20 pts (10.4%) received 1 dose. With a median follow-up of 7.6 months (range 1-26), the disease control rate among 188 pts evaluable for response was 38.3%, including 4 pts (2.1%) with a complete response, 24 (12.8%) with a partial response and 44 (23.4%) with stable disease. As of December 2012, median progression-free survival and overall survival were 3.7 months and 8.9 months respectively, with 1-year survival rate of 38%. In total, 96 pts (49.7%) reported an AE of any grade, which were considered treatment-related in 69 pts (35.7%), with a safety profile comparable to the general population. Grade 3/4 AEs were reported by 19 pts (9.8%) and drug-related in 11 pts (5.7%). AEs were generally reversible with treatment as per protocol-specific guidelines with a median time to resolution of 2.0 weeks. **Conclusions:** Based on the data from EAP, ipilimumab is a feasible treatment in the elderly population; efficacy and safety results were similar to those observed in the general population.

9549 General Poster Session (Board #29A), Mon, 1:15 PM-5:00 PM

Impact of bladder cancer (BC) on health-related quality of life (HRQL) in 1,476 older Americans.

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Background: The impact of BC on HRQL is poorly understood. To our knowledge, this is the first and largest cross-sectional study that compares HRQL of patients before and after BC diagnosis (DX). **Methods:** Our sample included 1,476 BC patients (≥ age 65) within the SEER-Medicare Health Outcomes Survey linkage database (1998-2007). We assessed differences in HRQL as measured by SF-36 physical (PCS) and mental (MCS) summary scores in patients who had a survey >1 yr before BC DX (n=620) and those who had a survey after BC DX (n=856). We compared groups by year from BC DX using regression analyses and results were adjusted for cancer stage, race, gender, age at BC DX, marital status, education, income, smoking status, activity of daily living (ADLs), and non-cancer comorbidities. **Results:** Patients who had a survey after BC DX were diagnosed with BC at an older age than those with a survey before BC DX (55.9% at age ≥75 yr vs. 36.8%; P<0.01). Other baseline demographic and socioeconomic characteristics were similar. Baseline HRQL were poor in patients before DX (PCS mean=40.1; MCS mean=51.1) with 50.6% and 31.9% of them having comorbidity score ≥2 and impairment of ≥1 ADLs, respectively. After BC DX, significant decreases in PCS (-2.7; 95% CI -3.8,-1.7) and MCS (-1.4; 95% CI -2.6, -0.3) were observed, with HRQL being lowest in those who had BC DX within 1 yr (PCS mean= 36.6; MCS mean=49.7). Declines in PCS during the <1, 1-3, 3-5, 5-10, and 10+ yr periods after BC DX compared to before BC DX were -3.8 (P<0.01), -2.5 (P<0.01), -2.2 (P=0.01), -1.1 (P=0.19) and -0.8 (P=0.57) whereas decreases in MCS were -2.0 (P=0.01), -2.2 (P<0.01), -1.2 (P=0.21), -0.1 (P=0.92), -0.8 (P=0.62) respectively. More advanced BC, lower educational level, higher comorbidity score, and impaired ADLs were significantly associated with both worse PCS and MCS after BC DX (P<0.05). Lower income and older age at BC DX showed significant association with low PCS (P<0.05). **Conclusions:** Older BC patients are a vulnerable population with poor baseline HRQL. HRQL of patients after BC DX is significantly worse than HRQL of patients before DX, possibly due to therapy and/or disease progression. Future research that evaluates interventions to improve HRQL in older patients with BC is critical.

9550 General Poster Session (Board #29B), Mon, 1:15 PM-5:00 PM

Local tumor control and survival outcomes of percutaneous radiofrequency ablation plus post-ablation chemotherapy for lung tumors in nonsurgical patients: A meta-analysis.

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Background: Local recurrence is a frequent outcome post radiofrequency ablation (RFA) for local control of lung tumors. We sought to examine local tumor control and survival benefits of RFA plus post-ablation chemotherapy *versus* RFA alone for management of lung tumors in non-surgical patients. **Methods:** *Search strategy:* MEDLINE, the Cochrane Library, and EMBASE databases from January 2000 to December 2012. *Inclusion criteria:* RFA +/- post-ablation chemotherapy in non-surgical patients with solid lung tumors. *Exclusion criteria:* Post-RFA radiation therapy, biologics, brachytherapy, or other ablation modalities. *Outcomes: L*ocal tumor progression (LTP), overall survival (OS), and disease-free survival (DFS) at 12 month follow-up. *Statistical analysis:* Fixed effect analyses, bias assessment, and sensitivity analyses (BioStat Inc., NJ, USA). **Results:** RFA plus post-ablation chemotherapy group: 11 clinical studies, 684 patients (mean age 64 years [range 50 to 74]; 434 men, ECOG $\leq$2), ablation of 1,314 lung tumors, with a 4:1 ratio being $<$3cm *versus* $\geq$3cm in diameter, and a 1:4 ratio being primary *versus* metastatic. RFA alone group: 38 clinical studies, 1,874 patients (mean age 65 years [range 49 to 75]; 1,041 men, ECOG $\leq$2), ablation of 2,604 lung tumors, with a 2.1:1 ratio being $<$3cm *versus* $\geq$3cm in diameter, and a 1:1 ratio being primary *versus* metastatic. RFA plus post-ablation chemotherapy *versus* RFA alone: LTP of 15% over median follow-up of 31 months [range 12 to 59]) *versus* 19% over median follow-up of 21 months [range 12 to 29]); OR 0.73 (95% CI: 0.61-0.86, $p<0.05$) at 12 month follow-up. OS was 89% *versus* 78%, respectively, at 12 month follow-up; OR 1.52 (95% CI: 1.16-2.00, $p=0.003$). DFS was 90% *versus* 82%, respectively, at 12 month follow-up; OR 3.18 (95% CI: 2.04-4.96, $p<0.05$). Sensitivity analyses were robust, publication bias relatively narrow, and heterogeneity within acceptable limits; Q statistic$<$21; $p>0.13$ for all outcomes. **Conclusions:** This meta-analysis reveals that RFA plus post-ablation chemotherapy of lung tumors yields improved outcomes in terms of LTP, OS, and DFS compared with RFA alone.

9551 General Poster Session (Board #29C), Mon, 1:15 PM-5:00 PM

Comparing elderly and non-elderly adult cancer survivors: Differences in modifiable behaviours of smoking and alcohol cessation and physical activity.

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Background: In developing a cancer survivorship program at Princess Margaret Cancer Centre (Canada), cancer survivors were surveyed on modifiable behaviours: smoking/alcohol intake and physical activity. We evaluated whether special considerations should be given to elderly cancer survivors (age 65 years or higher), where few data currently exists. **Methods:** 616 adult cancer survivors of all disease sites were asked about their smoking, alcohol, and physical activity habits, and their attitudes and knowledge about effects of these habits on cancer outcomes. Univariate and multivariate logistic regression models evaluated the effect of age on these factors. **Results:** 23% were elderly; 53% female; 15% breast, 20% gastrointestinal/gynecologic, 24% hematologic, 19% thoracic/head and neck, and 13% genitourinary cancers. Median follow up was 24 months. Elderly survivors were more likely to be ever smokers (OR=1.69, 95% CI [1.12-2.53]) and ex-smokers than current (OR=4.11 [2.02-8.33]), but less likely to know how smoking could affect cancer treatment (OR=1.72 [1.09-2.69]) or outcome (OR=1.66 [1.07-2.60]). Elderly patients were less likely to binge drink (OR=2.07 [1.34-3.19]), but more likely to perceive alcohol as improving quality of life (OR=1.98 [1.11-3.56]) and overall survival (OR=2.32 [1.22-4.41]) in their own situation. Elderly survivors were less likely to receive information about alcohol use (OR=2.89 [1.29-6.49]). Meeting exercise guidelines at diagnosis (OR=1.76 [1.16-2.67]) and improving/maintaining them after treatment (OR=2.02 [1.12-2.93]) was substantially lower in elderly survivors, but perceived benefits/harms of exercise did not differ with age. **Conclusions:** Elderly patients know less about the impact of smoking on their overall health, despite having higher rates of cumulative exposure. A lower proportion received information on alcohol use. Elderly patients are less able to achieve the same exercise goals as younger patients. Survivorship programs may need to tailor counselling on modifiable behaviours by age group. CN, LE, SMHA, and GL contributed equally.

9552 General Poster Session (Board #29D), Mon, 1:15 PM-5:00 PM

Identification of comprehensive geriatric assessment based risk factors for malnutrition in elderly Asian patients with cancer.

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Background: Elderly patients with cancer are at increased risk for poor nutrition. Malnutrition is associated with increased morbidity and mortality. There is limited information on the clinical risk factors for malnutrition in elderly Asian cancer patients. We aim to identify comprehensive geriatrics assessment (CGA) based clinical factors in elderly Asian cancer patients associated with an increase in malnutrition risk. **Methods:** CGA data was collected from 249 Asian patients aged 70 years or older who attended the outpatient oncology clinics at the National Cancer Centre Singapore. Nutritional status, one of the seven domains of CGA, was assessed based on the DETERMINE nutritional risk index. Univariate and multivariate logistic regression analyses were applied to assess the association between patient clinical factors together with domains within the CGA and moderate to high nutritional risk. Goodness of fit was assessed using Hosmer-Lemeshow test and discrimination ability assessed based on the area under the receiver operating characteristics curve (AUC). Internal validation was performed using simulated datasets via bootstrapping. **Results:** Among the 249 patients, 184 (74%) had moderate to high nutritional risk. Multivariate logistic regression analysis identified stage 3–4 disease (Odds Ratio [OR] 2.54; 95% CI, 1.14-5.69), ECOG performance status of 2-4 (OR 3.04; 95% CI, 1.57–5.88), presence of depression as measured by geriatric depression scale (OR 5.99; 95% CI, 1.99-18.02) and haemoglobin levels <12 g/dL (OR 3; 95% CI 1.54-5.84) as significant independent factors associated with moderate to high nutritional risk. The model achieved good calibration (Hosmer-Lemeshow test's $p = 0.17$) and discrimination (AUC $= 0.80$). It retained good calibration and discrimination (bias-corrected AUC $= 0.79$) under internal validation. **Conclusions:** Having advanced stage of cancer, poor performance status, depression and anaemia were found to be independent predictors of moderate to high nutritional risk. Early identification of patients with these risk factors will allow for nutritional interventions which may improve treatment tolerance, quality of life and survival outcomes.

9553 General Poster Session (Board #29E), Mon, 1:15 PM-5:00 PM

Gender differences in comprehensive geriatric assessment (CGA): Results from the IN-GHO registry.

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Background: Elderly cancer patients (pts) are a heterogeneous population. As chronological age does not provide sufficient information on individual limitations and resources, a CGA helps to describe the heterogeneity in a structured way. Assessment instruments might be sensitive to gender differences. We therefore analyzed the IN-GHO registry for gender associated differences in results of CGA. **Methods:** The internet based IN-GHO registry prospectively collects data of elderly cancer pts from > 100 centres in Germany and Austria. Data from 1,580 pts aged 70+ years were analyzed comparing results between female (n=883) and male (n=697) pts by Chi-square or Mann-Whitney U test. Analyses included results from CGA, physicians´ rating (fit vs. compromised vs. frail) and pts´ self rating of fitness for treatment (Likert scale 1 = very fit to 6 = very unfit), type (combination vs. monotherapy vs. no), and dosage (full vs. adapted) of treatment. **Results:** Mean age was 76.7 years (range 70-97), 71.5% had a solid tumor, and 28.5% a hematological malignancy. Mean age was slightly but significantly higher in women than in men (76.9 vs. 76.4; p=0.02), reflected in a higher number of pts. aged 80+ (26.5% vs. 21.1%; p=0.013). No gender differences were observed in physicians´ rating and pts´ self rating of fitness for therapy, or in type or dosage of treatment. Furthermore, no gender associated differences were noted in Karnofsky-Performance-Scale, comorbidity (Charlson-Comorbidity-Score), polypharmacy, and cognition (Mini-Mental-Status-Examination). Gender associated differences, however, were noted in body mass index (more women in categories <19 and >35), mean ADL (91.7 vs. 93.4, p=0.03), mean IADL (6.9 vs. 6.7 (p=0.049), and timed-up-and-go test (< 10 seconds 36.1% vs. 43.6%, p=0.005). The main differences between women and men in ADL and IADL scores were noted in the item bathing (ADL) and food preparation, housekeeping, and laundry (IADL). **Conclusions:** The internet based registry is a valuable tool to gain data on prognostic factors, treatment, and outcome in old cancer pts. In several items of CGA, significant differences exist between women and men.

9554 General Poster Session (Board #29F), Mon, 1:15 PM-5:00 PM

The prognostic value of rapid screening tests (RST) in geriatric assessment of patients with cancer over 70.

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Background: Comprehensive Geriatric Assessment (CGA) may help to evaluate the functional status of elderly patients, but, because time-consuming, RST have been proposed. However, whether these instruments may predict survival is still unclear. The aim of this study was to correlate overall survival (OS) with the results of 3 rapid tests: G8 (1), VES-13 (2, aCGA (3) in patients over 70. **Methods:** From April 2009 to April 2012, 530 unelected outpatients over 70, 263 males and 267 females, were evaluated. During the first oncologic visit, they were homogeneously assessed by a trained oncogeriatric team using a dedicated, expressly developed web-based software (www: oncoger.ro.it) including all of the 3 rapid tests. Survival curves were drawn using Kaplan-Meier method and compared with log rank test; multivariate analysis was performed according to Cox regression method. **Results:** The tests identified frail patients as follows: VES-13 69%, aCGA 50%, G8 68.5%. Frailty was significantly associated with poor OS, with different hazard ratios (HR) for each test. HRs for death of frail vs non-frail pts were for aCGA 1.45 (95%CI 1.09-1.89, $p=0.008$), for VES-13 1.55 (95%CI 1.12-2.00, $p=0.005$) and for G8 2.57 (95%CI 1.66-2.93, $p<0.0001$). In the multivariate analysis including the 8 items of the G8 test, appetite loss (HR 1.44, $p=0.002$), weight loss (HR 1.28, $p=0.003$), and personal perception of poor health (HR 1.58, $p=0.002$) were significantly associated with a higher risk of death. **Conclusions:** i) Frailty, as identified by RST (VES-13, aCGA, G8), is statistically associated with poor OS; ii) G8 presents the most meaningful HR for OS; iii) appetite loss, weight loss and personal perception of poor health are significantly associated with lower OS.Our data show that RST and in particular G8 represent a useful prognostic tool for the assessment of geriatric patients with cancer.

9555 General Poster Session (Board #29G), Mon, 1:15 PM-5:00 PM

A prospective study examining PROs and other geriatric outcomes in older adults with prostate cancer undergoing chemotherapy.

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Background: Treatment of metastatic castration-resistant prostate cancer (mCRPC) with chemotherapy improves disease control and survival in older men (age 65+) based on large clinical trials. Its effects, though, on more frail elderly men are not well understood and chemotherapy may negatively impact frailty, daily function, physical performance, and quality of life (QOL), particularly outside the clinical trial setting. **Methods:** Men aged 65+ with mCRPC starting first-line chemotherapy were enrolled in this prospective observational pilot study. Physical function was assessed with the timed up and go (TUG) test, timed chair stands, and grip strength. Frailty was evaluated using the Vulnerable Elders Survey (VES-13) questionnaire in addition to functional status (OARS-IADL), social activities limitations and social support (MOS measures). Patients completed the FACT-P and FACT-G to measure prostate-specific QOL and general QOL, respectively. Assessments were completed before each cycle of chemotherapy. Pre-post within-group comparisons were done using student's T-tests and linear regression. **Results:** 25 patients (mean age 75) receiving Docetaxel + Prednisone were enrolled, 3 of whom died and 2 dropped out. Both general and prostate-specific QOL improved over a median of 6 cycles. Patients' instrumental activities of daily living (IADL) scores remained stable. On average, grip strength was stable and lower extremity function improved on both the TUG and Timed Chair Stands. At baseline, 13 of 25 patients (52%) were frail (VES score 3+). Of the patients that completed chemotherapy, 40% were frail. **Conclusions:** Contrary to our hypotheses, QOL did not decline in this frail elderly cohort, IADL function remained stable, and physical function remained stable or improved during first-line chemotherapy. Frailty also did not increase at the end of treatment as hypothesized. Older men with mCRPC appear to tolerate first-line chemotherapy fairly well in terms of QOL and geriatric domains.

9556 General Poster Session (Board #29H), Mon, 1:15 PM-5:00 PM

Safety and tolerability in patients over age 75 included in phase I: The Institut Gustave Roussy experience.

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Background: Safety and tolerability of anti-cancer therapy in elderly people (>=75 years, EP) is of major interest since they represent 31% of US patients diagnosed with cancer. However proportion of EP recruited is only 9% in clinical trials and probably less in phase I trials, which aim to determine the recommended phase II dose. Our objective was to evaluate the safety of phase I trials in EP. **Methods:** Patients treated from 2007 to 2012 at Institut Gustave Roussy in phase I trials, in which patients aged over 75 years had been included. Population was divided into two groups: EP or patients aged < 75 years (YP). Time to occurrence of first high toxicity (any grade 3-4 adverse event (AE) or dose-limiting toxicity DLT) and overall survival were estimated using Kaplan-Meier method. Conditional Cox proportional hazards model was used to compare occurrence of AE in a sub population of patients aged >= 75 years matched with patients aged <75 years of same Royal Marsden Hospital (RMH) score (Albumin, LDH, Number of metastatic site) and protocol. **Results:** In the 33 EP and the 161 YP, 20(60%) and 100(62%) grade 3-4 AEs and 1(3%) and 18(11%) DLTs occurred. The median time to occurrence of high toxicity were 2 months (95%CI=1-4) and 2 months (95%CI=1-2). The median overall survival were 22 months (95%CI=11-non estimable) (EP) and 13 months (95%CI =10-16) (YP). Twenty-seven patients aged >=75 years could be matched: age over 75 years was not associated with higher risk of neither high toxicity (HR=0.85, 95%CI=[0.45 ; 1.61], p=.62) nor death (HR=1.03, 95%CI=[0.47;2.24], p=.94). **Conclusions:** No impact of age over 75 years on occurrence of neither high toxicity nor death was identified. Patients above 75 years are good candidates for phase I trials.

9557 General Poster Session (Board #30A), Mon, 1:15 PM-5:00 PM

Comparison of preoperative screening tools predicting postoperative complications in oncogeriatric surgical patients.

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Background: In the onco-geriatric surgical population it is important to identify patients at increased risk of adverse post-operative outcome in order to effectively implement preventive measures and to improve outcome in this population. There is need for a time saving and efficient screening tool. Our aim was to determine the predictive ability of the Mini Mental State Examination (MMSE), Brief Fatigue Inventory (BFI) and Timed "Up & Go" (TUG) concerning the occurrence of a major post-operative complication in a series of elderly patients undergoing elective surgery for solid tumors. **Methods:** In an international cohort, 329 patients ≥70years undergoing elective surgery for solid tumors were prospectively included. Primary endpoint was the incidence of a major complication during the first 30 days after surgery. Pre-operatively the MMSE, BFI and TUG were scored. TUG depicts the time needed to stand up from a chair, walk 3 meters, turn around, walk back and sit down. Data were analyzed using multivariable logistic regression analyses to estimate odds ratios (OR) and 95% confidence intervals (95%-CI). **Results:** The majority of patients underwent major surgery (n=219; 66.6%). A total of 71 (22.1%) patients experienced major complications. TUG, MMSE and BFI, adjusted for center, gender and minor or major surgery, were independent predictors of the occurrence of major post-operative complications (see Table). **Conclusions:** Screening tools are able to predict major post-operative complications in onco-geriatric surgical patients. TUG is most specific in identifying patients at risk and could be considered to allocate preventive measures effectively.

	OR (95% CI; p value)	Major complications in patients with good test results	Major complications in patients with poor test results
TUG	4.25 (1.69-10.68; 0.002)	15.3%	47.1%
BFI	2.03 (1.04-3.95; 0.04)	15.5%	30.7%
MMSE	2.56 (1.30-5.04; 0.006)	15.2%	32.3%

9558 General Poster Session (Board #30B), Mon, 1:15 PM-5:00 PM

Outcomes of severe sepsis in very elderly (age >80 years) patients with metastatic cancer.

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Background: With better treatment and prolonged life expectancy of cancer patients, more elderly patients with metastatic cancer are being treated aggressively for sepsis. There has been philosophical debate about how aggressive the treatment should be for very elderly patients with metastatic disease admitted to intensive care unit with severe sepsis. The data with regards to the outcome of severe sepsis in those above 80 years with metastatic disease is very limited. **Methods:** Using the Healthcare Cost and Utilization Project - Nationwide Inpatient Sample 2007-2008, patients older than 80 years, discharged with severe sepsis were identified using ICD-9-CM codes. Those with metastatic disease were identified using ICD-9-CM codes 196-199. The outcomes studied were mortality and discharge disposition. We also examined the rates of invasive mechanical ventilation, blood transfusion, use of central venous catheter, tracheostomy and dialysis. The outcomes were compared to those who did not have cancer. Chi square test was used to compare the variables. Significance was defined as p value <0.05. **Results:** There were 458,443 discharges with severe sepsis in patients aged ≥ 80 years. Of these 3.3% had metastatic disease. The in-hospital mortality was significantly higher in those with metastatic disease (43.7% vs. 33.3%, $p<0.001$). The discharge disposition of the very elderly is shown in the Table. The rates of invasive mechanical ventilation, tracheostomy, use of central venous lines and dialysis were similar in both the groups. Blood transfusions were observed to be higher in metastatic group. **Conclusions:** Resource utilization in elderly with severe sepsis is similar regardless of the presence of metastatic disease. However, the mortality is significantly higher in those with metastatic disease. Of the survivors, only a fraction reaches home with independent functioning. Involvement of palliative care services at an early stage and addressing code status promptly during the beginning of each hospitalization may help relieve resource and financial burden to health care providers.

Disposition (%)	No cancer	Metastatic disease
Home	12	12.5
Home health care*	13.9	21.6
Nursing home*	57.7	34.1
Hospice*	12.2	27.6
Others	4.2	4.2

* $p<0.05$

9559 General Poster Session (Board #30C), Mon, 1:15 PM-5:00 PM

The influence of autologous stem cell transplant (ASCT) on survival in older adults with multiple myeloma (MM).

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Background: In randomized trials, ASCT improves survival in MM patients (pts) < age 65. The impact of ASCT on survival in older adults with MM is unknown. **Methods:** In a retrospective cohort study, all pts ≥ age 65 with MM diagnosed between 2000 and 2010 were identified from the Barnes-Jewish Hospital Oncology Data Services Registry (N=199), including demographic, comorbidity (ACE-27 index) and survival data. Medical records were reviewed for stage, ECOG Performance Status (PS) and treatment. Pts > age 77 or who received only steroids/supportive care were excluded (N=53). The primary endpoint was overall survival (OS), defined as time from diagnosis to death, censored at last follow-up. Univariate analyses for factors associated with undergoing ASCT were performed using Fisher's exact test or nonparametric rank-sum test; multivariate logistic regression was used to create propensity scores for ASCT. The association between ASCT and OS was assessed using a multivariate Cox proportional hazard model with propensity scores adjustment; missing values in predictors were imputed using multiple imputations. **Results:** Of 146 pts included, the median age was 68 (range 65-77); 53% were male, 81% Caucasian; 43% underwent ASCT. Comorbidities were common (43.9% mild, 21.6% moderate and 9.3% severe). Durie-Salmon Stages were I – 9.5%, II-18.1%, III-72.4%. PS at diagnosis was 0 - 18.3%, 1 - 51.0%, 2 - 21.2% and 3 - 9.6%. Most received novel agents (thalidomide, lenalidomide or bortezomib) in their initial treatment (25.2% alkylators only, 58.6% novel single agents ± steroids, 16.2% novel combination regimens). Age ($p<0.0001$) and insurance/payer ($p=0.02$) were associated with ASCT. On univariate analysis, ASCT [Hazard Ratio (HR) 0.54 (95% confidence intervals (CI) 0.35-0.82)] and PS [PS 1: HR 2.3 (CI 1.0-4.9), PS2: HR 3.3 (1.4-7.9); PS 3: HR 3.5 (CI 1.3-9.3)] were associated with mortality. On multivariate analysis controlling for PS, comorbidity, stage and propensity to undergo ASCT, ASCT was associated with reduced mortality [HR 0.52 (CI 0.30-0.92), $p=0.02$]. **Conclusions:** In pts over age 65 with MM, ASCT is associated with better OS after adjusting for propensity to undergo ASCT.

9560 General Poster Session (Board #30D), Mon, 1:15 PM-5:00 PM

Best supportive care (BSC) in published clinical trials.

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Background: BSC as a control arm in clinical trials is poorly defined. A systematic review was conducted to evaluate clinical trial concordance with published, consensus-based framework for BSC delivery in trials. **Methods:** A consensus-based Delphi panel previously identified 4 key domains of BSC delivery in trials: multidisciplinary care; supportive care documentation; symptom assessment at least as often as the intervention arm; and guideline-based symptom management. A systematic review of trials including BSC control arms assessed BSC concordance to the consensus-based domains. Databases were searched from 2002-2012 using search strings: "cancer"; "best supportive care"; "randomized" or "random allocation"; and "supportive" or "palliative." Exclusion criteria were: no BSC arm, non-human trial, not randomized, not English, not advanced cancer, or not including anticancer therapy. Data were independently extracted by 2 reviewers and scored by 4 reviewers for conformance with consensus-based BSC framework. **Results:** 373 articles were retrieved, 17 retained after applying exclusion criteria. Overall, trials conformed to $<18\%$ of the consensus-based BSC standards. 35% of articles offered a detailed description of BSC. 65% reported baseline and regular symptom assessment, and 47% reported using validated symptom assessment measures. 35% reported symptom assessment at identical intervals in both experimental and BSC arms. None listed an evidence-based guideline for symptom management. None of the multicenter trials reported standardization of BSC across sites. No studies reported educating patients on symptom management or goals of anti-cancer therapy. No studies reported offering access to palliative care specialists, social workers, financial or spiritual counseling. **Conclusions:** Reporting of BSC in trials is incomplete, resulting in uncertain internal and external validity. Such poorly defined interventions and variation between sites is unacceptable for other aspects of a clinical trial. Unless it is truly *best* supportive care, such studies may risk systematically over-estimating the clinical effect of the comparator arms. Standardization of a BSC delivery framework is needed to improve trial design and data generalization.

9561 General Poster Session (Board #30E), Mon, 1:15 PM-5:00 PM

Cancer patients with ECOG-PS higher than 1: Who are those who benefit of palliative chemotherapy?

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Background: Palliative chemotherapy (PC) is a treatment option in pts with metastatic cancer. Although pts with ECOG-PS $>$ 1 are underrepresented in clinical trials, they are often treated with PC in daily practice. We aimed to identify factors associated with poorer survival and lack of benefit of PC in this subset of pts. **Methods:** We conducted a case-control retrospective analysis of 301 consecutive pts with solid tumors and ECOG-PS $>$ 1 when initiated PC, selected from 2514 pts who died between Aug/2011 and Jul/2012 in a tertiary cancer care institution or its hospice. Cases were defined as those pts who survived $<$ 90d after the first cycle of first line PC, and controls were those who had a longer survival. Frequencies were compared by chi-square test or Fisher exact test. Risks were estimated by odds ratios (OR) and logistic regression analysis. Overall survival (OS) was calculated by Kaplan-Meier method and curves was compared using log-rank test. **Results:** 142 cases/159 controls were included: median age 58/63 y.o. ($p=0.09$; t-test) and 49%/50% female ($p=0.941$; chi-square). Gastrointestinal and lung cancers were the most frequent primaries (31 and 17%, respectively). Factors associated with poorer OS were age $>$ 60 y.o. (OR 1.7; 95%CI 1.0–2.6), ECOG-PS $>$ 2 (1.9; 1.2–3.1), weight loss $>$ 10% (1.8; 1.1-2.8), hemoglobin $<$ 10 g/dL (2.6; 1.6-4.2), albumin $<$ 3 g/dL (2.7; 1.5-5.1), serum creatinine (sCr) $>$ 1 mg/dL (2.8; 1.6-5.0), C-reactive protein $\geq$ 5 mg/L (8.6; 1.0-72.9), altered mental status (4.2; 1.4-13.2) and in-hospital PC (3.2; 1.9-5.2). Cases were more likely to experience grade $\geq$ 3 toxicity (43 vs. 28%; $p=0.005$), die of toxicity (16 vs. 6%; $p = 0.0007$) and not be offered palliative care only (47 vs. 71%; $p<0.0001$). mOS was 204 and 34d among controls and cases, respectively (HR 0.177; 95%CI 0.015-0.033, $p<0.0001$). Median time to death was 39.5d (0-1103). Logistic regression analysis identified ECOG-PS $>$ 2 (OR 2.3, $p=0.044$) and sCr $>$ 1 mg/dL (OR 11.2, $p=0.0002$) as independent predictors of 3-mo fatality. **Conclusions:** ECOG-PS $>$ 2 and elevated sCr were identified as independent predictors of poor OS in these pts. PC needs to be prescribed with caution in ECOG-PS $>$ 1 pts, since it seems to offer no benefit in OS and could lead to abbreviation of life.

9562 General Poster Session (Board #30F), Mon, 1:15 PM-5:00 PM

Variation in health-related quality of life (HRQoL) during chemotherapy for advanced non-small cell lung cancer.

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Background: Physicians might overestimate benefits and underestimate toxicity of cancer therapy. Thus, patient reported HRQoL is an important part of evaluating treatment effect and assessing side effects. HRQoL is commonly reported once per chemotherapy cycle and just prior to administration of the next course (day 0). Several studies have not detected differences in HRQoL despite differences in physician-observed toxicity. We hypothesized that HRQoL varies during chemotherapy cycles; that side effects are most pronounced the first week after chemotherapy administration; and that repeated assessments improve the ability to detect differences in HRQoL. **Methods:** Patients were randomized to receive 3 courses of either vinorelbine/carboplatin (VC) or gemcitabine/carboplatin (GC) every 3 weeks. They reported HRQoL on the EORTC QLQ C30 + LC13 on day 0, 3, 8, 11, 15 and 22 of each cycle. A difference in mean scores of $>$ 5 points is considered clinically detectable. **Results:** 52 pts (VC: 25, GC: 27); median age 65; 56 % men; 85 % stage IV; 93 % performance status 0-1; 75 % completed 3 cycles; 32 % response-rate; 71 % grade 3-4 toxicity. Baseline characteristics; treatment administered and outcomes of therapy were similar between treatment arms. Completion rates of QLQs were 96-64 %. There were significant variations in mean scores during cycles for several domains (mean scores during cycle 1 for some domains are listed in the table). For several domains, there were differences of $>$ 5 points between the treatments arms at day 3-15 that were not detectable on day 22 (day 0 of next cycle). In general, treatment related symptoms were most pronounced on day 3 in every cycle. **Conclusions:** Our results suggest that timing and number of assessments influence the likelihood of detecting differences in HRQoL during chemotherapy. Day 3 was the best time point for assessing reduced function and side effects of the regimens administered in our trial.

Mean scores - All patients - Cycle 1	Day	0	3	8	11	15	22
Functional scales (a high score = better function)	Global quality of life	54	49	53	55	55	57
	Physical function	63	57	61	61	62	64
Symptom scales (a high score = more symptoms)	Fatigue	44	52	45	42	47	40
	Nausea - vomiting	6	16	15	9	9	6
	Constipation	25	34	34	33	29	25

9563 General Poster Session (Board #30G), Mon, 1:15 PM-5:00 PM

Long-term use of fentanyl pectin nasal spray in patients with breakthrough pain in cancer.

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Background: Given that patients with cancer are living longer, there is a need to ensure that treatments used for palliative care are well tolerated and effective during long-term use. The objective of this study was to investigate the use of fentanyl pectin nasal spray (FPNS) for the treatment of breakthrough pain in cancer (BTPc) in patients taking regular opioid therapy. **Methods:** A total of 401 adult patients, taking at least 60 mg/day oral morphine or equivalent, with an average of 1 to 4 episodes of BTPc per day, who were either newly enrolled or had completed a randomized controlled trial with FPNS, entered into an open-label assessment study (NCT00458510). Of these, 171 patients, continued into an extension period. Up to 4 episodes of BTPc per day were treated with FPNS at titrated doses between 100 μg and 800 μg. Patients returned to the clinic at 4-week intervals for assessment and reporting of any adverse events (AEs). **Results:** There were 163 patients with documented FPNS use. The mean duration of use was 325 days; 46 patients used FPNS for more than 1 year, while the maximum duration was 3 years and 8 months. In total, 2% of patients withdrew from the study due to lack of efficacy. Seventy-four percent of patients did not change their FPNS dose. The most common AEs, aside from disease progression, were: insomnia, 9.9%; nausea, 9.4%; vomiting, 9.4%; and peripheral edema, 9.4%. The overall incidence of treatment-related AEs was 11.1%, the most common being constipation (4.1%), with no apparent dose relationship. Ten patients (5.8%) experienced treatment-related nasal AEs, which, with the exception of 1 severe event, were all mild or moderate. **Conclusions:** FPNS appeared to provide a sustained benefit and was well tolerated during the long-term treatment of BTPc. Clinical trial information: NCT00458510.

9564 General Poster Session (Board #30H), Mon, 1:15 PM-5:00 PM

Epoetin biosimilars in the management of anemia secondary to chemotherapy in patients with solid tumors, lymphomas, and myelomas: The ORHEO study.

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Background: Chemotherapy may induce anemia with potentially severe consequences. The ORHEO (place of biOsimilaRs in the therapeutic management of anaemia secondary to chemotherapy in HaEmatology and Oncology) study examined the efficacy and safety of epoetin alfa biosimilars (EABs) for the treatment of chemotherapy-induced anemia (CIA) in the clinical setting. **Methods:** ORHEO was a multicenter, observational, prospective, post-marketing study conducted in France. Patients with CIA (Hb $<$110g/L) $>$18 years old, with solid tumors, lymphomas or myelomas and eligible for epoetin alfa treatment were included in the study; they received EAB as prescribed by their physician. Baseline patient characteristics and anemia-related data including baseline and target Hb level epoetin treatment, adverse events and any other concomitant treatments prescribed were recorded. The primary endpoint was the rate of responders (defined as an increase in Hb levels to 100 g/L or at least 10 g/L since inclusion visit, or reaching target Hb set at start of study, without any blood transfusions in the 3 weeks prior to measurement) at +3 months (M3). Other endpoints included rate of responders at +6 months (M6) and safety endpoints. **Results:** 2310 patients (51.43 % male, 48.57 % female) from 232 centers were included in this study. At baseline 79.6% had solid tumors, 13.0% lymphomas and 7.4% myelomas. Median age was 68 y (range: 18–93). Mean baseline Hb level was 96 g/L with a target Hb level of $>=$ 120 g/L for 52.7% of patients. Almost all (99.9%) received the biosimilar epoetin zeta (median dose 30,000 IU/week) with 26.6% receiving additional iron supplementation. A total of 2056 and 1664 patients had at least one Hb level value at M3 and M6 respectively. The rate of response was 81.6% and 86.5% at M3 and M6, respectively. In total, 17.0% of treated patients reported clinically relevant adverse events (all grades), the most common being infections (5.0%) and thromboembolic events (3.5%). Transfusion rates were reported as 9.4% and 5.8% at M3 and M6, respectively. No EAB-related deaths were reported. **Conclusions:** EAB was effective and well-tolerated in the management of CIA. Clinical trial information: NCT01626547.

9565 General Poster Session (Board #31A), Mon, 1:15 PM-5:00 PM

Safety and quality assurance of MR-guided focused ultrasound (MRgFUS) in palliation of painful bone metastases.

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Background: Palliation of bone metastases is typically performed with radiation therapy (RT). However, a significant minority of patients cannot obtain durable relief from RT. MRgFUS combines non-invasive focused ultrasound with MR guidance. Preliminary phase III results comparing MRgFUS to sham treatment have demonstrated efficacy. This study examines the safety of this procedure in a large prospective, multi-center study. **Methods:** Patients with a painful bone metastasis were randomized (3:1) to either MRgFUS or sham treatment for the single most painful lesion. Sham patients were given the opportunity to cross over after 2 weeks. Each adverse event (AE) was recorded prospectively and scored for severity and relation to treatment. **Results:** Thirty-seven patients were enrolled to receive sham treatment and 115 to receive MRgFUS. Sites of treatment were: 102 pelvis, 28 thorax, 7 lower extremity and 2 upper extremity. Seventy-seven target lesions were osteolytic, 29 were osteoblastic and 33 were mixed. Treatment was discontinued prior to completion in 8 treatments. Of these, 7 were pelvic targets and 6 lesions were osteolytic. The most common reasons for discontinuation were pain (4) and patient movement (2). Forty-seven percent of treatment patients and 2.7% of sham patients reported at least one AE. Of 76 AEs, 67 were considered non-significant and anticipated, 57 being intra-procedure pain. Four significant events included 2 possibly related fractures at treated lytic lesion sites, 1 grade 3 skin burn and 1 patient with neuropathy. Four patients experienced events unrelated to study treatment and 1 patient experienced temporary apnea from anesthesia described as incidental. **Conclusions:** MRgFUS is a safe treatment for palliation of painful bone metastases. Ninety-three percent of MRgFUS treatments were carried out to completion. Three percent of patients experienced significant AEs, including 2 fractures of treated lytic tumors. These safety data reinforce and confirm previous experience with this technology and encourage its use for patients not suitable for RT. Clinical trial information: NCT00656305.

9566 General Poster Session (Board #31B), Mon, 1:15 PM-5:00 PM

Integrated oncopalliative care versus standard care for patients with metastatic lung cancer: A single institution retrospective review.

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Background: Patients with metastatic non-small cell lung cancer (NSCLC) receiving early palliative care (PC) demonstrated improved anxiety, quality of life, and survival compared to standard oncology care (SOC). ASCO clinical practice guidelines recommend concurrent PC and SC be offered to patients with metastatic NSCLC. Our lung cancer clinic is partially integrated with PC. We performed retrospective chart review comparing patients seen in our integrated clinic with SOC patients for survival, trial participation, chemotherapy and hospice utilization. **Methods:** Charts of all patients with advanced lung cancer from July 2007-June 2011 were reviewed. Eligible patients were those who received any care at our center. Demographic, treatment details, survival, and hospice utilization data were obtained. Overall survival and length of hospice enrollment were calculated for patients treated with PC compared to SOC. **Results:** Of 207 patients, 82 received PC. Overall survival favored PC (11.9 months vs. 10.1 months, p=0.032). Hospice length of stay (LOS) favored PC (38.5 days vs. 24 days in SOC, p=0.047). There was not a significant difference in lines of chemotherapy, chemotherapy in the last 30 days of life, or trial participation. **Conclusions:** Our chart review provides confirmatory evidence that early integrated PC in lung cancer patients increases survival and hospice LOS without affecting chemotherapy utilization or trial participation.

	Concurrent oncology and PC (n=82)		Standard care (n=125)		
	Median	Range	Median	Range	P value
Age	62	41-95	64	29-85	0.978
LOS in hospice (days)	38.5	0 – 378	24	0 - 387	0.047*
	N	%	N	%	P value
ECOG PS	17	22	50	43	0.002*
0	39	51	34	30	
1	12	16	25	22	
2	9	12	6	5	
≥3					
Lines of chemotherapy	11	14	21	17	0.374
0	31	38	38	31	
1	27	33	35	29	
2	12	15	28	23	
≥3					
Chemotherapy last 30 days of life	65	89	99	83	0.265
N	8	11	20	17	
Y					
Clinical trial participation	55	71	97	81	0.0929
N	23	29	23	19	
Y					
OS (months)	11.9	0.6 – 35.8	10.1	0.7 – 44.6	0.113† 0.032‡*

9567 General Poster Session (Board #31C), Mon, 1:15 PM-5:00 PM

Patient-reported outcomes for determining prognostic groups in veterans with stage IV solid tumors starting systemic therapy.

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Background: A Recursive Partitioning Analysis (RPA) algorithm predicted four groups with distinct median survivals in patients with advanced cancer entering palliative care (ASCO 2010, Abst 9040). We investigated whether this algorithm could apply to cancer patients starting systemic therapy. **Methods:** The RPA algorithm is based upon Karnofsky performance status (KPS), Functional Assessment of Cancer Therapy (FACT) physical well-being (PWB) subscale, and Memorial Symptom Assessment Scale Short Form (MSAS-SF) physical symptom distress (PHYS) subscale. Starting in 2007, a convenience sample of Veterans who were prescribed systemic treatment for their cancer was enrolled in an IRB approved protocol, and completed quality of life (FACT- G) and symptom (MSAS SF) questionnaires prior to starting the first cycle of treatment. We analyzed records of patients with stage IV metastatic solid tumors enrolled through August 2011, and determined survival as of December 1, 2012. Analyses were performed with STATA 11.0. **Results:** There were 72 patients (pts). The median age was 63 yrs, (range 46-86). Men comprised 71 (98%) pts. First line systemic therapy was given to 59 (82%) pts. The most common primary sites were lung cancer (25 pts, 35%), prostate 9 pts(12%) and colon 7 pts (10%). Median KPS was 90% (range 40-100%), PWB median 23 (range 6-28), and MSAS SF median PHYS 0.73 (range 0-2.93). Overall median survival was 269 days (range 6-1762) and 57 pts (79%) had died. There was 1 pt in group 1, 45 pts in group 2, 8 pts in group 3, and 18 pts in group 4. Median survival (days) by RPA group was 155 for group 1, 177 for group 2, 292 for group 3, and 610 for group 4 (p=.011). **Conclusions:** These preliminary findings suggest that this algorithm is capable of dividing patients with metastatic solid tumor who are starting chemotherapy into prognostic groups. It may have applications in clinical trials. Further development is indicated.

RPA group	Definition	N (solid tumor)	Median survival (d)
1	KPS < 50%	1	155
2	KPS >50%, PWB<25	45	177
3	KPS >50%, PWB>25, PHYS>0.6	8	292
4	KPS >50%, PWB >25, PHYS <0.6	18	610

9568 General Poster Session (Board #31D), Mon, 1:15 PM-5:00 PM

Breaking bad news: Comparison of perspectives of Middle Eastern cancer patients and their relatives.

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Background: It is believed in some Middle Eastern (ME) cultures that disclosure of bad news to cancer patients may cause loss of hope. On many occasions the relatives' and patients' wishes are opposed regarding this matter. This study investigates cancer patients' and their relatives' perspectives regarding communication of cancer-related bad news in a ME population. **Methods:** Nine close-ended questions were designed in a questionnaire format to obtain cancer patients' (cohort I) and their relatives' (cohort II) perspectives regarding communication of cancer related bad news from diagnosis to end-of-life. The questionnaire was answered by patients and relatives during out-patient visits. Chi-square test was used to test differences in responses between the two cohorts. **Results:** 203 participants (100 patients and 103 relatives) completed the questionnaire. In cohorts I and II, 28% and 58% of participants were males respectively ($p<0.001$). In contrast to relatives' views, majority of patients preferred to be informed of diagnosis and possible adverse outcome of their illness, as detailed in the Table. **Conclusions:** Our study indicates that there is significant discordance between the preferences of ME cancer patients and their relatives regarding disclosure of cancer related bad news to the patient. As opposed to relatives' beliefs, most patients would prefer to know bad news throughout the course of their illness. Unless a patient indicates otherwise, physicians should strive to keep cancer patients informed of their health related events.

Percentage of "yes" answers by patients and relatives.

Should the patient be informed of:	Patients	Relatives	P value
Diagnosis of cancer?	87%	68%	0.001
Any poor outcome?	90%	57%	<0.001
Failure of treatment?	85%	39%	<0.001
Every change in their condition and outcome?	92%	71%	<0.001
Serious health-related news?	98%	85%	0.001
Unavailability of treatment options?	90%	61%	<0.001
Do you agree that doctors should not hold information from the patient at the request of family members?	80%	56%	<0.001
Should the patient be involved in end of life discussion?	56%	30%	<0.001
Bad news should be disclosed first to:			<0.001
The patient	43%	9%	
A family member	16%	61%	
Both at the same time	40%	30%	

9569 General Poster Session (Board #31E), Mon, 1:15 PM-5:00 PM

Practical assessment of psychosocial concerns associated with genetic testing in ovarian cancer patients using the MICRA questionnaire.

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Background: Ten to 15% of ovarian cancer patients are *BRCA* mutation carriers. By offering genetic testing, families at risk and healthy female mutation carriers will be identified and offered clinical follow-up. The MICRA questionnaire was developed as a brief, practical, and targeted assessment of concerns and psychosocial issues associated with genetic testing. This study evaluates the practical and psychometric properties of the MICRA (Norwegian translation) in tested ovarian cancer patient. **Methods:** Since 2002, ovarian cancer patients at Oslo University Hospital, Norwegian Radium Hospital are offered genetic counseling and testing. By the end of 2009, 1,032 were included. The 530 (51%) patients still alive, were mailed the MICRA and three other instruments relevant for mental distress. 354 (67%) patients responded. Among them 9% were *BRCA* mutation carriers, 7% had a personal history of breast cancer, 29% had a family history of breast and/or ovarian cancer, and 55% had no such family history. **Results:** In the *BRCA* mutation carrier group, the total MICRA score and its subscale scores of distress, uncertainty, and positive experiences were all significantly higher than in the other groups. Confirmatory factor analyses of the three subscales of MICRA showed inadequate fit indices, while a four factors solution including the new factor of Support from family (items #18 and #19), showed adequate fit. The Positive Experiences subscale showed a maximum of 4% explained variance in relation to the Hospital Anxiety and Depression Scale total score, the Impact of Event Avoidance and Intrusion scores, and the Eysenck's Neuroticism score. The subscales of Distress and Uncertainty showed maximum 12% and 41% explained variance, respectively, while the total MICRA score showed 22% explained variance. **Conclusions:** Our study supports the feasibility of the MICRA in ovarian cancer patients. Frail women may be identified for closer follow-up by using MICRA. Discrimant, content and construct validities of the MICRA were supported, while the factor structure still is open to further investigation.

9570 General Poster Session (Board #31F), Mon, 1:15 PM-5:00 PM

The Minneapolis-Manchester Quality of Life Instrument (MMQL): Reliability and validity of the Adult Form (AF).

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Background: Cancer survivors are at risk for deficits in health-related quality of life (HRQL). Youth (8-12y) and adolescent (13-20y) versions of the MMQL have been developed to address survivor-specific issues and are currently in use; the MMQL-AF has now been developed to assess HRQL in cancer survivors aged 21-55y, enabling cross-sectional and longitudinal assessment of childhood cancer survivors as they age. **Methods:** The MMQL-AF was administered to 499 adults: 65 patients undergoing cancer therapy, 107 off therapy, 327 healthy controls (matched on sex, age, education). Factor analysis was performed; items with factor loadings $\geq$0.40 were retained. The following psychometric properties were evaluated: internal consistency reliability (Cronbach's alpha), construct validity (concurrent administration of SF-36), known-groups validity (score comparisons across the 3 groups), and stability (intraclass correlations from patients completing MMQL-AF twice, 2 weeks apart). **Results:** Among patients, 46% had hematological malignancies, 33% were males, 64% were non-Hispanic whites; median age was 40y. Factor analysis resulted in retention of 44 items across 6 scales: social functioning (n=9), physical functioning (n=12), cognitive functioning (n=7), outlook on life (n=4), body image (n=5), and psychological functioning (n=7).Internal consistency was 0.8-0.9 for scales and 0.95 overall.The MMQL-AF distinguished between known groups; healthy controls scored significantly higher (better HRQL) than patients on 4 of 6 scales. Off-therapy patients scored higher than on-therapy patients on physical functioning.The MMQL-AF scales correlated highly with SF-36 scales hypothesized to tap similar domains (all P values $<$0.001), demonstrating construct validity.Intraclass correlations were 0.82-0.95 for scales and 0.98 overall (all P values $<$0.001), indicating high stability. **Conclusions:** MMQL-AF is a reliable and valid self-report instrument for measuring multi-dimensional HRQL in cancer survivors aged 21-55y. Development of this instrument ensures availability of a tool that can assess HRQL from 8-55y, thus addressing needs of childhood cancer survivors as they age.

9571 General Poster Session (Board #31G), Mon, 1:15 PM-5:00 PM

Taking control of cancer: Why women are choosing mastectomy.

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Background: Rates of both unilateral (UM) and bilateral mastectomy (BM) for early stage breast cancer (ESBC) have been increasing since 2003. Studies suggest that this is due to women playing a more active role in their decision making, however they do not describe why women are choosing this option. **Methods:** We conducted a qualitative study using grounded theory to identify factors influential in women's choice for mastectomy. Purposive sampling was used to identify women across the Greater Toronto Area (Ontario, Canada), who were suitable candidates for breast conserving surgery (BCS) but underwent UM or BM. Data were collected through semi-structured interviews. Constant comparative analysis identified key ideas and themes. **Results:** Data saturation was achieved after 29 in-person interviews. 12 interviewees were treated at academic cancer centres, 6 at an academic non-cancer centre and 11 at community centres. 15 women underwent UM; 14 underwent BM. Median age was 55. 'Taking control of cancer' was the dominant theme that emerged. There were 7 subthemes: 1.the Diagnosis of cancer was received with shock and fear; 2.during Surgical Discussion both BCS and UM were discussed; BM was discouraged by the surgeon 3.women Misperceived Risk, misunderstanding recurrence and survival rates 4.Women's choice for UM was due to fear of recurrence and/ or radiation 5.Women's choice for BM was due to fear of recurrence, 'never wanting to do this again' and/or need for cosmetic balance 6.Sources of Information varied in importance, previous cancer experience had the greatest impact 7.women were actively Controlling Outcomes, more surgery was seen as greater control. **Conclusions:** Women seeking UM and BM for treatment of their early stage breast cancer manage their fear of recurrence and 'never wanting to go through this again' by undergoing more extensive surgery. The patient's effort to control the cancer outcome is the driving factor behind women choosing mastectomy.

9572 General Poster Session (Board #31H), Mon, 1:15 PM-5:00 PM

Use of modafinil to moderate the relationship between cancer-related fatigue and depression in 541 patients receiving chemotherapy: A URCC CCOP study.

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Background: Over 50% patients with cancer report symptoms of depression; 15% meet diagnostic criteria for Major Depressive Disorder. Depression is associated with increased insomnia, fatigue and reduced quality of life. We previously found that modafinil is effective for reducing high levels of fatigue among patients undergoing chemotherapy. This study aims to test whether modafinil can alleviate symptoms of depression by reducing fatigue. **Methods:** This study is a secondary analysis of 541 cancer patients receiving chemotherapy and experiencing fatigue (Brief Fatigue Inventory (BFI) >=3) that were randomized to receive either 200 mg of modafinil (N=260) or placebo (N=281) daily from baseline (Cycle 2) until post-test (Cycle 4). Depression was measured by the Center for Epidemiologic Studies Depression Scale (CES-D) at baseline and post-test. The CES-D total score and its subscales (Positive Affect, Negative Affect, Somatic Symptoms, and Interpersonal Symptoms) were analyzed. A linear model with CES-D post (outcome) and BFI baseline, Arm, and BFI*Arm interaction term (independent variables) was used to address the hypothesis; $p<0.05$ indicates significance. **Results:** We found no overall effect of modafinil on depression; however, the model demonstrated a significant moderating effect of modafinil on the relationship between baseline fatigue and CES-D total scores ($p = 0.04$). For subjects with severe fatigue (BFI ≥ 7), the drug reduced CES-D scores by 3-4. Modafinil also significantly moderated the relationship between baseline fatigue and Positive Affect subscale scores ($p = 0.003$), but not the relationship between baseline fatigue and Somatic, Negative Affect, or Interpersonal subscales. **Conclusions:** Modafinil differentially impacts depression based on a patient's level of fatigue; reduced depressive symptoms occurred in those with extreme fatigue. This effect is driven by increases in positive affective symptoms. These results have significant implications for intervention; in patients with high levels of fatigue, modafinil might also reduce depression. Future RCTs are needed to confirm these results. Funding: U10CA37420, K07CA120025, K07CA132916.

9573 General Poster Session (Board #32A), Mon, 1:15 PM-5:00 PM

Spiritual/religious struggle in hematopoietic cell transplant survivors.

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Background: Spiritual/religious (SR) struggle (e.g., feeling abandoned or punished by God) has been associated with poorer coping and quality of life (QOL), greater depression and pain, and health declines in general cancer populations. Few studies have been conducted among survivors of hematopoietic cell transplantation (HCT). This study examined the prevalence and predictors of SR struggle in HCT survivors. **Methods:** Data were collected as part of an annual questionnaire of adult (age >18 years) survivors of HCT at Fred Hutchinson Cancer Research Center in Seattle, WA. The 2011 survey included a SR module that incorporated the following items: Negative Religious Coping subscale of Brief RCOPE, subscales from the McGill QOL Questionnaire and the SF-36, Patient Health Questionnaire-8, disease information and socio-demographics. SR struggle was defined as any non-zero response on the Negative Religious Coping subscale of the Brief RCOPE. A multi-variable logistic regression model was used to determine factors associated with SR struggle. **Results:** Of 2113 returned surveys (52% response rate), 83% returned the SR module (n=1745) and of those 1586 were included in this analysis. Subjects were 49% female; 67% Christian and 20% Agnostic/Atheist/No preference; and 91% white. Mean age was 55 years; survivors ranged from 6 months to 40 years post-transplant. Primary indications for transplant were leukemia (49%), lymphoma (20%), and multiple myeloma (15%). Twenty-eight percent indicated SR struggle. In a multi-variable model, SR struggle showed statistically significant associations with age >=65 years (odds ratio [OR] .57, p=.02); patient report of being religious only (OR 3.5, p<.001) or spiritual only (OR 1.8, p<.001) compared to being both religious and spiritual; depression (OR 1.1, p<.001); and better social support (OR 0.77, p<.001). Time since HCT, religious affiliation and race/ethnicity did not show statistically significant associations with SR struggle. **Conclusions:** SR struggle is common among HCT survivors, even years after HCT.Further study is needed to determine causal relations, longitudinal trajectory, impact of struggle intensity, and effects of SR struggle on health, mood and social roles for HCT survivors.

9574 General Poster Session (Board #32B), Mon, 1:15 PM-5:00 PM

Validation of the supplementary quality of life questionnaire for mouth/throat and hand/foot soreness.

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Background: PISCES is a randomized crossover trial evaluating patient preference of pazopanib versus sunitinib in advanced/ metastatic renal cell carcinoma. The Supplementary Quality of Life Questionnaire (SQLQ) was developed for this trial to assess hand/foot soreness and mouth/throat soreness (MTS). The objective of this project is to validate the SQLQ. **Methods:** SQLQ was administered at baseline and every two weeks thereafter. EQ-5D was administered at baseline, during the washout period, and end of second treatment period. Treatment arms were collapsed for validation. SQLQ assesses severity of MTS (1 item), limitations due to MTS (5 items), severity of hand soreness (1 item), severity of foot soreness (1 item), limitations due to foot soreness (5 items) and ability to work (1 item). Cronbach's coefficient alpha was used to evaluate the internal consistency reliability of the multi-item subscales.T-tests compared scores between groups defined by performance status (0 versus 1) and number of metastatic sites (0/1 versus 2+) at baseline. Effect sizes (ES = mean difference / pooled standard deviation) were calculated. **Results:** Of 169 patients randomized, data was available on 168. Over 80% of on-study patients completed the SQLQ at each assessment. Cronbach's coefficient alpha was ≥ 0.80 for both limitations subscales at all assessments except baseline (limitations due to MTS). Both scores differentiated between performance status groups at baseline with ES > 0.40 ($p<0.05$). Scores significantly differed by severity of soreness with large ES of 0.9-2.1. Moderate correlations with EQ-5D were observed for limitations scores; correlations were smaller for soreness ratings. MTS and limitations due to MTS worsened after baseline with moderate – large ES; moderate ES was observed for changes in other scores. Limitation change scores were minimal in groups with no change in soreness rating; patients with worsened soreness reported similarly worsened limitations due to soreness with moderate – large ES. **Conclusions:** SQLQ is a valid and responsive measure of MTS, hand/foot soreness, and limitations due to soreness. Use of the SQLQ in future clinical trials will provide further external validation.

9575 General Poster Session (Board #32C), Mon, 1:15 PM-5:00 PM

A feasibility study using a touchscreen tool in the AYA population.

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Background: Adolescent and young adults (AYA) 15 to 39 years present unique health care needs; however, barriers to communication of treatment-related and psychosocial difficulties exist. We hypothesized that a tailored AYA Touchscreen Tool (AYATT) in cancer patients/survivors would facilitate patient-provider communication, toward the larger goal of timely intervention. As a first step, we evaluated the feasibility of such a tool, operationally defined as an 80% acceptance and completion rate. **Methods:** Eligible City of Hope AYA patients receiving treatment and follow up care for oncologic or hematologic disease were systematically approached for study participation. Target accrual to assess feasibility was set at 50 participants. Consented patients completed a concise AYATT battery, mostly standardized measures, assessing access to care (CHIS), needs, neurocognitive function (BRIEF-A, CogState), and other quality of life (PedsQL) issues. Patients and clinical/support staff completed satisfaction and ease-of-use surveys to further evaluate feasibility. **Results:** 54 participants were accrued over 8 weeks, with a 96% completion rate exceeding our primary feasibility criteria. At the time of participation: Mean age=26.2 years; Range 15.3 to 38.9 years. Acceptability was high with positive responses throughout the survey. Based on patient responses, the AYATT helped 52% remember issues they had, or have, with their care or treatment; 39% were encouraged to discuss medical issues with their care team that they might not have discussed; 92% found it a useful way to communicate with their health care team; and 98% would recommend that other patients use AYATT. A separate survey from 31/36 clinical/support staff reported AYATT had minimal negative impact in clinic or patient care, increased communication, and was useful in maintaining/improving care. **Conclusions:** The aggregate findings from this feasibility study support utilizing a tailored touchscreen device in the AYA oncology population. Predictably, high levels of computer knowledge in our AYA cohort may account for the success and acceptance of using such a tool. These results provide evidence for further exploration and continued use in the AYA clinic and patient care setting.

9576 General Poster Session (Board #32D), Mon, 1:15 PM-5:00 PM

Attitudes regarding privacy of genomic information in personalized cancer therapy.

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Background: Cancer therapy is increasingly personalized to the molecular characteristics of a particular patient and his/her tumor. Patients and providers express interest in personalized therapy yet concerns regarding the privacy of genomic data have been raised, particularly in the context of research. We evaluated patients' attitudes regarding privacy of genomic data. **Methods:** Newly registered female breast cancer patients at MD Anderson Cancer Center were invited to participate. Of 308 consecutive patients approached, 100 completed a survey assessing attitudes regarding association of personal identifying information with genomic data, risks for potential insurance and employment discrimination based on genomic information, and willingness to share genomic data (32% response rate). **Results:** Most patients (83%) indicated that genomic data should be protected. However, only 13% endorsed concern regarding genomic data privacy, measured using a composite scale ($\alpha = 0.92$). Patients expressed more concern about insurance discrimination than employment discrimination (43% vs. 28%, $p<0.001$), and these two variables were highly correlated ($\chi^2=32.7$, $p<0.001$). Patients expressed greater trust in research institutions like MD Anderson to protect the security of their molecular data compared with government agencies or drug companies (80% vs. 63% vs. 56%; $p < 0.001$). Most did not endorse concern regarding association of their genomic data with their name and identities (51%), billing and insurance (56%), or clinical data (73%). Patients were more willing to share de-identified data than identified data with researchers other than their treating physicians ($p<0.001$). 36% of patients were willing to share identified data with any MD Anderson researcher and 14% with any cancer researcher. **Conclusions:** Patients generally expressed low levels of concern regarding privacy of genomic data. Cancer patients may recognize the clinical and research value of genomic testing and a significant proportion are willing to share their genomic data with researchers.

9577 General Poster Session (Board #32E), Mon, 1:15 PM-5:00 PM

Correlations of patient-reported measures (PRM) for health, quality of life (QOL), functional status, and social supports with survival in early-stage colon cancer.

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Background: PRM can enhance our understanding of patients' needs and facilitate cancer treatment decision making. Few studies have explored the relationships between brief PRM and outcomes in early stage colon cancer. Our aims were 1) to determine the effects of prospectively collected PRM on cancer-specific (CSS) and overall survival (OS) and 2) to examine if this association is modified in the elderly. **Methods:** Patients diagnosed with stage 1 to 3 colon cancer in 2008, evaluated at 1 of 5 regional cancer centers in British Columbia, and provided baseline PRM were included. PRM consisting of a series of short, self-administered scales that described patient-reported health, QOL, functional status and social supports were collected at baseline and correlated with CSS and OS using regression models that controlled for known prognostic factors such as tumor and nodal stage. We subsequently assessed for effect modification by age, stratifying the cohort into younger (YP; <70 years) and elderly patients (EP; $>/=70$ years). **Results:** In total, 223 patients were included: 94 (42%) were EP, 111 (49%) were women, and 152 (68%) were white. Compared to YP, EP were more frequently widowed (27 vs 9%, $p=0.0005$) and reported having children (92 vs 81%, $p=0.03$), but they were less likely to receive chemotherapy (57 vs 90%, $p<0.0001$). There were no significant differences in PRM based on age, with the majority indicating they had regular contact with family and friends (92%) and many describing good overall health, QOL, and functional status (48, 61, and 69%, respectively). However, a significant proportion wished for more emotional support (54%). In regression models, self-reported poor functional status was associated with worse OS (HR 2.69, 95%CI 1.09-6.65), but not CSS (HR 1.74, 95%CI 0.61-4.94). This did not differ significantly between YP and EP (p interaction >0.05). No other PRM correlated with OS or CSS (all $p>0.05$). **Conclusions:** For early stage colon cancer, self-reported functional status was independently associated with OS. Additional PRM failed to enhance prognostication, suggesting that more comprehensive tools may be required to improve patient assessments.

9578 General Poster Session (Board #32F), Mon, 1:15 PM-5:00 PM

Provider-patient communication about cost of care: Results from a national patient education program.

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Background: A 2010 NIH study indicates direct cancer care expenditures will reach $158 billion in the U.S. by 2020, impacting millions of Americans. The cost of insurance for a family of 4 has increased from $6000 (2000) to over $16,000 (2011). Medical debt is a significant cause of personal bankruptcy, even if insured. The financial realities posed by costs associated with cancer care greatly complicate a cancer diagnosis. The most recent American College of Physicians Ethics Manual recommends all parties must interact honestly, openly, and fairly. (Snyder L, et al. Ann Int Med 2012, p86) This analysis explores the occurrence and value of patient-provider communication surrounding costs associated with care in a national survey of those affected by cancer. **Methods:** From 2011-12, 505 individuals attending *Frankly Speaking About Cancer: Coping with the Cost of Care* workshops completed a survey assessing experiences about the costs of cancer care. This is a Cancer Support Community national evidence-based educational program. All attendees (n=708) were eligible to complete survey. **Results:** Most attendees (71.3%) responded. The majority (62.4%) were people with cancer/survivors; the remainder included spouses/partners, family members, and 8.7% were health care professionals. Most (80.8%) were Caucasian, and averaged 57.2 years. Of those with cancer, 89.9% were insured at diagnosis. 59.4% reported no one on their health care team initiated a discussion about the financial aspects of their care. Included in this figure, 22.7% actively sought information from health care team, and 36.7% received no information about cost. When topic was initiated, it was by social workers (16.2%), physicians (12.3%), nurses (6.3%) or financial specialists (8.2%). When information was provided, 72.1% found it somewhat or very useful. Also, regardless of provider discussion, respondents independently sought resources for managing costs, such as other patients (44.2%), the Internet (41.5%), and patient support organizations (38.1%). **Conclusions:** Patients want financial information but do not receive it. These data highlight the need and value of providers initiating a dialogue about the cost of cancer care with patients.

9579 **General Poster Session (Board #32G), Mon, 1:15 PM-5:00 PM**

Role of religiosity in medical decision making among patients with colorectal cancer.

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Background: Physician-based medical decision making (DM) has declined in favor of more patient-centered approaches. Most studies indicate that patients want to be involved; however, the level of desired involvement varies between patients wanting to make their own decisions and those preferring to leave decisions to physicians. Little is known of the factors associated with DM preferences. Given data demonstrating the influence of religion among cancer patients, we explored religiosity and decision making preferences in colorectal cancer (CRC) patients. **Methods**: We surveyed a population-based cohort of Stage III CRC patients from the Detroit and Georgia SEER registries. Patients were queried about desired level of involvement in DM, trust in physicians, religiosity, receipt of adjuvant chemotherapy, and demographics. Religiosity was assessed using the Holland System of Belief Inventory. Physician trust was assessed using the Wake Forest Physician Trust scale. Responses were collected along a Likert scale and results were dichotomized. Surveys were analyzed using univariate and bivariate methods. **Results**: Thus far, 430 CRC patients have responded (56% response rate). The median participant age is 61 years, 45% are female, and 19% are black. 54% indicated a preference for shared DM, 35% prefer "doctors to make [their] decisions", and 11% prefer to "make [their] own decisions". The distribution did not differ by age, gender, race, income, or level of education. Higher religiosity was associated with higher trust in the surgeon ($p=0.007$) but not the oncologist ($p=0.3$). Patients with higher religiosity scores and higher physician trust were more likely to prefer that their doctors make the decisions ($p= 0.023$, $p<0.001$). Preference for physician DM was associated with higher receipt of adjuvant chemotherapy ($p=0.002$). **Conclusions**: Patients who were more religious preferred to leave medical DM to physicians. Those who relied on physician DM were more likely to receive chemotherapy. This association may be mediated through higher trust. Understanding the influence of religiosity may be a tool to help providers get their patients appropriate cancer care.

9580 General Poster Session (Board #32H), Mon, 1:15 PM-5:00 PM

Impact of functional outcomes on long-term quality of life after open retropubic radical prostectomy.

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Background: Patients who underwent open retropubic radical prostatectomy (ORRP) for prostate-cancer (PCA) have excellent long-term survival. Besides oncologic safety, recovery of continence and erectile function are highly important, as adverse functional outcomes may have a detrimental effect on health-related quality of life (HRQOL). We report the long-term HRQOL of PCA survivors after ORRP using standardized tools. **Methods:** Men treated between August 2003 and December 2007 with ORRP for localized PCA at a single academic hospital received validated questionnaires (International consultation on incontinence questionnaire (ICIQ), International index of erectile function (IIEF-5), Erection hardness score (EHS), EORTC QLQ-C30) to assess functional outcomes and HRQOL. Results were correlated with the global-health score (GHS) of the EORTC QLQ-C30 to assess the impact of ORRP on HRQOL. **Results:** In the study period 1936 men underwent ORRP of whom 1156 (59.7%) received a nerve-sparing (NS) procedure. Questionnaire return-rate was 59% (n=1141) comprising the final study cohort. Median follow-up (FU) was 62 months. Mean age at surgery and FU was 63.7±6.2 and 69.2±6.2 years, respectively. Biochemical recurrence (BCR) occurred in 17.5% (n=200/1141) and 2% (n=40/1936) deceased. Mean GHS in the study population was 71.5±20.8. In the ICIQ 28% (n=320) scored 0 indicating complete continence and 9.9% (n=113) scored ≥11 indicating severe incontinence. The corresponding GHS was 78.1±19.5 and 55.4±21.8, respectively. 68.5% (n=782) of patients used no pads and 17.9% (n=204) ≥2 pads. Corresponding GHS scores were 74.9±19.8 and 58.9±20.7. Using the IIEF-5 in men who received NS, 24.1% (n=154) had no erectile dysfunction versus 50% (n=318) using the EHS. Corresponding GHS scores were 82.2±16.3 and 74.7±19.8, respectively. Patients with BCR had a GHS of 66.8±21.8 versus 72.5±20.5 for patients without. Men who achieved the Trifecta and Pentafecta criteria had a GHS of 83.1±15.1 and 83.3±15, respectively. **Conclusions:** Incontinence severely impacts the HRQOL of long-term survivors after ORRP while erectile dysfunction and BCR have a lesser effect. Every effort should be undertaken to maintain functional integrity.

9581 General Poster Session (Board #33A), Mon, 1:15 PM-5:00 PM

Differences in psychosocial factors among diverse women enrolled in a phase III cooperative group metastatic breast cancer trial (CALGB 40502/Alliance).

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Background: Previous metastatic breast cancer trials have shown lower overall survival among African American (AA) women. Studies have also shown links between higher comorbidities and lower levels of social support and survival. Whether these factors differ by race and ethnicity is not known. **Methods:** Breast cancer patients enrolling in a phase III cooperative group metastatic breast cancer trial completed a self-administered survey measuring psychosocial and socio-demographic factors and comorbidities. Results were analyzed by self-identified race/ethnicity and evaluated by other measured variables. **Results:** 703 out of 799 patients completed the survey (88%). Questions were answered by greater than 95% of participants. The table shows differences broken down by Race/Ethnicity. AA and Hispanic (H) patients were more likely to have trouble paying for medications and have incomes less than 15K per year. AA were less likely to be married, and had lower levels of social support. Differences in income did not mediate these social support differences. Marital status did not mediate lower social support for AA ($p=0.79$) but did so for whites ($p<0.001$) **Conclusions:** Compliance with the questionnaire was quite high. Differences in social support by race were apparent and were mediated by different factors according to race. Future efforts will analyze the impact of these factors on survival and as mediators for potential racial and ethnic differences in survival.

Variable	AA (n=96)	W (n=538)	H (n=35)	P value
Age (median)	54	58	52	0.0002
Committed relationship	35%	68%	68%	<0.0001
Trouble paying for meds (at least some of time)	40%	21%	37%	0.0052
Income: <15K	38%	14%	25%	<0.0001
Comorbidities: Hypertension	53%	38%	31%	0.0075
Comorbidities: Diabetes	21%	12%	23%	0.025
Depression	13%	22%	11%	0.06
Social Support mean (SD): Overall	81.3 (18.4)	88.6 (13.8)	85.5 (15.9)	0.0038
Social Support mean (SD): Tangible	82.9 (20.2)	89 (15.8)	87.3 (16.3)	0.010
Social Support mean (SD): Affectionate	85.6 (22.2)	92.8 (14.6)	93.9 (11.4)	0.014
Social Support mean (SD): Positive social interaction	77.6 (21.6)	87.4 (16.2)	83 (18.5)	0.0002
Loneliness mean (SD)	65.1 (6.8)	64.3 (6.2)	62 (6.8)	0.26

9582 General Poster Session (Board #33B), Mon, 1:15 PM-5:00 PM

ALGA: A cancer patient profiling tool to improve physician-patient communication—An analysis in breast cancer patients.

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Background: Considerable improvement of communication between physicians and patients (pts) will need to occur as personalised medicine becomes the norm. An accurate profile of the pt's cognitive and psychological status should help the physician shape his language and his messages to maximise the pt's understanding of her management options. To this aim a computerized tool (ALGA questionnaire) has been created and validated. **Methods:** The validation process produced a questionnaire with 4 main factors: Health State Perception, Psychological, Psychosocial and Cognitive aspects. To test its ability to discriminate between healthy people and pts, ALGA has been administered to 50 newly diagnosed primary Breast Cancer (BC) pts prior to their first visit with the oncologist to discuss their adjuvant treatment, and to 50 healthy women (age range:20-60), using an iPad. **Results:** A multivariate analysis showed a significant difference between BC pts and healthy women relatively to the four aforementioned broad areas: Psychosocial ($F(1,56)=13.42$, $p<.001$), Cognitive ($F(1,56)=6.53$, $p<.01$), and Psychological Aspect ($F(1,56)=2.77$, $p=.05$). ALGA detected pts with higher levels of anxiety and depression. Pts tended to ruminate more than healthy subjects. Finally, pts showed higher level of positive Health State Perception, suggesting a dissociation between cancer illness and general health. Cognitive and Psychological aspects and Health State Perception interacted with participants' level of education (respectively: $F(1,56)=12.23$, $p<.001$; $F(1,56)=4.58$, $p<.05$; $F(1,56)=7.9$, $p<.05$). Starting from this results a personal profile for each pt was created. **Conclusions:** The ALGA confirmed ability to discriminate between healthy people and BC pts, and is a good tool to create a personal pt's profile with which physicians can empower patient with tailored knowledge. Starting from ALGA questionnaire, a smart environment is being implemented as a decision support infrastructure to help communication, interaction and information delivery process from doctor to patient, influencing patient's quality of life and satisfaction.

9583 General Poster Session (Board #33C), Mon, 1:15 PM-5:00 PM

Factors affecting perceptions of clinical trials by cancer center patients.

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Background: Patient misconceptions concerning clinical trials may be barriers to accrual. We hypothesized that patients' perceptions regarding trials may be affected by the physician specialty being visited, and positively influenced by noncompulsory exposure to an educational videotape in the waiting area prior to physician interaction. **Methods:** Perceptions of all new patients at a suburban cancer center regarding clinical trials were assessed over 4.5 months using an 8-item questionnaire that allowed for quantitative assessment. A 13 minute educational videotape regarding the clinical trials process was created and displayed in patient waiting areas and all subsequent new patients were identically evaluated over the following 4.5 months. Responses were tabulated and the effect of physician specialty (medical oncology, radiation oncology, breast surgery, thoracic surgery, gynecologic surgery) and videotape exposure on the frequency of positive responses was evaluated. **Results:** 2201 questionnaires were collected during the total study period. Prior to videotape exposure, patients who visited breast surgery were more fearful of trials than those who visited gynecologic surgery ($p=0.01$) and thoracic surgery ($p=0.03$), and were also less likely to participate in a clinical trial ($p=0.001$ and $p=0.02$). Patients who visited medical oncology and radiation oncology were less likely to participate in clinical trials than those who visited gynecologic oncology ($p=0.007$ and $p=0.03$). Exposure to the videotape positively influenced breast surgery patients regarding their understanding of randomization ($p=0.001$), likelihood of receiving better care in a trial ($p=0.04$), and likelihood of participation in a trial ($p=0.02$). Gynecologic surgery patients understood the concept of a placebo better after videotape exposure ($p=0.02$). In no group of patients did exposure to the videotape have a negative effect on their perceptions of the clinical trials process. **Conclusions:** Cancer center patients have different perceptions of the clinical trials process depending on the type of specialist visited. These perceptions can be positively influenced in select patients by the noncompulsory exposure to an educational videotape.

9584 General Poster Session (Board #33D), Mon, 1:15 PM-5:00 PM

Assessment of executive function (EF) among pediatric survivors of acute lymphoblastic leukemia (ALL).

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Background: Childhood ALL survivors are at increased risk of impaired EF. Both parent ratings and performance-based measures are used to identify vulnerable patients. We seek to assess the association between these modalities to 1) each other, and 2) need for special education and stimulants. **Methods:** This 22-site cross-sectional study included 256 children in remission for standard-risk precursor-B ALL previously enrolled on legacy Children's Oncology Protocols from 1993 - 2000. Patients had no history of CNS leukemia, cranial radiation, or pre-existing neurodevelopmental disorders; were $\geq$1 year off-therapy; and were 6-16 years at evaluation. Patients were administered performance-based measures of working memory, Digit Span (DS) and Letter-Number Sequencing (LNS) comprising the Working Memory Index (WMI) from the Wechsler Intelligence Scales for Children - Fourth Edition. Patients completed the Controlled Oral Word Association Test (COWAT). Parents completed demographic surveys and a Likert-scale assessment of executive processes, Behavior Rating Inventory of Executive Function (BRIEF). **Results:** There were modest correlations between BRIEF-WM scale and WMI ($r=-0.20$, $p<0.01$) and subscales, DS ($r=-0.17$, $p<0.01$) and LNS ($r=-0.19$, $p<0.01$). BRIEF-Initiate and COWAT ($r=-0.22$, $p<0.01$) were correlated. However, impaired classification based on performance-based measures was a poor predictor of parent assessment classification. The WMI and BRIEF-WM independently predicted receipt of special education ($p=0.0017$ and 0.0003). The BRIEF-WM and Initiate scales predicted stimulant medication use ($p<0.0001$ and $p=0.0037$); however, performance-based measures did not. **Conclusions:** Rater and performance-based measures provide related, but different information about EF indicating the need for both. Both measurement modalities capture educational difficulties; however, only parent ratings are associated with stimulants. This may reflect the medication's success in modifying cognition in controlled environments and the BRIEF's sensitivity to the child's ability to execute tasks in the real-world setting.

9585 General Poster Session (Board #33E), Mon, 1:15 PM-5:00 PM

Chronic conditions and lifestyle behavior after cancer: The differences between 2,103 cancer cases and 4,185 age and gender matched controls.

Bogda Koczwara, Michelle Miller, Richard John Woodman, John Coveney, Sue Booth, James Dollman, Catherine Mackenzie, Narelle Berry; Flinders University of South Australia and Flinders Medical Centre, Bedford Park, Australia; Flinders University of South Australia, Adelaide, Australia; Flinders University, Adelaide, Australia; University of South Australia, Adelaide, Australia; South Australian Department for Health and Ageing, Adelaide, Australia

Background: Weight gain and inactivity after cancer are associated with poorer cancer outcomes and may predispose to chronic conditions but the prevalence of these among cancer survivors is not well defined. The objectives of this cross-sectional study were to determine whether those with history of cancer have a greater prevalence of chronic conditions and whether their lifestyle behaviours differ from cancer free controls. **Methods:** Cross-sectional self-reported data were obtained from adult telephone survey respondents between January 2010 and March 2012. Age and gender matched individuals who did not report a cancer diagnosis were randomly selected from the same data source as controls. Data reported included rates of cardiovascular disease, hypertension, hyperlipidaemia, diabetes, and osteoporosis, lifestyle behaviours (diet, physical activity and smoking), obesity, psychological distress and self-reported health. Between-group differences were assessed using McNemar's test. **Results:** 2,103 cases and 4,185 controls were included in the analyses. Cancer cases had a higher prevalence than controls for all chronic conditions: cardiovascular disease 22.1% vs 18.4%, $p=0.001$; hypertension 53.3% vs 50%, $p=0.015$; hyperlipidaemia 47.8% vs 41.8%, $p<0.001$; diabetes 16% vs 13%, $p=0.006$; osteoporosis 13% vs 11%, $p=0.013$. There were no differences in diet, exercise or obesity. Cancer cases were more likely to report "very high" psychological distress (2.9% vs 1.7%, $p=0.005$) and "poor-fair" self-rated health (33.5% vs 22.9%, $p<0.001$). **Conclusions:** Despite similar diet and exercise habits and levels of obesity the prevalence of chronic conditions was significantly higher amongst those with history of cancer compared to controls. Further research is warranted to explain this increased predisposition to chronic conditions.

9586 General Poster Session (Board #33F), Mon, 1:15 PM-5:00 PM

Depression and self-reported memory problems in adult-onset cancer survivors.

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Background: Memory impairments are debilitating adverse effects of cancer and its treatments. Depression may predispose or exacerbate memory problems. We examined the relationship between depression and memory problems in adult-onset cancer survivors. **Methods:** We included data from individuals who completed the National Health and Nutrition Examination Survey, a nationally representative, stratified, multistage probability sample of the civilian, non-institutionalized population of the United States from 2005 to 2010. We excluded individuals with a history of brain cancer or stroke since these conditions are expected to cause cognitive problems because of direct brain insults. We determined the prevalence of depression and its relationship to memory problems in cancer survivors by weighting our results proportionally. We controlled for demographic predictors of memory problems. **Results:** The sample included 14249 adults (6875 men and 7274 women) age 20 years and older. There were 6959 Whites, 2792 Blacks, 3903 Hispanics, and 589 other race/multiracial. Overall, individuals in the United States with a history of depression were 8.4 times more likely to report memory problems (Odds Ratio (OR), 8.406; 95%CI, 6.73 to 10.64). We further explored the depression-memory relationship in a subsample of cancer survivors. Adjusting for age, sex, race-ethnicity, education, income, and general health, cancer survivors with a history of depression were approximately 5 times more likely to report memory problems ($N=1283$; OR, 4.921; 95%CI, 2.141 to 11.313) than those without a history of depression. Other predictors of memory problems were age ($\geq$ 60 years old, OR = 4.756, 95%CI, 1.957 to 11.560) and lower income (OR, 3.721; 95%CI, 1.951 to 7.098). **Conclusions:** The likelihood of memory problems is higher in cancer survivors with a history of depression. Future studies are needed to systematically delineate the depression-memory problems relationship, and to inform the development of interventions to treat these conditions for cancer survivors.

9587 General Poster Session (Board #33G), Mon, 1:15 PM-5:00 PM

Nonalcoholic fatty liver disease after adjuvant therapy in nonmetastatic breast cancer.

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Background: Nonalcholic fatty liver disease (NAFLD) is an important health problem in the general population. Also NAFLD developing after treatment is very important in cases with cancer especially having long term life expectancy like breast cancer. The aim of this this study is to explore the rate and risk factors of NAFLD in cases with breast cancer receiving adjuvant therapy. **Methods:** In this prospective study, 201 cases with breast cancer treated by chemo and/or anti-hormonal treatment were included between years 2010-2012. Patients who had ductal carcinoma insitu and metastatic disease and also chronic HBV and HCV infections, chronic liver diseases with other reasons and liver cirrhosis were excluded. Body mass index (BMI) was calculated based on the following formula: weight in kilograms divided by height in meters squared. Diabetes mellitus, hypetension and hyperlipidemia, if there is in past medical history, were documented. NAFLD was deteced by abdominal ultrasound imaging and there was no history of alcohol consumption. Biopsy was performed in 2 patients who had refractory high transaminasis. **Results:** The patients were divided into three groups. Group I: Patients without NAFLD, Group II: Patients with NAFLD before cancer treatment, Group III: Patients with NAFLD after cancer treatment. There was no difference for age and menopousal status between three groups. Diabetes mellitus, hypetension and hyperlipidemiawere not important risk factors for the development of NAFLD after cancer treatment. (p values 0,085, 0,525, 0,207, respectively). BMI was found to be higher in cases with NAFLD and the occurrence of NAFLD was detected more frequently in obese patients (BMI>30 kg/m2) (p=0,001). Tamoxifen, LHRH analougs and aromatase inhibitors were not found to be asociated with NAFLD (p=0,7, 0,8, 0,5, respectively) while the combination of fluorouracil, antharcycline and cyclophospamide was found to be a risk factor in the development of NAFLD (p=0,02). **Conclusions:** High BMI (both before and after treatment), obesity and fluorouracil, antharcycline and cyclophospamide combinationin were found to be important risk factors for the occurrence of NAFLD.

9588 General Poster Session (Board #33H), Mon, 1:15 PM-5:00 PM

Discussions regarding reproductive and sexual health among young adult survivors of cancer.

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Background: Infertility and sexual dysfunction can result from many cancer treatments and may become a source of significant distress for young adult cancer survivors. Our aims were to 1) characterize the frequency in which reproductive and sexual health discussions occur in a population-based cohort of young cancer patients and 2) identify clinical factors associated with such discussions. **Methods**: Patients aged 20 to 39 years who were diagnosed with solid tumors from 2006 to 2008, evaluated at any 1 of 5 regional cancer centers in British Columbia, Canada and alive at 2 or more years after their initial diagnosis were included. Demographics, tumor and treatment characteristics, and information on patient-physician conversations were analyzed. Using regression models, we explored the relationships between clinical factors and whether or not discussions had occurred. **Results:** A total of 397 patients were identified: median age was 35 years (IQR 31-38), 28% were men, 88% had ECOG 0, and 73% reported being in a relationship. Tumor sites included breast (50%), testicular (27%), gynecological (17%), and colorectal (6%). A significant proportion of patients received chemotherapy and radiation that posed the potential risk of infertility or sexual dysfunction. However, only 224 (56%) and 24 (6%) of individuals had a discussion about reproductive and sexual health, respectively, within the first month of their diagnosis. At 6 months, an additional 25 (6%) and 16 (4%) patients had discussed these concerns with their physicians. Age, gender, ECOG, relationship status, and type of chemotherapy and radiation were not correlated with whether or not discussions had occurred (all $p>0.05$). In regression models, tumor site was associated with differences in reproductive and sexual health discussions between patients and physicians (Table). **Conclusions:** Among young adult survivors of cancer, fertility and particularly sexual function are inadequately addressed during discussions near the time of initial cancer diagnosis.

Cancer site	N	% of patients with fertility discussion	P value	% of patients with sexual health discussion	P value
Breast	199	65%	0.0003	7%	0.0119
Testicular	106	62%		9%	
Gynecologic	69	71%		24%	
Colorectal	23	22%		13%	

9589 **General Poster Session (Board #34A), Mon, 1:15 PM-5:00 PM**

Thromboembolic events in breast cancer patients: A large series.

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Background: Breast cancer is frequently associated with thromboembolic events (TEE). TEE may result in significant morbidity, a substantial economic burden and they represent a leading cause of death. **Methods:** We conducted a case-control study to analyze patients' baseline and treatment characteristics in predicting TEE occurrence as well as the prognosis of breast cancer patients with thromboembolic events. We identified all breast cancer patients with a TEE at INCA (Brazilian National Cancer Institute), between January 2007 and December 2011. The control group consisted of breast cancer patients that had a doppler ultrasound with normal findings during the same period. Variables found to be significant ($P < 0.10$) by univariate analysis were subsequently entered into a multivariate logistic regression model. We used Kaplan-Meier and Cox regression for survival analysis. **Results:** Overall, 225 patients that developed TEE were compared to 225 matched controls. The majority of events were deep vein thrombosis of the lower extremity (78.7%) and unilateral (94.2%). Most TEE occurred within the first 3 years after the diagnosis of cancer (66.2%), with the highest incidence observed in the initial 6 months. Factors associated with the development of TEE were: age above 50 years (OR 1.85, 95% CI: 1.16 to 2.95), ECOG performance status (PS) equal to or above 3 (OR 2.01, CI 95%: 1.24 to 3.26) and the presence of a central venous catheter (CVC) (OR 2.56, 95% CI: 1.42 to 4.62). The occurrence of TEE led to systemic treatment changes (44.9%) and, most importantly, it was associated with decreased survival (HR = 1.34, 95% CI: 1.01 to 1.77, p = 0.041). **Conclusions:** This large retrospective analysis of TEE in breast cancer patients confirms that most events occur early in the treatment course. The incidence of TEE was associated with patients' age, PS, and the presence of CVC. Prospective studies are needed to evaluate outpatient thromboprophylaxis for selected groups of patients.

9590 General Poster Session (Board #34B), Mon, 1:15 PM-5:00 PM

RESTART: Rehabilitation Evaluation in Survivors of Testicular Cancer after Radical Treatment—Pilot study effect on HADS-anxiety subscore.

Jeff D. White, Gordon J. S. Rustin, Jennifer Harrington, Chris Hewitt, Sandra White, Teresa Young, Claire Lawless, Elaine McCartney, Vivienne Abbas, Christine Brannan, Lesley Somerville, Nicola Thomson, Melanie Winterbotham, James Paul, National Cancer Research Institute's Testis Clinical Studies and Palliative & Supportive Care Groups; Beatson West of Scotland Cancer Centre, Glasgow, United Kingdom; Mount Vernon Hospital, Northwood, United Kingdom; Li Ka Shing Cancer Centre, Cancer Research UK Cambridge Institute, Cambridge, United Kingdom; Crosshouse Hospital, Kilmarnock, United Kingdom; Lynda Jackson Macmillan Centre, Mount Vernon Cancer Centre, Northwood, United Kingdom; Cancer Research UK Clinical Trials Unit, Glasgow, Glasgow, United Kingdom

Background: Most testis cancer (TC) patients are cured, but some experience significant physical and psychological consequences. Multi-dimensional rehabilitation programmes have largely been studied in breast cancer, with positive effects on physical and psychological well being. The needs of young males are likely to be significantly different. Addressing the 'Survivorship agenda', we performed a study of the feasibility, composition and acceptability of a rehabilitation programme for TC patients. **Methods:** TC patients, aged >16, who had completed all radical treatment within the preceding 8 weeks, with no major cardio-respiratory problems were eligible. The 6 week multi-dimensional programme consisted of the following; exercise, psychological wellbeing, nutrition, finance, fertility, return to work and follow up. Primary end point was change in the HADS anxiety sub-score from pre (Week 1) to post the programme (Week 6). To detect with 90% power at the 10% 1-sided level of statistical significance a within patient change of 1.5 in the HADS anxiety sub-score (assuming a within patient SD of 3), 26 evaluable participants were required. Secondary objectives were the effect on QOL, HADS depression, exercise capacity and BMI. **Results:** 35 patients were recruited in 5 cohorts between Feb 2012 and Nov 2012 from 2 UK Cancer Centres; 32 patients were evaluable for the primary end point. Mean age at registration was 38 years (SD =10.45). 94% of the evaluable participants attended 5 or more sessions (30/32 participants). Participant feedback; 36.7% rated their overall score as 10 out of 10, with 93% of participants rating the programme ≥8. **Conclusions:** A multi-faceted rehabilitation programme appears deliverable and acceptable in TC patients. The study demonstrates a positive effect with a reduction in HADS anxiety score following participation. Having established the feasibility of this programme, a RCT of the programme vs. standard care is planned. Clinical trial information: ISRCTN77608320.

		Week 1 (pre-programme)	Week 6 (post-programme)
HADS anxiety subscore	Valid N	32	31
	Mean	6.44	4.65
	Std Dev	3.62	3.28
Change in HADS anxiety subscore	Mean	n/a	-1.94 (p=0.001 ◇)
	Std Dev	n/a	2.74

◇ Wilcoxon signed-rank test one-sided.

9591 General Poster Session (Board #34C), Mon, 1:15 PM-5:00 PM

Anthropometric change among breast cancer survivors provided a behaviorally based weight loss intervention.

Kim Dittus, Janice Bunn, Zachary Paul, Jean Harvey-Berino; University of Vermont College of Medicine, Burlington, VT; Universityy of Vermont, Burlington, VT; University of Vermont, Burlington, VT

Background: A majority of women with breast cancer are overweight or obese. Weight gain and loss of lean body mass often accompany chemotherapy. Excess weight is associated with increased risk of recurrence and decreased overall survival. Our aim was to determine the feasibility of a behavioral based weight loss intervention for breast cancer survivors who did and did not receive chemotherapy and to determine if additional resistance training enhances weight loss. **Methods:** Women with a BMI of 26-50 and stage I-III breast cancer were recruited for a 6 mo weight loss program which included individualized calorie reduction, 300 min of weekly exercise and a weekly online "chat". Resistance training consisted of 2x/wk 30 min resistance exercises. Anthropometric measures; kcal measured by 24-hr recalls; and physical activity measured by accelerometer were assessed. **Results:** Seventy-four women were recruited and 52 completed post testing. The average age was 54 and average time since diagnosis was 33 mos. The average BMI at study initiation was 33 kg/m^2. Overall the survivors lost 5.9 kg (6.7 % of baseline weight). Based on paired t-test evaluation weight, BMI and % body fat were all significantly lower after the intervention for completers and when using intent to treat analysis. There were no differences between groups for anthropometric change. The kcal deficit was significant for the chemo + wt loss + resistance (274kcal) and the no chemo (327kcal) groups but not the chemo+ wt loss group (196kcal). Exercise did not significantly increase between the baseline and post testing. **Conclusions:** Breast cancer survivors lose significant amounts of weight with a standard behaviorally based weight loss intervention. Receipt of chemotherapy did not influence ability to lose weight. Resistance training may increase weight loss while decreasing amount of fat free mass lost. Supervised exercise may be needed to achieve increases in exercise. Clinical trial information: NCT01482702.

Anthropometric change baseline to 6 months for completers.

	Chemo + wt loss (n=17)	Chemo + wt loss + resistance (n=18)	No chemo (n=17)
Weight	-4.4 kg*	-7.7 kg*	-5.98 kg*
BMI	-1.6 kg/m^2	-2.8 kg/m^{2*}	-2.3 kg/m^{2*}
% body fat	-2.0%*	-4.7%*	-2.7%*
Fat free mass	-1085.3 g*	-709.4 g	-957.2g

* $p \leq 0.05$

9592 General Poster Session (Board #34D), Mon, 1:15 PM-5:00 PM

Prevalence of cardiovascular disease (CVD) risk factors and preventive care among U.S. cancer survivors.

Kevin A. Pearlstein, Laura H. Hendrix, Ronald C. Chen; The University of North Carolina at Chapel Hill, Chapel Hill, NC

Background: CVD is a major cause of mortality in cancer survivors. Prior claims-based studies suggested underutilization of preventive care in cancer survivors, but most CVD preventive care items are not available in claims data. We directly examined the prevalence of CVD risk factors and receipt of care in survivors compared to the non-cancer general population (control) using the National Health Interview Survey. **Methods:** 32,934 cancer survivors interviewed between 1999 and 2011 were matched to 65819 controls based on age, race, and history of CVD events (angina, myocardial infarction, stroke). Statistical analysis accounted for population sampling weight. **Results:** CVD risk factors were prevalent among cancer survivors (Table), and 33% continued to smoke. Primary care visits were reported more often among survivors compared to controls (83% vs 74%, $p<0.001$). A high proportion of survivors and controls received monitoring for diagnosed CVD risk factors, while rates of interventions to modify the risk factors were more modest. On multivariable logistic regression models, having a general doctor visit was associated with increased monitoring for all CVD risk factors examined (hypertension, hyperlipidemia, diabetes, obesity, smoking),but there was no significant difference between cancer vs control. **Conclusions:** Cancer survivors in the US receive comparable monitoring and interventions for CVD risk factors compared to non-cancer individuals. Survivorship care involving a general doctor was associated with improved monitoring of CVD risk factors.

	Prevalence	Monitoring in individuals with risk factor				Intervention in individuals with risk factor			
Risk factor	Cancer survivor	Definition	Cancer	Control	P	Definition	Cancer	Control	P
Hypertension	49%	Blood pressure check in past year	96%	93%	<.01	Instructed to modify lifestyle	75%	75%	.79
						Prescribed medication	89%	88%	.42
						Taking medication	91%	92%	.44
Diabetes	14%	Glucose check in past 3 years	85%	86%	.29	Taking oral hypoglycemic	48%	49%	.14
						Taking insulin	19%	20%	.47
Hyperlipidemia	41%	Cholesterol check in past year	91%	89%	.05	-	-	-	-
Obesity	30%	-	-	-	-	Exercise in past month	44%	41%	<.01
Smoking	33%	-	-	-	-	Smoking cessation attempt in past year	45%	41%	<.01

9593 General Poster Session (Board #34E), Mon, 1:15 PM-5:00 PM

Utility of standardized letters in assisting primary care providers (PCPs) with the care of cancer survivors (CS).

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Background: Survivorship care plans have strong face validity, but individualizing plans to each patient's needs can be resource intensive. At our institution, a 1-page standardized letter that outlines the essential components of follow-up care is mailed to PCPs at the time of a patient's discharge. This letter highlights the recommended frequency and interval of tests and physician visits. Our study aims were to 1) characterize PCPs' attitudes regarding these letters and 2) identify potential strategies to improve this channel of communication with PCPs. **Methods:** Self-administered surveys were mailed to high-volume PCPs in British Columbia, defined as those whose practices followed >/=5 breast or colorectal CS in the preceding year. The survey asked about practice characteristics and PCPs' views towards the content and format of these standardized letters. Logistic regression models were constructed to delineate factors associated with follow-up preferences. **Results:** Among 787 PCPs, 507 (64%) responded: median year since graduation was 27 (range 1-62), 67% were men, 38% had a faculty appointment, 71% practiced in a group, and 92% were paid fee-for-service. When asked about their perspectives regarding the care of CS, 388 (77%) indicated they were comfortable providing follow-up with 299 (74%) reporting that the standardized letter contained adequate information. In regression models, PCPs who were comfortable with cancer surveillance and those who graduated greater than 30 years ago were more likely to view the standardized letter as useful (OR 2.50, 95% CI 1.41-4.43 and OR 2.31, 95% CI 1.24-4.33, respectively) and important (OR 4.07, 95% CI 1.80-9.19 and OR 3.14, 95% CI 1.01-9.74, respectively). Among 103 (26%) PCPs who found the letter to be insufficient, most wanted additional details about the cancer diagnosis (88%), specific information on the toxicities of therapy (88%), and the estimated risk of recurrence (84%). **Conclusions:** Most PCPS were satisfied with a simple, standardized letter that outlines the necessary components of cancer follow-up. PCPs with less familiarity with cancer surveillance may be a target group that benefits most from individualized survivorship care plans.

9594 General Poster Session (Board #34F), Mon, 1:15 PM-5:00 PM

Gaps in survivorship care plan delivery and potential benefits to survivorship care.

Laura Pence Forsythe, Carla Parry, Catherine M. Alfano, Erin E. Kent, Corinne Leach, David Haggstrom, Patricia A. Ganz, Noreen Aziz, Julia Howe Rowland; Patient-Centered Outcomes Research Institute, Washington, DC; National Cancer Institute, Rockville, MD; Office of Cancer Survivorship, National Cancer Institute, Bethesda, MD; American Cancer Society, Atlanta, GA; Indiana University School of Medicine, Indianapolis, IN; NSABP; and the Division of Cancer Prevention and Control Research, UCLA's Jonsson Comprehensive Cancer Center, Los Angeles, CA; National Institute of Nursing Research, Bethesda, MD; National Cancer Institute, Bethesda, MD

Background: Survivorship care plans (SCPs), consisting of a treatment summary and follow-up plan, are intended to promote coordination of post-treatment cancer care. Yet, little is known about the provision of these documents by oncologists to primary care physicians (PCPs). This study compared self-reported oncologist provision and PCP receipt of treatment summaries and follow-up plans, characterized oncologists who reported consistent provision of these documents to PCPs, and examined associations between PCP receipt of these documents and survivorship care. **Methods:** A nationally representative sample of medical oncologists (N=1130) and primary care physicians (PCPs; N=1020) were surveyed regarding follow-up care for breast and colon cancer survivors using the cross-sectional Survey of Physician Attitudes Regarding the Care of Cancer Survivors (SPARCCS) in 2009. **Results:** Nearly half of oncologists reported always/almost always providing treatment summaries, while 20.2% reported always/almost always providing SCPs (treatment summary + follow-up plan). Approximately one-third of PCPs indicated always/almost always receiving treatment summaries, while 13.4% reported always/almost always receiving SCPs. Oncologists who reported training in late and long-term effects of cancer and use of electronic medical records were more likely to report SCP provision ($p<0.05$). PCP receipt of SCPs was associated with better PCP-reported care coordination, physician-physician communication, and confidence in survivorship care knowledge compared to receipt of neither treatment summaries nor SCPs ($p<0.05$). **Conclusions:** Providing SCPs to PCPs may enhance survivorship care coordination, physician-physician communication, and PCP confidence in caring for survivors. However, a minority of oncologists report routinely delivering SCPs to PCPs. Considerable progress will be necessary to achieve sharing of SCPs among oncologists and PCPs.

9595 General Poster Session (Board #34G), Mon, 1:15 PM-5:00 PM

Perceptions of benefits and harms of alcohol consumption as predictors of alcohol cessation in adult cancer survivors.

Geoffrey Liu, Dan Pringle, Osvaldo Espin-Garcia, Chongya Niu, Mary Mahler, Oleksandr Halytskyy, Rebecca Charow, Christine Lam, Ravi M. Shani, Jodie Villeneuve, Kyoko Tiessen, M Catherine Brown, Shabbir M.H. Alibhai, Doris Howell, Jennifer M. Jones, Wei Xu, Peter Selby, Lawson Eng; Princess Margaret Hospital, Ontario Cancer Institute, Toronto, ON, Canada; Princess Margaret Hospital, Toronto, ON, Canada; Epidemiology, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada; University Health Network, Toronto, ON, Canada; University Health Network-Princess Margaret Hospital, Toronto, ON, Canada; Centre for Addiction and Mental Health, Toronto, ON, Canada; Princess Margaret Hospital, University of Toronto, Toronto, ON, Canada

Background: Survivorship programs are being developed at many cancer centers, addressing secondary prevention and healthy lifestyle issues. We evaluated whether perceptions regarding the harms and benefits of alcohol use influenced alcohol cessation or recidivism in adult cancer survivors. **Methods:** 531 cancer patients of all subtypes were surveyed at a comprehensive cancer center for their alcohol habits before and after cancer diagnosis and their perception of benefits/harms for continued drinking. Multivariate logistic regression models evaluated the association of each variable with change in alcohol consumption after diagnosis adjusted for significant socio-demographic and clinico-pathological covariates. **Results:** Among 325 current drinkers at diagnosis, 55% quit or cut down their alcohol consumption 1 year after diagnosis, while 16% of 95 ex-drinkers at diagnosis restarted drinking at 1 year. Negative perceptions of the effects of alcohol on the individual patient were strongly associated with cessation: the adjusted odds ratio (aOR) of quitting were significant for a perceived negative effect on quality of life (aOR=2.2, p=0.006), survival (aOR=3.8, p=1.3E-5), fatigue (aOR=3.1, p=4.6E-5) or an increased chance in self-harm (aOR=2.6, p=0.01). Perceptions of how alcohol affected the average cancer patient had similar associations. While perceptions did not influence alcohol recidivism rates, receiving chemotherapy was the only variable associated with continued abstinence (aOR=5.5, p=0.007). Although only 8% of patients received alcohol cessation information from an oncologist, it had the greatest impact on cessation (aOR=6.6, p=0.006), an association not seen with other information sources or other healthcare providers. **Conclusions:** Perception to the negative effects of alcohol use on their health in cancer survivors strongly predicted for alcohol cessation. The oncologist had a most significant counselling role for alcohol cessation.

9596 General Poster Session (Board #34H), Mon, 1:15 PM-5:00 PM

Risk and predictors of suicide in colorectal cancer patients: A SEER analysis.

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Background: Colorectal cancer (CRC) patients have a higher risk of suicide as compared with the general population. Due to differences in the sites/morbidity of recurrences as well as ostomy rates, we sought to evaluate the distribution and predictors of suicide among patients with colon and rectal cancer. **Methods:** A retrospective analysis was undertaken using the Surveillance, Epidemiology, and End Results (SEER) database from 1973-2009. Patients included were >18yrs and had confirmed adenocarcinoma of the colon or rectum. **Results:** Included in this analysis were 187,996 rectal cancer and 443,368 colon cancer patients. Colon cancer patients were older (median age 71 *vs.* 67 yrs, $p < 0.001$) and included more females (51 vs. 43%, $p < 0.001$) as compared to rectal cancer patients. Suicide rates were similar (611 [0.14%] *vs*. 337 [0.18%], $p < 0.001$), as was the median time to suicide for colon *vs.* rectal cancer patients respectively (37 *vs.*32 months, $p = 0.13$). On univariate analysis, having rectal cancer was a predictor of suicide (HR 1.26; 95% CI: 1.10-1.43). However after adjustment for age, sex, race, marital, primary site surgery, stage and one primary, rectal cancer was not a predictor of suicide (HR 1.05; CI: 0.83- 1.33). In the combined CRC cohort, independent predictors of suicide included age >70 (HR 1.55; CI: 1.23-1.94), male gender (HR 7.56; CI: 5.34-10.70), being single (HR 1.56; CI: 1.14- 2.13), distant metastases at diagnosis (HR 1.58; CI: 1.13-2.21), and white race (HR 3.21; CI: 1.75- 5.88). Also, lack of resection of primary tumor was associated with increased risk of suicide (HR 2.83; CI: 1.97- 4.05). Among colon cancer cohort, older age, male gender, and white race as well as lack of primary resection were independent predictors of suicide. Similarly, the aforementioned predictors as well as metastatic disease on presentation were the independent predictors of suicide in the rectal cohort. **Conclusions:** The suicide risk in CRC patients is low (< 0.2%) and no difference was found based on location of primary tumor. Gender, age, distant spread of disease, intact primary tumour and race are the main predictors of suicide among colorectal patients. Future studies and interventions are needed to target these high risk groups.

9597 General Poster Session (Board #35A), Mon, 1:15 PM-5:00 PM

Five-year trajectories of financial recovery in low-income breast cancer survivors.

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Background: Breast cancer may have devastating consequences on the financial stability of low-income families due to its impact on employment and limited duration of emergency Medicaid coverage. **Methods:** A consecutive sample of 921 low-income, uninsured/underinsured, English/Spanish-speaking women diagnosed with breast cancer through the California Breast and Cervical Cancer Treatment Program was surveyed 6 months after diagnosis. Previously uninsured women were enrolled in MediCal. Follow-up surveys were administered at 18, 36, and 60 months. Our primary outcome was self-reported adequacy of financial resources. Trajectories of financial adequacy were compared by ethnicity and by trajectories of employment and insurance status. **Results:** 6 months after diagnosis, 38% said they had adequate financial resources to meet their needs, compared to 39%, 49%, and 55% at 18, 36, and 60 months, respectively. Trajectories of financial adequacy varied by ethnicity and by trajectories of employment and insurance status (Table). Of 549 who reported on financial resources in all 4 surveys the most common trajectory was inadequate resources in all surveys (n=120) followed by adequate resources in all surveys (n=83). Of 208 who had adequate resources at 6 months, 60% reported inadequate resources in ≥1 subsequent survey. Of 341 who had inadequate resources at 6 months, 87% reported inadequate resources in ≥1 subsequent survey. **Conclusions:** Low-income breast cancer survivors are at risk of long-term financial instability. Latinas and survivors who are not working and/or are uninsured are at highest risk. Additional research is needed to better understand the factors that impact financial recovery after treatment.

Percentage who reported adequate financial resources.

	6 months, n=904 No. (%)	18 months, n=797 No. (%)	36 months, n=661 No. (%)	60 months, n=599 No. (%)
Ethnicity	144 (30)†	145 (34)*	151 (41)†	150 (46)†
Latina	139 (51)	119 (51)	119 (60)	129 (69)
Non-Latina white	57 (39)	46 (38)	52 (55)	48 (59)
Other				
Employed	83 (51)*	133 (56)†	142 (57)‡	159 (63)†
Yes	258 (35)	178 (32)	181 (44)	106 (44)
No				
Insured	N/A	300 (39)	303 (51)¥	294 (57)*
Yes		11 (37)	20 (31)	35 (43)
No				

N/A: All participants had MediCal at 6 months. *p<.0005 †p<.0001 ‡p<.005 ¥p<.05.

9598 General Poster Session (Board #35B), Mon, 1:15 PM-5:00 PM

Young adult cancer survivors' (CS) follow-up care expectations of their primary care providers (PCPs) and oncologists.

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Background: The delivery of cancer survivorship care can be complicated by a lack of clarity surrounding physician roles during follow-up. This can be particularly challenging for young adult CS who face unique needs. Our aim was to characterize young CS' follow-up care expectations of their PCPs and oncologists. **Methods:** A self-administered survey was mailed to all CS diagnosed with cancer from 2005 to 2009, aged 20 to 39 years at the time of diagnosis, evaluated at any 1 of 5 regional cancer centers in British Columbia, and lived beyond 2 years. The questionnaire focused on demographics, prior treatment, and CS attitudes regarding physician responsibilities during survivorship, specifically their views about their PCPs' and oncologists' roles. Descriptive statistics and regression analyses were used to summarize these expectations and to determine if they differed based on physician type. **Results:** A total of 426 patients were included (response rate 59%): current median age was 40 years (range 24-45) and 301 (71%) were women. Common tumor sites were breast (48%), testicular (27%), and gynecological (18%). Most patients (63 and 65%, respectively) expected PCPs to be responsible for following their most recent cancer and screening for future cancers. Nearly all (85 and 93%, respectively) indicated that PCPs should also provide preventive care and manage their co-morbidities. Conversely, a significant proportion (65%) felt that oncologists should remain responsible for addressing side effects of cancer treatments throughout survivorship. In terms of fertility discussions, half of patients viewed this as a role for oncologists whereas the remainder perceived this to be more suitable for PCPs. Interestingly, neither PCPs nor oncologists were seen to have any significant role in addressing social reintegration, interpersonal relationships, or sexual function, with $<30\%$ of respondents expecting these to be discussed by either physician. **Conclusions:** Young adult CS expect PCPs to be responsible for most aspects of their ongoing care. More clarity regarding physician roles is required with respect to specific survivorship issues, such as fertility, sexual function and psychosocial health.

9599 General Poster Session (Board #35C), Mon, 1:15 PM-5:00 PM

Discriminatory power of a 25-item distress screening tool CancerSupport Source: A cross-sectional study of 251 cancer survivors.

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Background: Distress screening and integrated psychosocial care is imperative for cancer patients, yet no tools are specifically tailored for the community provider setting where the majority of US patients are treated. Any screening tool must be validated and effective at discriminating those at risk for greater distress and the associated poorer health outcomes. The study objective was to test the discriminatory power of a 25-item distress screening tool CancerSupportSource for use among cancer survivors. **Methods:** A total of 251 members (90% female, median age 57 years; mixed diagnoses, 46% breast, 9% gynecologic, 7% blood, 6% colorectal, 32% other) of a community-based cancer support network completed a web-based distress screening tool. Participants were asked to rate each of 25 items according to the question "Today, how concerned are you about. . .?" using a five-point scale (0 not at all to 4 very seriously concerned). A summary score was calculated as the count of items rated ≥ 2 and the item discrimination index (IDI) as the difference between proportions of high and low scorers rating an item≥ 2. Cut-points at 13 and 4 yielded equal-sized groups and were used to classify participants as high (n=59) and low scorers (n=60). Results: Items with the greatest discriminatory power (IDI≥ 0.8) were: changes or disruptions in work, school or home life; worrying about the future and what lies ahead; feeling too tired to do the things you need or want to do; feeling sad or depressed; ability to exercise or be physically active; and feeling nervous or afraid. Conversely, items with the lowest IDI included: eating and nutrition; tobacco or substance use; transportation to treatment and appointments; considering taking your own life. Conclusions: The results highlight, among 25 items of a distress screening tool, those items with the greatest discriminatory power to identify cancer survivors with psychosocial distress. Results suggest priority areas for distress screening and referral for support services.

9600 General Poster Session (Board #35D), Mon, 1:15 PM-5:00 PM

Tumor mutation status of Hodgkin lymphoma survivors with secondary lung adenocarcinoma.

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Background: In a multi-institutional, retrospective study of 1976 patients treated for Hodgkin's lymphoma (HL) from 1969-2007, 55 patients developed second primary lung cancers a median of 19.5 years after treatment. Of these 55 cases, 32 were identified as lung adenocarcinoma (ACA). The development of targeted therapies in recent years has made the detection of specific genomic alterations important for disease prognosis and treatment in lung ACA. The prevalence of certain genomic alterations (EGFR, ALK, and KRAS) is highly correlated with smoking history. We hypothesize that the prevalence of genomic alterations also may differ in patients with a significant exposure to radiation. **Methods:** This observational retrospective case series includes 6 patients treated with mediastinal radiation for HL who subsequently developed lung ACA. All patients were treated at Ohio State University Wexner Medical Center. Patients were identified by searching billing diagnosis codes in the electronic medical record and by query of the physicians in the department of thoracic oncology at our institution. IRB approval was obtained. **Results:** The average age at diagnosis of HL was 25 years (range 18-46) and the average age at diagnosis of lung cancer was 58 (range 52-73). All patients were treated with radiation therapy; two patients were treated additionally with chemotherapy. None of the patients received HDT-ASCT. The average time from diagnosis of HL to diagnosis of lung cancer was 33 years. Of our six cases, 2 were positive for EGFR mutations and the other four were triple negative (-EGFR, -ALK, -KRAS). Three were never smokers, one had a 1.5 pack year history, and two had 10 pack year histories. Lung cancer stages at diagnosis were 1B (n=2), 2B (n=1), 3A (n=2), 4 (n=1). **Conclusions:** To our knowledge, this is the first report of mutational status of second primary lung ACA following radiation therapy for Hodgkin disease. Although the number of patients is small, the higher prevalence of the EGFR mutation in this sample suggests that ACA related to radiation therapy may have a similar mutational profile to that of never smokers. Further investigation is needed to define the disease characteristics of lung ACA in HL survivors.

9601 General Poster Session (Board #35E), Mon, 1:15 PM-5:00 PM

Racial and ethnic variation in employment and financial experiences of breast cancer survivors.

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Background: Concerns exist regarding the employment and financial experiences of cancer survivors and whether they differ by race/ethnicity. **Methods:** In a longitudinal survey of women reported to the Los Angeles and Detroit SEER registries for nonmetastatic breast cancer, we compared experiences of 4-year survivors by race/ethnicity. **Results:** Overall, 31% of 1,536 respondents (68% response rate) felt their financial status was worse since diagnosis (63% attributed this to breast cancer). This varied by race/ethnicity: 41% of Spanish-speaking Latinas (SSL), 33% English-speaking Latinas (ESL), 23% blacks (B), and 29% whites (W), $p<0.001$. The median respondent had spent ≤$2000 on breast cancer medical expenses; 16% had spent >$5000. 12% had medical debt 4 yrs post-diagnosis: 17% of ESL, 14% B, 10% SSL, and 9% W ($p=0.01$). Minority respondents were more likely to report foregoing medical care due to cost and other privations due to their medical expenses (Table). Overall, 14% felt their employment status was worse since diagnosis, and 61% of these attributed this to breast cancer. 755 worked for pay some time after diagnosis, of whom 56% said it was at least somewhat important to work to keep health insurance (55% of SSL, 65% ESL, 65% B, 50% W, $p=0.03$); 24% would look for a new job if assured of comparable benefits (45% of SSL, 29% ESL, 22% B, 17% W, $p<0.001$); 7% had increased work hours to cover cancer-related expenses; 27% had decreased work hours due to cancer-related health issues; and 7% believed they had been denied job opportunities because of cancer. **Conclusions:** In this population-based sample of breast cancer survivors, job lock was common, and many women perceived being worse off with respect to finances and employment as a result of their breast cancer. Medical debt and privation varied significantly by race/ethnicity.

	SSL	ESL	Black	White	P
In past 12 months, due to cost:					
Went without medication	6%	7%	6%	4%	0.08
Took less than fully prescribed amount	4%	4%	6%	3%	0.01
Missed doctor's appointment	6%	10%	11%	6%	0.02
Since diagnosis, due to personal medical expenses:					
Went without health insurance	8%	9%	8%	2%	<0.001
Had utilities turned off because of unpaid bills	5%	4%	11%	2%	<0.001
Had to move out of home because couldn't afford to stay	5%	6%	6%	2%	<0.001

9602 General Poster Session (Board #35F), Mon, 1:15 PM-5:00 PM

The unmet needs of cancer survivors and their preferences for discussing them with oncologists and general practitioners (GPs).

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Background: Cancer survivors experience a range of post-treatment issues which are not well met by current services. This study explores the unmet needs of adult cancer survivors and their levels of comfort in addressing issues with oncologists and GPs. **Methods:** A cross-sectional survey was mailed to adult cancer survivors 4 years from diagnosis from 6 oncology units. Self-report data were obtained ranking physical, psychological and practical areas of importance to survivors; unmet needs in these areas; and the providers with whom they were happy to discuss each issue. Descriptive statistics were obtained regarding needs and preferences. Univariate and multivariate logistic regression analyses assessed demographic and clinical variables associated with 4 or more unmet care needs. **Results:** 228 surveys were returned (response rate 50.5%). Respondents had a mean age of 59.3 years (range 32-87), 71.5% were female, with most common primary cancers being breast (71.5%), colorectal (13.9%), prostate (4.5%) and ovarian (2.2%). The most commonly reported unmet needs were information about late effects (50.3%), managing fatigue (41.7 %), genetic risk to family (34.7%), reassurance (32.0 %) and diet (31.4 %). The median number of unmet needs was 4 (range 0-23). On univariate analysis, female gender, younger age and tertiary education were associated with greater unmet needs ($p<0.001$, $p=0.01$ and $p=0.02$). On multivariate analysis higher education ($p=0.04$) remained independently associated. **Conclusions:** Cancer survivors report significant unmet care needs, and their comfort levels for discussing them varies between providers. Some key issues are not entrusted to either oncologists or GPs. Models of care for survivors must address these potential deficits in care.

Preferred provider for addressing needs (%).

Issue	Oncologist	GP	Neither
Cancer treatment	89.9	40.1	5.5
Follow-up care	80.8	42.4	9.1
Frequency of check-ups	87.8	28.5	6.8
Late effects	77.8	35.1	12.5
General health	6.4	94.9	3.7
Lifestyle behaviors	26.1	62.5	28.1
Fatigue	35.0	61.2	24.0
Finances	4.3	11.5	85.5
Education	3.1	12.5	84.4
Employment	19.7	22.8	65.2
Psychological support	18.4	36.3	54.8
Exercise	16.4	41.3	52.5
Diet	16.1	42.6	51.1

9603 General Poster Session (Board #35G), Mon, 1:15 PM-5:00 PM

Do patients with cardiovascular diseases have earlier relapse in stage I-III non-small cell lung cancer?

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Background: Diabetes mellitus (DM) has been reported to be an independent risk factor in the development of recurrence of NSCLC following treatment of early stage disease. We evaluated to see if there was a similar effect of cardiovascular disease in patients with newly diagnosed NSCLC. **Methods:** Using the Moffitt Cancer Center (MCC) databases, patients were identified who were treated for stage I, II and III NSCLC at MCC from 2001-2003. Charts were reviewed and descriptive data were recorded including histories of DM, coronary artery disease (CAD), hypertension, cerebrovascular disease and congestive heart failure (CHF). The use of aspirin and antihypertensive agents at the time of diagnosis were also recorded. Primary endpoint was disease free survival (DFS). Overall survival (OS) was a secondary endpoint. Kaplan Meier curves and Cox regression analyses were used for DFS and OS. **Results:** A total of707 patients were identified. Ninety-seven patients had DM, 158 had CAD, 396 had hypertension, 43 had cerebrovascular disease and 56 had CHF. DFS was worse in patients with DM ($p<0.001$, OR 0.63, 95% CI 0.50-0.80), CAD ($p<0.001$, OR 0.70, 95% CI 0.57-0.85), hypertension ($p=0.016$, OR 0.81, 95% CI 0.67-0.96), cerebrovascular disease ($p=0.006$, OR 0.62, 95% CI 0.45-0.87) and CHF ($p<0.001$, OR 0.56, 95% CI 0.42-0.75). Bivariate analysis showed that CAD, cerebrovascular disease and CHF were associated with shorter DFS independent of DM. OS was also worse in patients with DM ($p<0.001$, 95% CI 0.50-0.81), CAD ($p<0.001$, OR 0.62, 95% CI 0.51-0.78), hypertension ($p=0.004$, OR 0.77, 95% CI 0.64-0.92), cerebrovascular disease ($p=0.02$, OR 0.66, 95% CI 0.47-0.94) and CHF ($p<0.001$, OR 0.54, 95% CI 0.41-0.73). In patients with hypertension, there was an improvement in DFS ($p=0.047$, OR 1.35, 95% CI 1.004-1.819) for those treated with thiazide diuretics. There were no other statistically significant differences in patients based on antihypertensive regimens or aspirin use. **Conclusions:** DM,CAD, hypertension, cerebrovascular disease and CHF are associated with shorter DFS and worse overall prognosis in patients with non-metastatic NSCLC. CAD, cerebrovascular disease and CHF are associated with shorter DFS independent of DM.

9604 General Poster Session (Board #35H), Mon, 1:15 PM-5:00 PM

Bridging to survivorship in breast cancer: Learning how treatment impacts mental health among early-stage breast cancer survivors.

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Background: Depression (D) and anxiety (A) complicate survivorship in breast cancer (BC) patients (pts). The prevalence of D and A after BC treatment (Tx) in the community and concordance with BC Tx type is poorly described, but vitally important to characterize risks of Tx and optimize support for BC pts and goals for survivorship care planning. **Methods**: We queried the electronic health record (EHR), iKnowMed, from a a large network of community oncology practices for pts treated with stage I-III breast cancer from 2007-2010 with at least 5 visits and follow up through 2012 for our retrospective study. We excluded pts who developed metastatic disease or died. We stratified pts by chemotherapy (CT) utilization (yes/no),hormone receptor (HR) status, age, and documented body mass index (BMI) at diagnosis, and post diagnosis development of D (y/n), A (y/n) or utilization of venlafaxine (E) like antidepressants (Ads), non-E like Ads or anti-A medications within the study period. Time to onset of A or D was analyzed using Cox proportional hazard methodology. **Results**: We identified 8,506 patients with a documented BMI at 1, 2, and 3 years (yrs) post diagnosis. 4369(51%) of patients received adjuvant CT and 4137 (49%) did not. Baseline characteristics were similar between tx groups, and active D or A was low at the time of dx, but as a whole rose to 41% during the study period. Pts with pre-existing D or A at the time of diagnosis were excluded. CT increases the risk of D or A (HR: 1.23, CI: 1.15-1.33). HR+ status also increases the risk of D or A (HR: 1.21, CI:1.11-1.32). Age conveyed a small diminished risk of D or A (HR: 0.98, CI: 0.98-0.99) while baseline BMI conveyed a small increased risk (HR: 1.02, CI 1.01-1.3). When excluding E like compounds that are often used to treat hot flashes in BC pts, CT was still found to have an increased risk of D or A (HR: 1.28, CI: 1.18-1.39), and HR+ was still associated with higher risk of D or A as well (HR: 1.11, CI: 1.01-1.22). **Conclusions**: Mental health disorders such as D and A are common among BC survivors, and more prevalent among BC survivors who received CT and have HR+ disease. This warrants further investigation on how to evaluate and support the mental health needs of BC survivors.

9605 General Poster Session (Board #36A), Mon, 1:15 PM-5:00 PM

Bridging to survivorship in breast cancer: How BMI weighs in.

Janet L. Espirito, Brian Turnwald, Robyn K. Harrell, Debajyoti Bhowmik, Neelima Denduluri, Barry Don Brooks, J. Russell Hoverman, Roy A. Beveridge, Debra A. Patt; The US Oncology Network/McKesson Specialty Health, The Woodlands, TX; The US Oncology Network/McKesson Specialty Health, The Woodlands, TX; Virginia Cancer Specialists/US Oncology, Arlington, VA; Texas Oncology, Dallas, TX; Texas Oncology, The Woodlands, TX

Background: Obesity and depression complicate survivorship in early stage breast cancer (BC) by having a direct impact on survival and morbidity among patients (pts) who complete treatment (tx). The prevalence of obesity after BC tx in the community and concordance with BC tx type is poorly described, but important as we characterize risks of tx and optimize goals for survivorship care planning. **Methods**: We queried the electronic health record (EHR), iKnowMed, from a large network of community oncology practices for pts diagnosed with stage I-III BC from 2007-2010 with at least 5 office visits and follow up through 11-2012 for our retrospective study. We excluded pts who developed metastatic disease or died. We stratified pts by chemotherapy (CT) utilization (yes/no), hormone receptor (HR) status, age, and documented body mass index (BMI) at first office visit and annually. We evaluated changes in BMI characteristics by tx cohort. **Results**: We identified 8,506 pts with a documented BMI at first office visit and 1, 2, and 3 years (yrs) thereafter. 4369 (51% of the total) pts received adjuvant CT and 4137 (49%) did not. 6897 pts (81%) were HR positive. Baseline BMI between tx cohorts were similar, though the prevalence of overweight (31%) and overweight or obese (68%) is high. Percent change of BMI at 3 yrs varied significantly between T cohorts ($p<0.01$) with greater rise among the cohorts who received CT in comparison to those who did not. Pts receiving CT were 46% more likely to have a 5 point or more increase in BMI at 3 yrs compared to pts that did not receive CT (OR 1.46, CI[1.08-1.96]). A stronger association for BMI increase of at least 0.5 points at 3 yrs (OR 1.53, CI [1.4-1.7]) was also observed amongst pts who received CT compared to those that did not. HR positive pts were less likely than HR negative or unknown pts to increase their BMI by at least 0.5 points (OR 0.84, $p<0.01$), but there was no difference at detecting a difference of 5 points in BMI (OR 0.88, $p=0.49$). **Conclusions**: With 3 yrs of follow up, overweight and obese status is remarkably common among BC survivors in the community and appears to be more prevalent after CT tx. Determinants of obesity require further study and point to necessary intervention to improve the health of early stage BC pts.

9606 General Poster Session (Board #36B), Mon, 1:15 PM-5:00 PM

Body mass index (BMI) and its impact on quality of life (QOL) in childhood leukemia survivors.

Anne Hudson Blaes, Kevin Scott Baker, Jill Lunsford Lee, Catherine Moen, Daniel A. Mulrooney, Srilakshmi Vankina, Rachel Isaksson Vogel, Alicia Kunin-Batson; University of Minnesota, Minneapolis, MN; Fred Hutchinson Cancer Research Center, Seattle, WA; University of Minnesota Physicians, Minneapolis, MN; St. Jude Children's Research Hospital, Memphis, TN; Honors Mentor Connection, Wayzata, MN; University of Minnesota Medical School, Minneapolis, MN

Background: Obesity after childhood cancer carries implications for survivors' future health risks; however little is known about the impact of weight after treatment on QOL. **Methods:** Adult survivors of childhood leukemia in remission (51% male) completed the Health Related QOL Short Form (SF-36) between 2006-2012. Standard BMI cut points were assessed at the time of survey completion. 97% received treatment with chemotherapy, 55.6% stem cell transplant (SCT), 27.8% were in remission from a second cancer. The impact of demographic (age at diagnosis, current age, gender), treatment [radiation therapy, SCT, total body irradiation (TBI), cranial radiation, disease characteristics, history of relapse] were explored. For each subscale, linear regression models were performed. All statistical tests were two-sided, P-values < 0.05 considered statistically significant. **Results:** 73 survivors diagnosed at a median age of 9.0 (1.0-27.0) years and surveyed at a median of 17.4 (2.5-34.7) years later completed SF-36. 75.6% had received a median dose of 1800 (800-8750) cGy of radiation. The distribution of BMI was underweight $<$18.5 (9.6%), normal 18.5-24.9 (42.5%), overweight 25-29.9 (27.4%), or obese $>$30 (20.6%). Consistent with previous studies, those who received whole brain radiation had greater BMI at the time of survey than those who did not receive radiation and those who received TBI ($F=2.52$, $p=0.065$). In analyses adjusted for age at diagnosis and time since diagnosis, the reported vitality (fatigue) for those who were obese (mean 45.0+/-8.9) or underweight (45.8+/-9.5) was significantly lower ($p=0.002$) than normal (55.7+/-10.4) or overweight (50.4+/-10.0), and those who were underweight (39.0+/-13.3) also reported poor physical functioning (endurance and strength) ($p=0.038$) compared with the others (52.3+/-8.1 normal weight, 49.5+/-11.7 overweight, 47.1+/-9.0 obese). **Conclusions:** Weight management in leukemia survivors is problematic with 48% of our sample being overweight or obese. Weight status is associated with QOL, impacting survivors' fatigue and physical functioning. Interventions to help survivors achieve a healthy weight after cancer treatment are needed, and may lead to improvements in QOL.

9607 General Poster Session (Board #36C), Mon, 1:15 PM-5:00 PM

Longitudinal changes in physical activity of head and neck squamous cell carcinoma patients.

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Background: Head and neck cancer (HNCa) treatment results in unfavorable changes in physical function, body composition and quality of life. The ability of these patients to perform physical activity after cancer treatment has not been previously evaluated. To develop clinical models that will guide the care of HNCa survivors, it is important to characterize these physical activity changes. **Methods:** From 2008 to 2011, as part of an institutional Head and Neck SPORE longitudinal epidemiology project, health survey data including the Physical Activity Scale in the Elderly (PASE) was collected at baseline, 6 months and annually thereafter. The PASE score assesses the hours doing leisure time physical activity, walking, occupational, and household chores over a typical 7-day period. During follow up, subjects deceased, were lost to follow-up, or refused survey completion. Paired t-test was used to compare the mean PASE score at various endpoints from baseline. **Results:** 294 HNCa patients completed the survey at baseline. Following a mean follow-up of 25.7 (+/-11.9) months, 66%(n=193), 73%(n=215) and 42%(n=124) of patients completed the assessment at 6-months, 1-year and 2-years respectively. Majority (97%) of the HNCa patients had oropharynx, oral cavity or larynx cancer, which were treated by chemoradiation (36%), surgery followed by chemoradiation (23%) or surgery alone (20%). Results of the PASE score revealed the lowest levels of physical activity at baseline with steady statistically significant improvement at each subsequent timepoint ($p<0.05$). Stratifying by treatment modality, the difference between baseline and 1-year PASE score was significant only for chemoradiation patients ($p<0.05$). **Conclusions:** Baseline cancer burden appeared to have the most impact on physical activity levels in HNCa patients. In patients who completed the survey, the levels of physical activity improved longitudinally over time and are most notable for patients treated by chemoradiotherapy. Therefore, the most benefit of a physical activity intervention would be either during or immediately following treatment.

9608 General Poster Session (Board #36D), Mon, 1:15 PM-5:00 PM

Who is receiving survivorship care plans? Findings from the 2012 Livestrong survey.

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Background: There are more than 14 million cancer survivors in the US – a number that is on the rise. Care coordination resources will be essential to provide support to this growing population. Key stakeholders, including the Commission on Cancer (CoC) and the Institute of Medicine, have proposed survivorship care plans (SCPs) as a way to extend support. However, limited research has been conducted to date on SCPs. **Methods:** In 2012, the LIVESTRONG Foundation (LIVESTRONG) administered a survey to understand the role of a treatment summary (TS) and SCPs and how they fit into survivors' care. Logistic regression models were conducted to identify factors associated with receiving SCPs or TS. **Results:** 5,303 survivors responded to these questions (Table). While 92% of these respondents received information about where to return to for cancer check-ups, only 51% reported receiving a TS and 17% reported receiving a SCP. Survivors who were more likely to receive SCPs if they had a navigator ($p<.001$) and if they were male, Black, had finished treatment within the past year, or received care at a university-based medical center or community cancer center ($p < 0.05$). Also, those receiving a SCP were significantly more likely to have had a detailed discussion with a provider regarding long-term side effects, emotional needs, and lifestyle recommendations. Specifically, 60% of those with a SCP discussed long-term effects compared to 39% who did not. **Conclusions:** Results here indicate that few survivors receive SCPs but survivors reported benefits from receiving them. Currently many workflow barriers impede delivering SCPs, and LIVESTRONG is working with key stakeholders including the CoC to automate the LIVESTRONG Care Plan powered by Penn Medicine's OncoLink through a registry and EMR system to understand how to address this issue.

Percentage of respondents receiving SCPs and TS (N=5,303).

Characteristics	SCPs %	TSs %
Overall	17	51
Gender		
Male	20*	60*
Female	15	46
Race/ethnicity		
White, non-Hispanic	16*	50*
Black, non-Hispanic	31	68
Hispanic	19	54
Other/multiple race	20	61
Survivorship stage		
Living with cancer as a chronic disease	14*	43*
Finished tx < 1 year	21	57
Finished tx 1-5 years	17	54
Finished tx ≥ 5 years	15	48

*p<.001

9609 General Poster Session (Board #36E), Mon, 1:15 PM-5:00 PM

Psychosocial health in survivors of adult versus childhood cancer.

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Background: The growing population of cancer survivors is characterized by two subgroups, those diagnosed as children and those diagnosed as adults. While psychosocial challenges are recognized in these survivors, little data exists comparing the psychosocial health between these two subgroups. Our objective is to compare adult and childhood cancer survivors for symptoms of depression, anxiety, somatic complaints, and post traumatic stress disorder (PTSD). **Methods:** At entry to the Vanderbilt Cancer Survivorship program, survivors of childhood and adult onset cancer, ages 15 – 55 years old, completed the Achenbach System of Empirically Based Assessment and the revised Impact of Event Scale. Using normalized *T* scores, independent sample *t* tests,and χ^2 analyses, responses were compared to normative data for each group and responses of the two survivor groups were compared to one another. **Results:** There were 172 survivors of childhood cancer (M= 9 years old at diagnosis) and 125 survivors of adult cancer (M= 41 years old at diagnosis). Childhood cancer diagnoses included hematologic cancer (56%), sarcoma (17%), brain tumor (8%), and other (19%). Adult cancer diagnoses included breast cancer (45%), colon cancer (8%), hematologic cancer (14%), sarcoma (4%), and other (29%). After adjusting for age-related population norms, adult survivors were significantly more likely to have symptoms of depression ($p=.011$), anxiety ($p=.029$), somatic problems ($p=.043$), and PTSD ($p=.004$) compared to their childhood counterparts. Compared to age-expected norms, significantly more adult, but not child, survivors scored in the clinical range for depression (29%, $p<.001$; vs. 18% n.s) and somatic problems (23%, $p=.013$; vs. 12%; n.s.). Time elapsed from cancer diagnosis to completion of the questionnaires was not significantly correlated with any of the measures. **Conclusions:** Survivors of adult onset cancer face a significantly higher amount of psychologic distress, particularly depressive and somatic symptoms, compared to their childhood counterparts and age-expected norms. Analyses are ongoing to evaluate other demographic, disease, and treatment related risk factors that may contribute to this age-related phenomenon in order to develop interventions.

9610 General Poster Session (Board #36F), Mon, 1:15 PM-5:00 PM

Use of intravaginal 17-β estradiol to improve sexual function and menopausal symptoms in postmenopausal women with breast cancer on aromatase inhibitors.

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Background: The majority of women with early stage breast cancer (BC) will become long-term survivors, living with the sequelae of treatment. Attention to symptoms and quality of life (QoL) are therefore of increasing importance both during treatment and survivorship. Aromatase inhibitors (AIs) are used to treat postmenopausal women with hormone-receptor positive (HR+) BC and can lead to profound urogenital atrophy. Atrophic vaginitis in BC survivors is prevalent, its management is complex and it negatively impacts QoL. **Methods:** A prospective longitudinal IRB-approved study was performed at MSKCC in26 postmenopausal women with stage I-III HR+ BC on adjuvant letrozole or anastrozole for at least 3 months and had urogenital atrophy. All women were initiated on 10μg intravaginal 17-β estradiol. Patients completed the Female Sexual Function Index (FSFI) and Menopausal Symptom Checklist (MSCL) at baseline and wks 12 & 24. Increase in FSFI score means better sexual function and a decrease in MSCL score means improved symptoms. We used the Wilcoxon Signed Rank Sum test to compare QoL measures at baseline to wks 12 and 24. The primary endpoint was change in systemic estradiol level from baseline to wk 12. Serial estradiol/FSH levels were measured at baseline and wks 2, 7, 12, 18 & 24; we used a highly sensitive estradiol radioimmunoassay, ESTR-US-CT, from Cisbio US, Inc. Herein we report the results from the QoL secondary endpoints. **Results:** During treatment with intravaginal 17-β estradiol 10mcg, improvement in sexual function as measured by the FSFI was seen from a median of 12.4 at baseline to 21.2 at wk 12 ($p=.0091$) and 21.8 at wk 24 ($p=.0271$). Improvement was seen from baseline to wk 12 in lubrication ($p=.0091$), desire ($p=.0303$), satisfaction ($p=.0331$) and pain ($p=.0005$) and from baseline to wk 24 in lubrication ($p=.0210$), desire ($p=.0309$) and orgasm ($p=.0369$). A reduction in menopausal symptoms was also seen from 30.0 at baseline to 23.6 at wk 12 ($p=.01$) and 22.5 at wk 24 ($p=.003$). **Conclusions:** Intravaginal 10μg 17-β estradiol provided relief from menopausal symptoms and improvement in sexual dysfunction in the domains of lubrication, desire, satisfaction, orgasm, and pain.

9611 General Poster Session (Board #36G), Mon, 1:15 PM-5:00 PM

High-flow oxygen (HFO) and bilevel positive airway pressure (BiPAP) for refractory dyspnea in patients with advanced cancer: A randomized controlled trial.

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Background: Dyspnea is one of the most common and distressing symptoms in cancer patients. Few treatments are evidence based because research in this area is difficult. The role of HFO and BiPAP in the palliation of severe refractory dyspnea has not been well characterized.We examined the changes in dyspnea, physiologic parameters and adverse effects in patients receiving HFO and BiPAP. **Methods:** In this phase II "pick the winner" randomized trial, we assigned hospitalized advanced cancer patients with refractory dyspnea to either HFO or BiPAP for 2 hours. We assessed dyspnea with the numeric rating scale (NRS) and modified Borg scale (MBS) before and after intervention. We also documented the vital signs, transcutaneous carbon dioxide and adverse effects. We used the sign rank test to compare before and after each intervention, and the Wilcoxon rank sum test to compare between arms with intention-to-treat analysis. **Results:** Thirty patients were enrolled (1:1 ratio) and 23 (77%) completed the assigned intervention. The median baseline dyspnea NRS was 7/10 (Q1-Q3 5-8), despite being on supplemental oxygen and opioids. Both HFO and BiPAP were associated with significant improvement in dyspnea after 2 h, with no differences detected between arms (Table). We observed prolonged dyspnea relief in 6 patients 1 h after completion of the study intervention. HFO improved oxygen saturation. No adverse effects were observed. **Conclusions:** HFO and BiPAP alleviated dyspnea, improved physiologic parameters and were safe. Our results justify larger randomized controlled trials to confirm these findings. Clinical trial information: NCT01518140.

Improvement in dyspnea and physiologic parameters with HFO and BiPAP.

Variables	Mean change with HFO (95% CI)	P value	Mean change with BiPAP (95% CI)	P value	BiPAP vs. HFO P value
Dyspnea NRS	-1.9 (-3.4, -0.4)	0.02	-3.2 (-5.1, -1.3)	0.004	0.32
Dyspnea MBS	-2.1 (-3.5, -0.6)	0.007	-1.5 (-3.2, 0.3)	0.13	0.29
Heart rate	-3.6 (7.8)	0.42	-5.0 (5.1)	0.02	0.43
Respiratory rate	-3.0 (5.2)	0.11	-2.0 (4.0)	0.11	0.97
Oxygen saturation (%)	5.3 (5.2)	0.003	3.3 (5.3)	0.11	0.62
Carbon dioxide (mmHg)	-0.9 (5.5)	0.06	1.9 (2.7)	0.04	0.02

9612 General Poster Session (Board #36H), Mon, 1:15 PM-5:00 PM

Aprepitant, granisetrone, and dexamethasone for prevention of CINV after high-dose melphalan in autologous transplantation: Results of a randomized, placebo-controlled phase III trial.

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Background: Aprepitant (A) is a NK1-antagonist approved for prevention of chemotherapy-induced nausea and vomiting (CINV). Though melphalan (M) is regarded only moderately emetogenic, CINV after high-dose M conditioning in autologous TPX can severely interfere with patients' (pts) quality of life. Here we present the results of our monocentric, randomized (1:1), placebo-controlled, double-blind phase IIIb trial of A, granisetrone (G) and dexamethasone (D) in this setting. **Methods:** Pts were treated with A 125 mg po day 1, A 80 mg po days 2-4, G 2 mg po days 1-4 and D 4 mg po day 1, D 2 mg po days 2-3 (arm A) or placebo (P) days 1-4, G 2 mg po days 1-4 and D 8 mg day 1, D 4 mg days 2-3 (arm B). Melphalan 100 mg/m^2 iv was administered days 1-2. Episodes of emesis, modified functional living index – emesis questionnaire (FLIE) and intensity of nausea by visual analogue scale (VAS) were recorded between days 1-6. Primary endpoint was defined as no episode of vomiting and no additional antiemetic therapy within 120h of M administration. **Results:** Between 07/05 and 01/12 a total of 362 pts were randomized. 361 subjects (arm A=180; arm B=181; male n=229; female n=132; median age arm A=59.5 years; median age arm B=58 years) were available for the efficacy analysis. There were no significant differences in gender distribution and previous experience of CINV. Significantly less pts receiving A failed the primary endpoint (42% vs. 59%, OR=0.53 [0.34; 0.82], p=.0046). This effect was stressed in women (57% vs. 82%, OR=0.30) and patients with previous CINV (48% vs. 71%, OR=0.38). Emesis within 120h occurred in 22% of pts receiving A and 35% receiving P (OR=0.5 [0.31; 0.80], p=.0036). Though differences in overall nausea (16% vs. 22%, OR=0.65 [0.83; 1.10], p=.11) did not reach statistical significance, major nausea (VAS >25mm) was reduced (6% vs. 12%, OR=0.42 [0.19; 0.92], p=.026). Difference in FLIE score was -8.2 (p=.0007). Study medication was well tolerated. PK analyses showed no interaction between M and A. **Conclusions:** The combination therapy with A resulted in significantly less CINV compared to placebo. This effect was pronounced in women and pts with previous CINV. Clinical trial information: NCT00571168.

9613 General Poster Session (Board #37A), Mon, 1:15 PM-5:00 PM

Complementary and alternative medicine (CAM) use in lung cancer: The impact of control.

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Background: Lung cancer (LC) remains the leading cause of cancer death for both men and women in the U.S., and is associated with significant symptom burden. The diagnosis and treatment of LC can make patients feel a loss of control, and desire for control has been associated with CAM use. While interest in CAM has surged recently, scant literature exists on its use in LC. This study aimed to quantify the prevalence of and identify the factors associated with CAM use in patients (pts) with LC with a specific focus on perceived control. **Methods:** We performed a cross sectional survey in pts with LC treated at the oncology clinic of an academic medical center. Self-reported CAM use was the primary outcome. Demographic and clinical variables were collected by chart abstraction. Pts' perception of their degree of control was measured using the Cancer Locus of Control scale. Multivariate logistic regression was performed to determine which factors were independently associated with CAM use. **Results:** 296 pts were surveyed (77.5% response rate) with a mean age of 63.1 (28-84). 45.6% were male, 83.5% were Caucasian, 21% had never smoked, and 52.4% had Stage IV disease. 50.9% of pts used $\geq$1 form of CAM, most commonly vitamins (31.5%), herbs (19.3%), relaxation techniques (16%) and special diets (15.7%). In multivariate analysis, CAM use was associated with age$\leq$65 (AOR 1.64, 95% CI 1.01-2.67), college level or greater education (AOR 2.17, 95% CI 1.29-3.64), never having smoked tobacco (AOR 2.39, 95% CI 1.25-4.54), and having a greater feeling of control over the cause of cancer (AOR 2.27, 95% CI 1.35-3.80). Gender and perceived control over treatment outcome were not associated with CAM use. **Conclusions:** In the largest study evaluating CAM in LC, half of pts surveyed used CAM. CAM use was associated with younger age, increased education, never having smoked tobacco and a greater feeling of control over the cause of cancer. In contrast to prior research, we did not find an association with CAM usage and gender or perceived control over treatment outcome. Since CAM use is common, future research is needed to evaluate how to integrate CAM into clinical care to help patients with LC regain a sense of control and improve their quality of life.

9614 General Poster Session (Board #37B), Mon, 1:15 PM-5:00 PM

Aprepitant (AP) versus dexamethasone (D) for preventing delayed emesis induced by anthracyclines plus cyclophosphamide (A+C) chemotherapy (CT) in breast cancer patients (pts): A double-blind, multicenter, randomized study.

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Background: A combination of AP + a 5-HT3 receptor antagonist + D and AP alone is recommended, respectively, for the prophylaxis of acute and delayed emesis induced by A+C CT in breast cancer pts. In the registrative study the role of AP in delayed emesis was not defined because prophylaxis of acute emesis was different between the two arms, and the superiority of AP on delayed emesis could be the consequence of a dependent effect on the different results achieved in acute phase. Aim of this study was to compare the efficacy of AP versus D in preventing delayed emesis in pts receiving the same prophylaxis of acute emesis. **Methods:** A randomized double-blind study comparing AP versus D was completed in naive breast cancer pts treated with A+C. Before CT, all pts were treated with intravenous palonosetron 0.25 mg and D 8 mg, and oral AP 125 mg. On days 2 and 3 pts randomly received D 4 mg bid or AP 80 mg qd. Primary endpoint was rate of complete response (no vomiting, no rescue treatment) from days 2 - 5 after CT. **Results:** From September 2009 to July 2012, 580 pts were enrolled; 551 were fully evaluated, 273 in arm D and 278 in arm AP. Day 1 complete response rates were similar: 239/273 (87.6%) in D arm and 236/278 (84.9%) in AP arm. From day 2-5, complete response was the same with both antiemetic prophylaxes (79.5%), and all secondary endpoints (complete protection, total control, no vomiting, no nausea, score of FLIE) assumed similar values. During the delayed phase, incidence of insomnia (2.9% vs. 0.4%) and heartburn (8.1% vs. 3.6%) was significantly superior in D arm. **Conclusions:** In breast cancer pts submitted to A+C CT and receiving the same antiemetic prophylaxis for acute emesis, D and AP present similar efficacy and toxicity. Clinical trial information: NCT 00869973.

9615 General Poster Session (Board #37C), Mon, 1:15 PM-5:00 PM

Pain sensitivity and aromatase inhibitor (AI)-associated arthralgias (AIAA).

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Background: AIAA affect up to half of AI-treated women with early stage breast cancer, and can lead to treatment discontinuation in 20-30%. The etiology is thought to be related to estrogen deprivation although the mechanism is unknown. In premenopausal women, lower estrogen levels have been associated with increased pain. Impaired descending pain inhibitory pathways, which may be a risk factor for developing chronic pain, have also been associated with lower estrogen levels. We prospectively tested whether AI-induced estrogen deprivation alters pain sensitivity, thereby increasing the risk of developing AIAA. **Methods:** Fifty postmenopausal women with early stage breast cancer initiating AI therapy were enrolled to the study. Subjects underwent experimental pressure pain testing and conditioned pain modulation (CPM) assessment and completed symptom questionnaires prior to AI initiation and after 3 months. Positive CPM values (>0) signify impaired descending pain inhibition. Serum estradiol concentrations were determined using an ultrasensitive assay. T-tests, Fisher's exact test, and linear regression models were used to assess associations among baseline (BL) experimental pain measures, patient-reported pain, and clinical factors. P values <0.05 were considered statistically significant. **Results:** All subjects had decreased serum estradiol concentrations with AI therapy. No statistically significant change in pressure pain threshold or CPM with AI therapy was detected. In addition, no association between change in patient-reported pain with AI therapy and change in pain threshold or CPM was identified. Patients demonstrated impaired CPM at baseline (mean 8.0, SD 14.9), and this impairment was greater in patients previously treated with chemotherapy 14.4 vs 2.0, $p=0.006$), with non-significant trends towards this being more pronounced in those with more severe pain. **Conclusions:** AI therapy did not impact pressure pain threshold or CPM, suggesting that AIAA is not likely due to pain amplification from estrogen depletion. Studies examining chemotherapy-induced changes in pain processing are needed to better understand how these alterations might contribute to the pain that these patients often develop.

9616 General Poster Session (Board #37D), Mon, 1:15 PM-5:00 PM

Determination of evidence-based diagnostic thresholds for upper limb lymphedema secondary to treatment for cancer.

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Background: Diagnosis of upper limb lymphedema (LE) secondary to treatment for cancer has been complicated by the range of diagnostic thresholds used. Traditional thresholds were arbitrarily chosen but recently normative-based cut-offs have been established. However, the diagnostic power of these thresholds has not been compared to changes identified with lymphoscintigraphy, the gold standard for diagnosis of LE. The aim of this study was to determine thresholds for commonly used clinical diagnostic tools based on lymphatic imaging outcomes. **Methods:** Women previously diagnosed with LE secondary to treatment for cancer (n=67), and women without LE (n=20) participated. Lymphoscintigraphy was completed and the presence and severity of dermal back flow qualitatively scored as none to mild or moderate to severe by an experienced nuclear medicine physician. On the same day, circumference measurements and segmental bioimpedance spectroscopy (BIS) for 10 cm intervals from the ulnar styloid to 40 cm proximal were recorded. The BIS inter-limb ratio for each segment and the inter-limb circumference differences were compared to diagnostic thresholds based on 2 and 3 standard deviations (SD) above the mean from normative data. **Results:** The number of BIS segments and circumferences measurements above a 3SD threshold correlated significantly with the dermal backflow score (R_s= 0.710 and 0.824 respectively).The number of abnormal BIS segments detected did not differ significantly between a 2SD and 3SD threshold (χ^2=0.23 p=0.63). Of the 20 new abnormal segments detected, 7 were from participants with no or mild evidence of dermal backflow on lymphoscintigraphy including 3 from control participants. In contrast, 46 new abnormal inter-limb circumference differences, all from those with a LE diagnosis, were detected using a 2SD threshold (χ^2= 31.785, p<0.001) **Conclusions:** The need for a standardized, evidenced-based approach for identification of LE is essential. We recommend diagnostic thresholds for segmental BIS be set at 3SD above the mean to minimize false positive diagnoses whereas a lower threshold of 2SD is necessary for the less sensitive inter-limb circumference difference measurements.

9617 General Poster Session (Board #37E), Mon, 1:15 PM-5:00 PM

Is there an additional health-related quality of life (HRQL) benefit with abiraterone acetate (AA) in metastatic castration-resistant prostate cancer (mCRPC) beyond that mediated by clinical endpoints?

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Background: HRQL was evaluated as part of COU-AA-301, a randomized phase 3 trial of AA + prednisone (P) vs placebo + P in mCRPC patients (pts) post-docetaxel, where AA + P demonstrated significant benefits over P in numerous HRQL measures. Here we report post hoc analyses investigating the role of disease progression (px) in mediating the HRQL benefits of AA. **Methods:** Intensity of pain and fatigue and their interference with daily activities were assessed with the BPI-SF and BFI questionnaires and multiple domains of HRQL with the FACT-P questionnaire. Mediation analyses were conducted using a series of 3 models (Baron & Kenny *J Pers Soc Psychol* 1986), to assess whether presence and timing of disease px mediated treatment effects of AA + P vs P on HRQL changes: in Model 1, HRQL (i.e. the outcome variable) is predicted by treatment, in Model 2, px (i.e. the mediator variable) is predicted by treatment, and in Model 3, HRQL is predicted by both treatment and px. Three different disease px indicators (ie, PSA px, radiographic px, and a composite px variable) were used. **Results:** Treatment predicted the change in FACT-P total score from baseline (Model 1; $p = 0.011$). Treatment (as sole predictor) was significantly ($p \leq 0.001$) predictive of both PSA px and radiographic px (Model 2). Some of the treatment benefit of AA + P on the FACT-P total score was not explained as the result of the effect of treatment on PSA and radiographic px (Model 3; $p = 0.030$). In Model 3, pts with late (> 250 d post-randomization) or no px had better FACT-P scores than those with early px for PSA px ($p = 0.019$, no px; $p = 0.008$, late px) and radiographic px ($p = 0.054$, no px; $p = 0.017$, late px). Models evaluating the mediating role of the composite px variable showed the same pattern of results. Identical sets of mediation analyses conducted for the BPI and BFI also exhibited very similar outcomes. **Conclusions:** In post-docetaxel mCRPC pts, the benefits of AA to HRQL appear to be related to both treatment assignment and the mediating effects of disease px. HRQL end points expand understanding of treatment benefit beyond clinical disease px end points. Clinical trial information: NCT00638690.

9618 General Poster Session (Board #37F), Mon, 1:15 PM-5:00 PM

Effect of abiraterone acetate (AA) on patient-reported pain in metastatic castration-resistant prostate cancer (mCRPC) post-docetaxel: Results of longitudinal sensitivity analyses.

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Background: The COU-AA-301 phase 3 trial showed that AA + prednisone (P) improved overall survival in mCRPC patients (pts) post-docetaxel. Compared with P alone, AA + P also had significant benefits on patient-reported pain. Here we describe post hoc sensitivity analyses of pain data from that trial, using different methods to compensate for the potential impact of missing data. **Methods:** Pts with mCRPC progressing after docetaxel-based chemotherapy were randomized 2:1 to AA + P or placebo + P. Pain intensity and interference of pain with daily activities were assessed with the Brief Pain Inventory-Short Form (BPI-SF) questionnaire at baseline, Day 15 of Cycle 1, and Day 1 of each 28-day treatment cycle thereafter until treatment discontinuation. The effect of treatment on BPI-SF scores was analyzed using repeated measure mixed-effects (RMM) models, piecewise linear mixed-effects (PWLME) models, and joint mixed-effects and log time-to-dropout (JMEL) models. RMM and PWMLE models assumed missing data (due to death, study dropout, or administrative issues) to be missing at random, the JMEL model to be missing not at random. Model results were compared between treatment arms. **Results:** 797 pts were randomized to AA + P, and 398 to P only. RMM model estimates suggested statistically significant ($p < 0.05$) differences in change from baseline for pain intensity and pain interference scores in favor of AA + P at the majority of study visits through cycle 11. PWLME models yielded significantly smaller areas under the curve (AUCs) for AA + P vs P for pain intensity ($p = 0.0031$) and pain interference ($p = 0.0006$); smaller AUCs reflect better pain outcomes. Results using JMEL models were nearly identical to those with PWLME models, with AUCs for AA + P significantly smaller than for P alone for pain intensity ($p = 0.0031$) and pain interference ($p = 0.0007$). **Conclusions:** Using various modeling methods that assess the impact of missing data, AA + P showed superior patterns of pain outcomes over time compared with P only in mCRPC pts refractory to docetaxel. These results support the previously reported pain benefits of AA + P over P alone from the same trial. Clinical trial information: NCT00638690.

9619 General Poster Session (Board #37G), Mon, 1:15 PM-5:00 PM

Real-world symptom burden and early treatment discontinuation in first-line metastatic breast cancer (MBC).

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Background: Treatment options in 1st line metastatic breast cancer (MBC) vary and may include chemotherapy, targeted, and hormone therapy. Some patients (pts) do not complete therapy as planned, perhaps due to treatment related toxicities. The current study examined the association of symptom burden with early treatment discontinuation (ETD) of 1st line therapy of MBC in real-world settings. **Methods:** Data were abstracted from medical records of pts at 9 community oncology practices. Eligible pts had stage IV breast cancer with start of 1st line therapy on 1/2004 to 6/2012, were $\geq$ 18 years, and had $\geq$ 1 Patient Care Monitor (PCM) survey during 1st line. The PCM is an 86-item survey of cancer-related symptoms collected as part of routine clinical care. Age, race, HER2 status, hormone status, oral and infused agents, dates of diagnosis, treatment, progression, and death were recorded. ETD was defined by direct indication of early stopping in the medical record, or by treatment duration $\leq$ 6 weeks without evidence of disease progression. Cox regression of ETD with time varying covariates was used to examine the impact of 23 separate symptoms as well as an overall composite symptom burden score based on pt responses on each symptom. **Results:** 797 pts were included, with mean age of 58.4 years, 62.1% White; with 340 on Chemotherapy (CT), 349 on CT + Targeted therapy (T) and 108 on Hormone therapy only (H). Overall, ETD occurred in 95 (11.9%) pts, with rates highest among CT (15.3%), followed by T (10.0%) and H (7.4%). Cox regression showed that 21 of 23 symptoms each increased the risk of ETD. In the composite symptom burden score (median 7.1; range 0 - 21) analysis, overall symptom burden was found to be significant (HR = 1.124, $p < 0.0001$), indicating a 12.4% increased risk of ETD with each additional symptom. Pts with 10+ symptom score had a significantly increased risk of ETD (HR = 3.09, $p < 0.0001$) compared to pts with < 5 symptom score. Pts with 15+ symptom score had the highest risk of ETD (HR = 5.75, $p < 0.0001$). **Conclusions:** Pts treated with CT for 1st line MBC had the highest rate of ETD. The likelihood of ETD increased as the number of symptoms increased. Future research is needed to evaluate ETD on pt outcomes, including overall survival.

9620 General Poster Session (Board #37H), Mon, 1:15 PM-5:00 PM

Randomized double-blind placebo-controlled trial of celecoxib for radiation-induced oral mucositis.

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Background: Oral mucositis (OM) is a painful complication of radiation therapy (RT) for head and neck (H&N) cancer. OM can compromise nutrition, require opioid analgesics and hospitalization for pain control, and lead to treatment interruptions. Due to the role of inflammatory pathways in the pathogenesis of OM, this study investigated the effect of inhibition of cyclooxygenase-2 (COX-2) on severity and morbidity of OM. **Methods:** In this randomized double-blind placebo-controlled trial,40 H&N cancer patients were randomized to daily use of 200 mg celecoxib or matched placebo, for the duration of RT. Eligibility criteria included planned RT dose of $\geq$ 5000 cGy to 2+ areas of the mouth and no contraindication for celecoxib use. The planned sample size of 20 per arm provided 80% power to detect a 1 point difference in mean Oral Mucositis Assessment Scale (OMAS) score (range 0-5) at 5000 cGy RT (primary endpoint), applying a two-tailed, two-sample t-test at the 5% level of significance. Clinical OM, normalcy of diet, pain scores and analgesic use were assessed 2-3 times a week by blinded investigators during the 6-7 week period of RT, using validated scales. **Results:** Twenty subjects were randomized to each arm, which were similar with respect to tumor location, radiation dose, and concomitant chemotherapy. In both arms, mucositis and pain scores increased over the course of RT. Intent-to-treat analyses demonstrated no significant difference in mean (SD) OMAS scores at 5000 cGy [celecoxib 1.32 (0.71), placebo 1.27 (0.86), $p = 0.83$, two sample t-test]. There was also no difference between the celecoxib and placebo arms respectively, in mean OMAS scores over the period of RT (SD) [0.98(0.77) & 0.97 (0.86), $p = 0.84$], mean worst pain scores [3.38 (3.07) & 3.31 (3.32), $p = 0.83$], mean normalcy of diet scores [5.43 (3.86) & 5.11(3.94), $p = 0.65$], or mean daily opioid medication use in IV morphine equivalents [19.08 (16.57) & 20.48 (19.07), $p = 0.48$], all by linear mixed model fixed effects regression analysis. There were no SAEs attributed to celecoxib use. **Conclusions:** Daily use of a selective COX-2 inhibitor, during the period of RT for H&N cancer, did not reduce the severity of clinical OM, pain, dietary compromise or use of opioid analgesics. Clinical trial information: NCT00698204.

9621 General Poster Session (Board #38A), Mon, 1:15 PM-5:00 PM

Palonosetron (PALO) versus granisetron (GRA) in the triplet regimen with dexamethasone (DEX) and aprepitant (APR) for preventing chemotherapy-induced nausea and vomiting (CINV) in patients (pts) receiving highly emetogenic chemotherapy (HEC) with cisplatin (CDDP): A randomized, double-blind, phase III trial.

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Background: Standard antiemetic care for preventing CINV due to HEC is a combination of 5-HT_3 receptor antagonist (RA), DEX, and APR. This study compared the efficacy of two 5-HT_3drugs, PALO and GRA, in the triplet regimen. **Methods:** Pts with a malignant solid tumor who were receiving HEC containing 50 mg/m^2or more CDDP were enrolled. They were randomly assigned to either Arm A (PALO 0.75 mg, i.v.) or Arm B (GRA 1 mg, i.v.), 30 min before chemotherapy on day 1, both arms with DEX (9.9 mg on day 1 and 6.6 mg on day 2-4, i.v.) and APR (125 mg on day 1 and 80 mg on day 2–3, p.o.). Primary endpoint was complete response (CR; defined as no emetic episodes and no rescue medications) at the overall (0-120 hours) phase. Secondary endpoints included CR at the acute (0-24 h) and delayed (24-120 h) phases, and total control (TC; no emetic episodes, no rescue medications, and no nausea) at the overall, acute, and delayed phases. The planned sample size of 840 provided 90% power to detect a 10% improvement in the CR at 0-120 h with two-sided alpha of 0.05. Primary analysis was conducted with exact Cochran-Mantel-Haenszel (CMH) test. **Results:** Between July 2011 and June 2012, 842 pts were enrolled and 827 were evaluable. The median CDDP dose was 76.1 mg/m^2 in Arm A and 75.7 mg/m^2in Arm B. Baseline factors were well-balanced. Efficacy results are summarized in the Table. **Conclusions:** The present study did not meet its primary endpoint. However, it has shown that the clinical utility of PALO exceeds that of GRA. PALO is a more preferable 5-HT_3RA in the triplet regimen than GRA in the prevention of CINV due to HEC. Clinical trial information: 000004863.

		Arm A, N=414	Arm B, N=413	Odds ratio (95%CI)	P
CR %	Overall	66%	59%	1.35 (0.99, 1.82)	0.0539
	Acute	92%	92%	1.00 (0.58, 1.71)	1.0000
	Delayed	67%	59%	1.45 (1.07, 1.96)	0.0142
TC %	Overall	48%	41%	1.36 (1.01, 1.82)	0.0369
	Acute	81%	81%	1.00 (0.69, 1.45)	1.0000
	Delayed	49%	41%	1.36 (1.02, 1.83)	0.0369

9622 General Poster Session (Board #38B), Mon, 1:15 PM-5:00 PM

Differential effects of bevacizumab on the risk of hand-foot syndrome associated with cytotoxic chemotherapy: An updated meta-analysis.

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Background: Hand-foot syndrome (HFS) is a dose-limiting toxicity of many chemotherapeutic agents. In a prior meta-analysis of published randomized-controlled clinical trials (RCTs) we showed that the risk of HFS increased significantly with the use of bevacizumab, an angiogenesis inhibitor that is widely used for the treatment of many cancers. In this study, we have included more recent trials and updated our findings. **Methods:** Databases from PUBMED, Cochrane Database, and abstracts presented at the American Society of Clinical Oncology until December, 2012 were searched for the identification of relevant studies. Eligible studies included prospective RCTs in which the addition of bevacizumab to chemotherapy was compared directly to chemotherapy alone in cancer patients. Relative risk (RR), and 95% confidence interval (CI) were calculated using a fixed- or random-effects model based on the heterogeneity of the studies. **Results:** A total of eight RCTs including 8,150 patients (bevacizumab 4211, control 3939) with a variety of tumors were analyzed. The summary incidence of HFS was 14.3% (95% CI: 4.8-36.0%). The addition of bevacizumab to chemotherapy did not significantly increase the risk of developing all-grade (RR: 1.17, 95% CI: 0.90-1.51, P=0.240) and high-grade HFS (RR: 1.50, 95% CI: 0.92-2.47, P=0.11) as opposed to chemotherapy alone. The risk of HFS did not vary significantly with tumor types (P=0.21) and bevacizumab dose (P=0.28). However, the risk of HFS varied significantly with concurrent chemotherapeutic agents (P=0.004). Bevacizumab significantly increased the risk for 5-FU based agents (RR 1.2, 95% CI 1.08-1.33, P=0.001) but decreased the risk for non-5-FU based agents (RR 0.63, 95% CI: 0.41-0.96, P=0.03). **Conclusions:** Bevacizumab may enhance or reduce the risk of HFS depending on particular chemotherapeutic agents used in cancer patients. These findings are of importance to direct supportive care efforts.

9623 General Poster Session (Board #38C), Mon, 1:15 PM-5:00 PM

A randomized multicenter phase II trial on efficacy of a hydrocolloid dressing containing ceramide with a low-friction external surface for hand-foot skin reaction caused by sorafenib in patients with renal cell carcinoma.

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Background: Hand-foot skin reaction (HFSR) is the most clinically significant and dose-limiting dermatologic toxicity in metastatic renal cell carcinoma (mRCC) patients who receive sorafenib (SOR). At present, evidence-based management strategy is not completely established. Since HFSR may be attributed to keratinous disorders of the skin and tends to develop in areas on the soles of the feet subject to strong pressure, a hydrocolloid dressing containing ceramide (a protective dressing against pressure ulcer) may prevent the development and worsening of HFSR. The purpose of the study is to investigate the usefulness of this material for HFSR on the soles of the feet in mRCC patients treated with SOR. **Methods:** Patients with grade 1 HFSR on the soles of the feet were randomly assigned 1:1 to receive a hydrocolloid dressing containing ceramide (Arm A) or 10% urea cream (Arm B). The detailed protocol of this study was presented in ASCO 2011 (Trial in Progress; TPS 233). A hydrocolloid dressing containing ceramide was applied to affected sites on the soles of the feet, but not to the hands. The primary endpoint was the incidence of Grade 2 or 3 HFSR on the soles of the feet in the first 4 weeks. **Results:** Thirty-three patients were evaluated; 17 patients in Arm A and 16 patients in Arm B. There were no significant differences in baseline characteristics between two arms. Over the 4 weeks period of this study, the incidence of Grade 2 or 3 HFSR on the soles of the feet was significantly lower in Arm A than Arm B; 5 (29%) patients in Arm A versus 11 (69%) in Arm B, $p=0.03$. On the other hand, the incidence of HFSR on the hands was similar between two arms. The median time to Grade 2 or 3 HFSR on the soles of the feet was significant longer in Arm A compared with Arm B; not reach (95%CI 13-28+) in Arm A versus 22 days (95%CI 15-27), $p=0.03$. Regarding the pain levels on the soles, Arm A was superior to Arm B ($p=0.05$). **Conclusions:** These results indicate that a hydrocolloid dressing containing ceramide with a low-friction external surface is effective in preventing the worsening of HFSR caused by SOR in mRCC patients. Clinical trial information: UMIN000002016.

9624 General Poster Session (Board #38D), Mon, 1:15 PM-5:00 PM

Risk of arterial (ATE) and venous thromboembolism (VTE) in a population-based cohort of bevacizumab-treated metastatic colorectal cancer (mCRC) patients.

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Background: Bevacizumab potentiates the risk of ATE and VTE in cancer patients who are in a prothrombotic state. Whether there are specific factors that add to this risk and how bevacizumab-related thromboembolisms are best managed remain unclear. Our objectives were to 1) characterize the incidence of ATE and VTE in a population-based cohort of mCRC patients, 2) describe patient and treatment factors associated with thromboembolisms, and 3) examine how ATE and VTE are managed in routine practice. **Methods:** All patients diagnosed with mCRC from 2006 to 2008, evaluated at 1 of 5 regional cancer centers in British Columbia, and offered bevacizumab were included. Multivariate regression models were constructed to explore the associations between clinical factors and thromboembolisms. **Results:** A total of 541 mCRC patients were identified: 27 never started bevacizumab and 14 were lost to follow-up. Of the 500 remaining patients: median age was 61 years (IQR 53-67), 297 (59%) were men, 309 (62%) had ECOG 0/1, and 39 (8%) reported prior ATE or VTE. Median number of bevacizumab cycles was 11 (IQR 7-15). After receiving bevacizumab, 91 (18%) patients developed 12 ATE and 88 VTE, with 8 patients experiencing >1 event. Baseline characteristics, such as median age (61 vs 61 years), gender distribution (61 vs 58% men), and ECOG 0/1 (66 vs 58%) were similar between patients with and without thromboembolisms, respectively (all $p>0.05$). In regression models, individuals who experienced ATE or VTE were more likely to have a prior history (14 vs 6%, $p=0.02$), reported greater pre-existing cardiac comorbidities (42 vs 32%, $p=0.05$), and received a higher median number of bevacizumab cycles (13 vs 9, $p<0.01$), suggesting a potential dose-related effect. Following the development of ATE or VTE, management varied: bevacizumab was discontinued in 46%, held temporarily in 14%, and continued in 40% of patients. **Conclusions:** In this population-based cohort, the thromboembolism risk is high, especially in patients with pre-existing risk factors and those heavily treated with bevacizumab. Management of bevacizumab-related ATE and VTE appears variable, underscoring the need for guidelines.

9625 General Poster Session (Board #38E), Mon, 1:15 PM-5:00 PM

Population-based patterns of granulocyte colony stimulating factor (GCSF) use in breast cancer (BrCa) patients receiving myelosuppressive chemotherapy.

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Background: Prophylaxis with GCSF can reduce hospitalization due to neutropenic fever, but early studies show that use of GCSF is frequently suboptimal. Our aims were to 1) characterize patterns of GCSF use in a population-based cohort of BrCa patients, 2) determine the rate of neutropenia and neutropenic fever in those who received and did not receive GCSF, and 3) identify patient and physician factors associated with appropriate GCSF prophylaxis. **Methods:** Patients diagnosed with BrCa from January to December 2008, seen at any 1 of 5 regional cancer centers in British Columbia, Canada and treated with chemotherapy protocols that posed >20% risk of neutropenic fever were reviewed. Using regression models that adjusted for confounders, the relationship between GCSF use and 1) various patient and physician characteristics and 2) treatment outcomes, such as neutropenic fever, were analyzed. **Results:** A total of 525 women were included: median age was 51 years (IQR 45 to 59 years), 38% reported smoking, 50% used alcohol regularly, 62% were ECOG 0, and 26% had private health insurance. In the entire cohort, 203 (38%) patients were given GCSF. Among those treated with GCSF, 80 (39%) and 123 (61%) individuals received GCSF as primary and secondary prophylaxis, respectively. Overall, neutropenia was noted in 292 (56%) cases while neutropenic fever was experienced by 117 (22%) patients. When compared to those who did not use GCSF, patients who used GCSF experienced a lower rate of neutropenia (15 vs 49%, $p<0.01$) and a decreased incidence of neutropenic fever (7 vs 13%, $p<0.01$). In regression models, patients lacking extended medical coverage (35 vs 49%, $p=0.02$), poor performance status (31 vs 53%, $p=0.03$), and those who were evaluated at non-teaching institutions (24 vs 68% $p<0.01$) were less likely to receive GCSF. Patients seen at non-teaching institutions were also given primary GCSF prophylaxis less frequently (15 vs 57%, $p<0.01$) than those at teaching centers. **Conclusions:** GCSF prophylaxis was associated improved neutropenia-related outcomes. However, use of GCSF was low in this population-based cohort of BrCa patients, especially in specific marginalized subgroups.

9626 General Poster Session (Board #38F), Mon, 1:15 PM-5:00 PM

Sustainability of antiemetic responses with APF530 (sustained-release granisetron) during multiple cycles of moderately (MEC) and highly (HEC) emetogenic chemotherapy regimens: Results of a randomized phase III trial.

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Background: Patients receiving MEC or HEC were administered subcutaneous (SC) APF530 500 mg, a sustained delivery formulation of granisetron (10 mg). The complete antiemetic response rates (CR; no emetic episodes and no rescue medication) were non-inferior to those of palonosetron in preventing acute and delayed chemotherapy-induced nausea and vomiting (CINV) (Grous et al. ASCO 2009, #9627). We report on sustainability of CR with APF530 (10 mg) during multiple chemotherapy cycles in this study. **Methods:** 1428 patients scheduled to receive single doses of MEC or HEC were randomized to APF530 SC (5 or 10 mg granisetron) or 0.25 mg palonosetron intravenously (IV) prior to cycle 1 (C1). In C2-4, patients who received palonosetron in C1 were randomized to APF530 5 or 10 mg; those who received APF530 continued with their C1 APF530 dose. Treatment cycles were separated by 7-28 days. CR rates were compared between cycles using McNemar's test. **Results:** No significant differences in within-cycle CR occurred between APF530 doses during acute and delayed phases in C2-4 for MEC and HEC, but a trend toward higher CR rates was seen in successive cycles. For the 2 doses, CR was sustained across all 4 cycles in 56.5-62.6% and 68.4-71.7% in acute phase, and 41.8-42.4% and 57.5-57.9% in delayed phase with MEC and HEC, respectively. Examination of CR rates in C2, C3, or C4 compared with the rate in C1 showed that CR rates were sustained and that the proportion of patients with no CR in C1 but CR in later cycles was consistently higher than that of patients with CR in C1 but no CR later. For illustration, the table shows C4 CR and C1 CR for patients who received APF530 10 mg in C1 and C4. **Conclusions:** CR rates achieved with APF530 during acute and delayed phases of CINV in MEC and HEC were maintained over multiple cycles. Clinical trial information: NCT00343460.

		AFP530 (10 mg) CR in C4/CR in C1, n4/n1 (%)			
	Phase	CR4/CR1	CR4/No CR1	No CR4/CR1	No CR4/No CR1
MEC	Acute	59/67 (88.1)	16/25 (64.0)	8/67 (11.9)	9/25 (36.0)
	Delayed	45/57 (78.9)	15/35 (42.9)	12/57(21.1)	20/35 (57.1)
HEC	Acute	70/77 (90.9)	9/14 (64.3)	7/77 (9.1)	5/14 (35.7)
	Delayed*	62/67 (92.5)	15/24 (62.5)	5/67 (7.5)	9/24 (37.5)

*p = 0.0414

9627 General Poster Session (Board #38G), Mon, 1:15 PM-5:00 PM

Antibiotic prescribing in primary care for end-of-life cancer patients.

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Background: There is ongoing debate on whether it is appropriate to administer anti-infection medications to patients approaching end of life. Population-based epidemiologic data on current antibiotic prescribing status is needed to shed lights on this issue. **Methods:** A population-based retrospective cohort study, based on data extracted from the General Practice Research Database (GPRD). Patients (N=29,810) with one of five major cancers (lung, colorectal, breast, prostate, head and neck), and who died in 2000-2008 were included for this analysis. Prescriptions of antibiotics(BNF codes: 5.1.1-5.1.13) for individual patients in the last 3 months of life were reviewed and analysed. The outcome was with (1) or without (0) antibiotic prescriptions. A Generalized Estimating Equation (GEE) logistic regression model was used to assess for the associations between outcome and explanatory variables. **Results:** Overall, 26.8% of patients(95%CI: 26.3-27.3%) had been prescribed antibiotics. There was an increasing trend in antibiotic prescribing for end-of-life cancer patients, rising from 23.2%(21.5-24.9%) in 2000 to 29.5%(28.0-31.0%) in 2008 ($p<0.001$). Patients with the following characteristics were more likely to be prescribed antibiotics($p<0.001$): being younger(<70:ORs 1.14-1.27) vs 80+, male gender(OR: 1.10; 1.03-1.18), lung & head & neck cancer(ORs:1.50-2.00) vs colorectal cancer, higher co-morbidity score(ORs vs 0-3:1.02-1.19), smoking(OR vs non-smoking 1.17;1.07-1.27), living in Northern Ireland(OR:1.43; 1.17-1.75) and Scotland(ORs: 1.23; 1.03 to 1.47) vs London. No difference by whether they drank alcohol or social economic status. **Conclusions:** Antibiotic prescribing at the end of life was common and increasing over the years. Further studies need to investigate clinical conditions associated with antibiotic prescribing to inform clinical practices and end of life care policy.

9628 General Poster Session (Board #38H), Mon, 1:15 PM-5:00 PM

Hypocalcemia in patients with metastatic bone disease receiving denosumab.

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Background: Patients (pts) with metastatic bone disease (MBD) are at risk of skeletal-related events (SREs). Potent antiresorptives reduce the risk of SREs, by inhibiting cancer-induced bone destruction, which also reduces release of skeletal calcium (Ca) into the bloodstream. Hypocalcemia (hypoCa) may occur if Ca and vit D intake is inadequate while taking antiresorptive agents. A combined analysis of 3 phase III trials in pts with MBD showed denosumab (DMAb) was superior to zoledronic acid (ZA) in preventing SREs. The overall safety profiles were similar; hypoCa was more common with DMAb (9.6%) than ZA (5.0%). Characteristics of hypoCa events in DMAb pts in these clinical trials and from post marketing adverse event (AE) reports are presented. **Methods:** Pts with solid tumors or multiple myeloma and MBD were randomized (1:1) to DMAb 120 mg SC or ZA 4 mg IV (adjusted for renal function) every 4 weeks (Q4W). Pts were advised to take daily Ca ($\geq$ 500 mg) and vit D ($\geq$ 400 IU); intake was collected by pt report. Albumin-corrected serum Ca was measured Q4W by central lab. HypoCa events were collected as decreases in serum Ca per central lab and investigator-reported AEs. Post marketing data from spontaneous reports of hypoCa to the sponsor's global safety department (AGS) were reviewed. **Results:** In the 3 trials, 2841 pts received DMAb and 2836 pts received ZA. The median Ca levels for both treatment groups were similar over time. Among DMAb pts, hypoCa was most common within 6 months of starting treatment and was more common in pts who did not report use of Ca and vit D vs those who did (15.8% vs 8.7%). Grade 3 or 4 ($<$ 7 mg/dL; $<$ 1.75 mmol/L) decreases in serum Ca were reported in 3.1% of DMAb pts and 1.3% of ZA pts. No fatal cases of hypoCa were reported in the trials. From May to Nov 2012, 37 cases of severe symptomatic hypoCa (seizures, tetany, prolonged QTc, altered mental state) were reported to AGS; fatal outcomes were reported for 3 other pts with advanced cancers and various comorbidities. **Conclusions:** HypoCa is a known risk with antiresorptive therapy, including DMAb 120 mg. HypoCa occurred less often in pts who reported taking Ca and vit D. HypoCa should be corrected prior to starting DMAb and Ca monitored during treatment. Pts should take adequate Ca and vit D while receiving DMAb. Clinical trial information: NCT00321464, NCT00321620, and NCT00330759.

9629 General Poster Session (Board #39A), Mon, 1:15 PM-5:00 PM

Impact of fosaprepitant use on dermal and vascular adverse events in anthracycline-based regimens administered through peripheral lines.

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Background: Fosaprepitant is effective in the prevention of chemotherapy-induced nausea and vomiting. In January 2012, we started using fosaprepitant in anthracycline- and cisplatin-based regimens and observed a tendency for an increase in dermal and vascular adverse events (AEs) at local infusion sites, particularly in the anthracycline group. In this study, we tested the hypothesis that fosaprepitant use is associated with dermal and vascular AEs differentially between anthracycline- and cisplatin-based regimens. **Methods:** We conducted a retrospective cohort study consisting of all patients who were administered anthracycline- or cisplatin- based regimens in 2011 and 2012 at St. Luke's International Hospital, Tokyo. Aprepitant was used in 2011 and fosaprepitant was used in 2012. All other factors including pre- and post-hydration, premedication, and injection schedule were the same. Dermal and vascular AEs was defined as any grade pain or skin changes at local infusion sites or infusion veins. Factors we considered include fosaprepitant use, chemotherapy regimen, age, number of prior regimens, and body mass index. Interaction analysis using multivariate logistic regression was used to evaluate the association between treatment regimen, fosaprepitant, and risk of AEs. **Results:** A total of 268 patients (aged 54.3±12.3) were included, of which 120 (44.8%) used fosaprepitant. Among fosaprepitant users, 50 patients (41.7%) developed dermal and vascular AEs, whereas only 16 patients (10.8%) experienced AEs among non-users ($P < .001$). When stratified by regimen, fosaprepitant was associated with a statistically significant increased risk of AEs (OR 12.10; 95% CI 5.45-26.93) in the anthracycline group. In contrast, no association was observed in the cisplatin group (OR 1.04; 95% CI 0.29-3.75). Statistically significant evidence of interaction was found ($P < .001$) between regimen and fosaprepitant in the risk of AEs. **Conclusions:** Our results support the finding that using fosaprepitant in anthracycline-based regimens increases dermal and vascular AEs. In response, we discourage the use of fosaprepitant in anthracycline-based regimens through peripheral lines.

9630 General Poster Session (Board #39B), Mon, 1:15 PM-5:00 PM

A genetic variant of 5-hydroxytryptamine receptor 3C (HTR3C): A novel link to chemotherapy-induced side effects.

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Background: Symptom clusters are defined as three or more concurrent symptoms that are related to each other. Clusters may stem from common physiological mechanisms and may better represent adverse effects to chemotherapy compared to individual symptoms. We aimed to identify association between the experience of symptom clusters and specific genetic alterations. **Methods:** Study population consisted of 108 breast cancer patients who received over two cycles of adjuvant doxorubicin and cyclophosphamide (AC) treatment at the oncology institute of the Sheba Medical Center. Participants completed the Memorial Symptom Assessment Scale, the Lee Fatigue Scale and the Center for Epidemiological Studies Depression Scale. Hierarchical cluster analysis was used to identify patients' subgroups based on their symptom experience. For the genetic analyses, DNA was extracted from peripheral blood and single nucleotide polymorphisms (SNPs) of candidate genes were tested using restriction endonuclease assays. **Results:** Two distinct subgroups were identified based on severity of fatigue, depression, nausea, and change in food tastes: ″all high″ (n=79) and ″all low″ (n=29) level of all symptoms. As patients did not have active cancer, symptoms were attributed solely to chemotherapy. A genetic variant of HTR3C (rs6766410) results in a substitution of asparagine to lysine (N163K) may be associated with nausea and vomiting. We tested the association between this variant and symptom score. 51 of 75 (68%) patients with high symptom score harbored the variant allele, compared to 13 of 28 (46%) of those with low symptom score (p=0.038). **Conclusions:** Analysis of genetic background of clusters, rather than for individual symptoms, represents a novel approach for the study of chemotherapy-induced side effects. This approach enabled the identification of HTR3C variant as a possible mediator of side effects following treatment with AC. Discovering the genetic basis of symptom clusters may lead to the development of novel diagnostic and therapeutic modalities able to improve symptom management. This may translate to improved outcome among chemotherapy-treated cancer patients.

9631 General Poster Session (Board #39C), Mon, 1:15 PM-5:00 PM

Treatment of depressive symptoms in breast cancer patients undergoing adjuvant therapy.

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Background: Studies have shown a high prevalence of depression in patients with cancer. Women with breast cancer may have a high risk of depression particularly in a post-menopausal or estrogen deficient state and may develop a high level of depressive symptoms at the time of initial diagnosis. Newly diagnosed early stage breast cancer patients were screened for depressive symptoms prior to the initiation of adjuvant therapy. The oral antidepressant fluoxetine was studied to determine if its use affected depressive symptoms, completion of adjuvant treatment, quality of life, and survival. **Methods:** Patients with newly diagnosed early stage breast cancer were screened for depressive symptoms prior to the initiation of adjuvant therapy. Patients with depressive symptoms were randomized in a double blind fashion to daily oral fluoxetine (20 mg) or placebo. Patients were then followed for 6 months and evaluated for quality of life, completion of adjuvant treatment, and depressive symptoms. Patients with stage I disease at the time of initial diagnosis were subsequently assessed for disease recurrence and survival at five years. **Results:** Two hundred three of 357 screened patients with newly diagnosed early stage breast cancer were found to have depressive symptoms prior to the initiation of adjuvant therapy. One hundred ninety-three patients were randomized to fluoxetine or placebo. The use of fluoxetine for 6 months resulted in a significantly ($p<0.01$) higher number of patients with an improvement in quality of life, a higher completion of adjuvant treatment (chemotherapy, hormonal therapy, chemotherapy plus hormonal therapy) and a reduction in depressive symptoms compared to patients who received placebo. At five years, there was a significant ($p<0.01$) improvement in survival for patients with Stage I disease who received fluoxetine, possibly related to a higher completion of adjuvant treatment. **Conclusions:** An antidepressant should be considered for early stage breast cancer patients with depressive symptoms who are receiving adjuvant treatment.

9632 General Poster Session (Board #39D), Mon, 1:15 PM-5:00 PM

Final results of a phase I trial of fasting prior to platinum-based chemotherapy.

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Background: Fasting confers dramatic protection against chemotherapy toxicity in mice (PNAS 2008). We studied safety and feasibility of escalated fasting duration prior to platinum doublet chemotherapy in cancer patients (pts). Insulin, glucose, ketones and insulin-like growth factor (IGF) were measured as potential biomarkers of the fasting state. **Methods:** 3 fasting cohorts were evaluated: 24, 48 and 72 hours (hr) (48 pre/24 post chemotherapy). Subjects recorded all calories consumed during the fast period. Feasibility was defined as 4/6 subjects in each cohort consuming $<$ 200 kCal/24 hr without excess fasting toxicity (using CTCAE v4.0). **Results:** Primary cancer: Urothelial 5, breast 5, ovarian 7, uterine 1, NSCLC 1. Regimens: gemcitabine+ cisplatin 6, docetaxel + carboplatin (C) + trastuzumab 5, C + paclitaxel 8. Median age: 61y (31-73). 4/6 pts, 5/7 pts and 4/6 pts in the 24, 48 and 72 hr groups were fasting compliant $<$200 kCal/24 hr with no significant toxicities. Median weight change was 0 after 1 cycle of fasting (-3.8% to +3.1%); 1 pt failed to regain 25% of lost weight prior to second cycle and per protocol did not fast again. Reasons for failure included forgetting and inability to maintain fast. Worst symptoms during the 48 and 72 hr fast: grade 1 hypoglycemia and hyponatremia; grade 2 headache, fatigue and dizziness; there were no grade 3 or 4 fasting-related toxicities. After fasting, insulin levels fell by medians of 69% in 24hr pts and 60% in 48hr pts ($p=0.014$). Median IGF1 levels Δ by -18.3% ($p=0.012$), interestingly 3 pts who fasted 72 hr had further Δ -19% to -59% from 48 to 72 hr. **Conclusions:** Fasting for up to 72 hr around chemotherapy is safe and feasible for cancer pts and resulted in significant decline in insulin and IGF1 levels. The randomized phase II portion of the trial commenced with 72 hr fast, seeking to delineate insulin and IGF1 as potential biomarkers of chemotherapy toxicity reduction. Clinical trial information: NCT00936364.

9633 General Poster Session (Board #39E), Mon, 1:15 PM-5:00 PM

A prospective multicenter, single blinded, randomized phase III trial to compare the efficacy of ramosetron, aprepitant and dexamethasone with ondansetron, aprepitant, and dexamethasone for preventing chemotherapy-induced nausea and vomiting: KCSG PC10-21.

Hyo Jung Kim, Eun-Kee Song, Jun Suk Kim, Jin Seok Ahn, Hwan Jung Yun, Yo Han Cho, Keon Uk Park, Si-Young Kim, JoungSoon Jang, Sang-We Kim, Hyun Woo Lee, Se Ryeon Lee, Yang Soo Kim, Soon-Nam Lee, Yoon-Ho Ko, Hwa Jung Kim, Jin Hyoung Kang, Sang Won Shin, Korean Cancer Study Group; Department of Internal Medicine, Hallym University Medical Center, Hallym University College of Medicine, Anyang, South Korea; Division of Hematology/Oncology, Department of Internal Medicine, Chonbuk National University Medical School, Jeonju, South Korea; Korea University Guro Hospital, Seoul, South Korea; Department of Medicine, Division of Hematology-Oncology, Samsung Medical Center, Sungkyunkwan University School of Medicine, Seoul, South Korea; Chungnam National University Hospital, Daejeon, South Korea; Konkuk University Medical Center, Seoul, South Korea; Dongsan Medical Center, Keimyung University, Daegu, South Korea; Department of Internal Medicine, Kyunghee University Hospital, Seoul, South Korea; Chung-Ang University Hospital, Seoul, South Korea; Department of Oncology, Asan Medical Center, University of Ulsan College of Medicine, Seoul, South Korea; Ajou University School of Medicine, Suwon, South Korea; Korea University Ansan Hospital, Ansan, South Korea; Kosin University Gospel Hospital, Busan, South Korea; School of Medicine, Ewha Womans University, Seoul, South Korea; Uijeongbu St. Mary's hospital, Kyounggi-do, South Korea; Clinical Epidemiology and Biostatistics, University of Ulsan College of Medicine, Asan Medical Center, Seoul, South Korea; Seoul St. Mary's Hospital, The Catholic University of Korea, Seoul, South Korea; Korea University College of Medicine, Seoul, South Korea

Background: Combination of aprepitant, 5-HT_3 receptor antagonist and steroid improve complete response (CR) of chemotherapy induced nausea and vomiting (CINV). But until now, there was no information whether ramosetron is as effective as other 5-HT_3receptor antagonists for the combination regimen. Therefore, we compared a ramosetron, aprepitant and dexamethasone (RAD) with ondansetron, aprepitant and dexamethasone (OAD) to establish the non-inferiority of RAD in controlling highly emetogenic chemotherapy induced nausea and vomiting. **Methods:** A total of 334 patients with malignant disease who were scheduled to receive highly emetogenic chemotherapy were randomized to RAD or OAD. Aprepitant (125 mg day 1; 80 mg day 2, 3) and dexamethasone (12 mg day 1; 8 mg day 2-4) were administered to both group. Intravenous ramosetron (0.3mg day 1) or ondansetron (16mg day1) was given to RAD or OAD, respectively. Patients recorded vomiting and nausea (VAS score) on the diary. The primary end point was CR (no vomiting or retching and no rescue medication) rate in the acute period (chemotherapy day 1). The non-inferiority margin was defined as -15% differences. **Results:** 299 patients (RAD 143, OAD 156) were eligible for the efficacy analyses of modified intention-to-treat. Median age and sex were 60 (IQR 52 – 66) and 61 (51.5 – 68, $p=0.54$), 90 Male/66 Female and 114 Male/29 Female ($p<0.0001$) in RAD and OAD, respectively. There were no significant differences between two groups on the other baseline characteristics. The CR rates of RAD vs OAD were 84.6% vs 77.6% (95% C.I. -0.4 – 14.5%) at acute period, 69.5% vs 62.6% (-2.1 – 16.0%) at delayed period (days 2-5), and 66.7% vs 58.1% (-0.6 – 17.8%) at overall period. Median nausea score at acute period were 4 (IQR 2 – 5) and 3 (2-5, $p=0.14$) in RAD and OAD, respectively. There were no grade 3 or 4 toxicities. **Conclusions:** RAD regimen is as effective and tolerable as OAD antiemetic combination for the prevention of CINV in patients receiving highly emetogenic chemotherapy. Ramosetron could be considered as one of the best partners for aprepitant. Clinical trial information: NCT01536691.

9634 General Poster Session (Board #39F), Mon, 1:15 PM-5:00 PM

N-telopeptide of type I collagen (NTX) dynamics over one year of determinations in patients with breast cancer (BC) with bone metastases (BM): Predictive factors of outcome.

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Background: The bone resorption marker NTX at baseline is a prognostic marker in BC patients with BM treated with zoledronic acid (ZOL), Coleman RE, JCO 2005. We investigate how the response of urinary NTX levels during ZOL therapy is related to patient outcome and disease characteristics. **Methods:** Consecutive BC patients with BM were prospectively included if they received monthly intravenous ZOL. Urinary NTX was determined at baseline and at following 1, 3, 6, 9 and 12 months from the initial ZOL treatment. NTX levels were considered elevated if $>$ 50 nmol/mmol creatinine. The NTX changes were compared with patient and disease characteristics. Relative risks for negative clinical outcomes were estimated with Cox regression models. **Results:** Seventy-one BC patients with BM, mean aged 61.4 (29-87), were included. Mean survival was 34.1 months (3-131), with 21 patients alive after the last follow up (median 29 months). Thirty-nine patients also had extraskeletal metastases (BM-E+). Totally 329 urinary NTX samples were evaluated. At baseline, mean NTX was 153.0 (15.4 – 700.7) and 78.9% had elevated levels. Mean baseline NTX increased with age: 71.2 ($<$40); 139.3 (50-59); 241.8 (70-79). Among patients with normal NTX at 3 months, 89.5% continued to show normal NTX at 12 months. After ZOL treatments, 46.9%, 54.7%, and 61.0% of patients had normal NTX at 3, 6 and 12 months, respectively. NTX variance (1-12 months) was higher for BM-E+ patients compared with BM-only patients, $p<0.001$. Risk factor of death for patients with persistent elevated NTX at 3 months was 1.74 ($p=0.074$). Age and BM-E+ were also associated with risk of death. There was a trend to shorter survival in BC-E+ patients ($p=0.056$). Majority of patients (88.2%) with longer survival ($>$ 36 months) and younger (age $<$ 60) received endocrine therapy. **Conclusions:** Early (3 months) urinary NTX normalization to ZOL correlates with long-term NTX normalization and survival. BC-E+ patients have a reduced NTX normalization rate compared to BM-only patients and may deserve further investigation for a more adequate schedule of bone-targeting agents.

9635 General Poster Session (Board #39G), Mon, 1:15 PM-5:00 PM

A randomized, double-blind study of "Scrambler" therapy versus sham for painful chemotherapy-induced peripheral neuropathy (CIPN).

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Background: CIPN is a debilitating, dose-limiting toxicity. The MC5A is a non-invasive electro-analgesia device delivering "Scrambler Therapy," which has shown benefit for painful CIPN in uncontrolled studies. No sham-controlled trials of MC5A have been performed. **Methods:** Eligible patients included adults with neuropathic pain (NP) for $>$ 6 months, pain scores $\geq$4/10 numerical rating scale (NRS), and no history of diabetes or other peripheral neuropathies. Patients received up to 10 daily sessions of 50 minutes with either MC5A or a novel active sham device constructed to deliver a just perceptible electrical sensation. Sham output is neither a TENS nor MC5A and is designed to be nontherapeutic. Active and sham treatments were applied to the affected limbs. 14 patients were randomized with no baseline differences. Patients and evaluators were blinded to study arm. Pain was measured before, daily during, after and 3 months post-treatment (verbal NRS). The primary endpoint was change in pain. Secondary endpoints included quantitative neurosensory testing (QST), validated patient-report measures, and cytokines. **Results:** There were 7 patients in each arm. The table shows changes in pain scores pre- and post-treatment by day and group. There was no difference between arms and no arm x day interaction. There was no significant day or arm effect for the function sub scales. **Conclusions:** In a small pilot study, MC5A was not significantly different from sham therapy for the primary outcome. The sham is feasible and provides a mechanism for future controlled studies with MC5A. Secondary endpoints, e.g. QST are forthcoming. Clinical trial information: NCT01261780.

NRS change by day and treatmen.

	MC5A (n=7)				Sham (n=7)				
Day	N	NRS Change	SD	P value[1]	N	NRS Change	SD	P value[1]	P value[2]
1	7	-0.14	0.38	0.99	7	0.57	0.98	0.31	0.10
2	7	-0.14	0.94	0.81	7	0.43	1.27	0.75	0.46
3	7	0.00	0.00		7	-0.50	1.08	0.34	0.05
4	7	0.00	0.65	0.99	7	0.21	0.39	0.50	0.52
5	7	-0.43	1.27	0.75	7	-0.36	0.48	0.25	0.67
6	7	-0.21	0.39	0.50	6	-0.42	0.38	0.12	0.30
7	7	-0.50	0.76	0.25	5	-0.60	0.55	0.25	0.65
8	5	-0.40	0.55	0.50	5	0.10	0.55	0.99	0.28
9	5	-0.30	0.45	0.50	5	-0.80	0.57	0.12	0.18
10	5	-0.10	0.89	0.99	5	-0.40	0.55	0.50	0.57

[1] Within comparison: Wilcoxon Signed Rank Test. [2] Between comparison: Wilcoxon Rank Sum Test.

9636 General Poster Session (Board #39H), Mon, 1:15 PM-5:00 PM

Patterns of palliative radiation near the end of life: A single-institution retrospective analysis.

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Background: The care of patients who receive radiation therapy (RT) at the end of life (EOL) is under scrutiny to ensure effectiveness and value, with many patients not completing RT (Gripp, 2010; Toole, 2012). This retrospective analysis seeks to describe patterns of utilization of palliative RT, including rates of completion of RT offered at the EOL and the use of single fraction RT for bone metastases. **Methods**: Electronic medical records were used to create a database of 3,383 RT plans for brain, bone, lung, and other metastatic sites in patients treated at Johns Hopkins Hospital from 9/1/2007-7/15/2012. RT plans without palliative intent were excluded. T-tests and logistic regression compared patient and treatment characteristics between patients who died $>$ 1 month versus $\leq$ 1 month after their last RT fraction. **Results**: A total of 983 patients were treated to 1,524 sites, with an average of 1.7 RT sites (SD 1.3) per patient. Of these, 872 (89%) patients had complete records and were included in analysis. At the time of analysis, 85% had died. The mean age of 62.1 years (SD 3.4) did not differ statistically based on time from RT to death. Death $\leq$ 1 month after RT was documented in 215 (24.7%) patients. Compared to patients living $>$ 1 month after RT, patients receiving RT within the last month of life were more likely to be lung (17% versus 9%), less likely to be brain (34% versus 44%), and equally likely to be bone (45% versus 43%) sites. Patients who died $\leq$ 1 month after completing RT spent on average 5 days (16.6%) of the last month of life receiving RT, with no significant difference by disease site. **Conclusions**: Most patients receiving palliative RT finish therapy, with 25% dying $\leq$ 1 month after RT. Single fraction bone RT was relatively uncommon, with no significant difference in the rates of single fraction RT based on time from RT to death. These data provide a framework to match treatment patterns with national guidelines. Additionally, they provide context to model risk of death shortly after RT, which can aid in clinical decision-making.

	Results		
Patterns of care	Died ≤ 1 month after RT	Died > 1 month after RT	Total
Percent completing RT	51%	96%	83%
Number of last 30 days of life spent in RT	5 days (range 2-15)	-	-
Single fraction bone RT	6.3%	7.8%	7.4%

9637 General Poster Session (Board #40A), Mon, 1:15 PM-5:00 PM

Efficacy of rebamipide-gargle for chemotherapy-induced oral mucositis.

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Background: Chemotherapy-induced oral mucositis (CIOM) is a severe adverse event resulting from cancer chemotherapy, and causes severe pain which impacts eating, nutrition, infection and overall quality of life. CIOM can result in unplanned treatment interruptions including dose reduction or treatment delay. Toxic free radicals and several pro-inflammatory cytokines produced by anti-cancer drugs have been reported to correlate with CIOM. Rebamipid, an endogenous inducer of prostaglandins, is widely used for gastric ulcers and gastritis in Asia. It has been shown to increase gastric endogenous prostaglandin E2 and I2, to promote gastric epithelial mucin, to behave as an oxygen–free radical scavenger, and to have other anti-inflammatory actions. In this study, we made a rebamipide gargle using rebamipide and ultrahydrogel, which is added for mucosal protection and to sustain the rebamipide on oral mucosa for a long time. **Methods:** The objective of this study is to evaluate the efficacy of the rebamipide gargle in relieving CIOM. Each 300ml of rebamipide gargle is made by combining rebamipide 600mg, high molecular weight polyethylene oxide 3g, carrageenin 1.2g, pineapple flavor and water. Patients were instructed to use the rebamipide gargle 5-6 times a day. The severity of CIOM was assessed according to the National Cancer Institute Common TerminologyCriteria for Adverse Events (CTCAE version 4.0). **Results:** From November 2009 to December 2012, 175 patients with CIOM were enrolled in this study (colorectal cancer 95 patients, breast cancer 32, gastric cancer 22, lung cancer 14, and other cancers 12). The patients' CTCAE grades (3/2/1/0) changed from (n=13/64/98/0) to (0/10/103/62) respectively after initiation of rebamipide gargle ($p<.01$; paired t test). A decrease in CTCAE was observed in 142 patients (81.1%) including 62 patients (35.4%) achieving grade 0. The mean duration to best response was 14 days (range: 1-49), and rebamipide gargle was continued 42 days (range: 5-970).There were no unexpected safety events. **Conclusions:** Rebamipide gargle was well tolerated and demonstrated significant therapeutic response for CIOM.

9638 General Poster Session (Board #40B), Mon, 1:15 PM-5:00 PM

Symptom clusters and demographic characteristics in advanced cancer.

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Background: Little is known about demographic variations in cancer symptom clusters (SC). Our objective was to determine whether SC are associated with age, gender, race, performance status (PS), or primary cancer site. **Methods:** Symptoms from 1000 advanced cancer patients referred to a palliative medicine program were recorded prospectively. Among 922 patients with complete symptom data, hierarchical cluster analysis identified 7 SC. A SC was considered present if the patient had ≥50% of the symptoms in the cluster. Comparisons were made between patients with and without each cluster using the chi-square test (age <65 vs. ≥65 years; gender female (F) vs. male (M); race Caucasian (C) vs. African American (AA); 10 primary site groups (PSG), or Wilcoxon rank sum test (ECOG PS 0-4). A p value <0.05 indicated statistical significance. **Results:** 83% of patients were C, 52% ≥65 years, 56% M, and 55% had ECOG PS 3-4 Most common PSG were lung (25%), genitourinary (18%), and gastrointestinal (GI) (11%). Fatigue/anorexia-cachexia cluster was associated with race (58% AA vs. 68% C, p=0.032) and PSG (range 47% melanoma to 83% pancreas, p=0.012); Neuropsychological cluster was associated with older age (29% ≥65 vs. 39% <65, p<0.001) and race (22% AA vs. 36% C, p=0.001). Upper GI cluster was associated with female gender (16% M vs. 22% F, p=0.035) and PSG (range 8% Head & Neck to 32% pancreas, p=0.035). Nausea/Vomiting cluster was associated with younger age (35% ≥65 vs. 43% <65, p=0.010) and female gender (33% M vs. 47% F, p<0.001). Aerodigestive cluster was associated with male gender (36% F vs. 44% M, p=0.010) and PSG (range 24% pancreas to 58% Head & Neck, p<0.001). Debility cluster was associated with race (33% AA vs. 44% C, p=0.016) and poor PS (range 17% PS0 to 54% PS4, p<0.001). Pain cluster was associated with younger age (88% ≥65 vs. 92% <65, p=0.028). **Conclusions:** We identified 7 SC whose prevalence were influenced by age, gender, race, PS, or primary cancer site. This supports the clinical relevance of the cluster concept in palliative and supportive care. Demographic characteristics may warrant different clinical approaches to patient care. Identification of these differences may help develop more effective cancer treatment and management strategies.

9639 General Poster Session (Board #40C), Mon, 1:15 PM-5:00 PM

Electro-acupuncture for joint pain related to aromatase inhibitors among breast cancer survivors: A randomized placebo-controlled trial.

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Background: Arthralgia is a common and debilitating symptom in a significant proportion of breast cancer patients receiving aromatase inhibitors (AIs). **Methods:** We conducted a randomized, placebo-controlled trial of electro-acupuncture compared to waitlist control (WLC) and sham acupuncture in postmenopausal women with breast cancer who self-attributed their arthralgia to taking AIs. Acupuncturists delivered ten treatments of tailored acupuncture with 2 Hz electro-stimulation via a TENS unit. Sham acupuncture used non-penetrating Streitberger needles at non-traditional acupuncture points and lacked electro-stimulation. The primary endpoint was pain severity measured by the Brief Pain Inventory (BPI) between electro-acupuncture and WLC at Week 8; durability of response at Week 12 and comparison of electro to sham acupuncture were secondary aims. **Results:** Sixty-seven patients were randomized to the three arms. The mean reduction in BPI pain severity was significantly greater in the electro-acupuncture group than WLC group at both Week 8 (-2.2 vs. -0.2 $p=0.0004$) and Week 12 (-2.4 vs. -0.2, $p<0.0001$). The BPI pain-related interference also improved significantly in the electro-acupuncture group compared to WLC group at Weeks 8 (-2.0 vs. +0.2, $p=0.0006$) and 12 (-2.1 vs. -0.1, $p=0.0034$). Sham acupuncture reduced pain severity (-2.3) and pain-related interference (-1.5) at Week 8 similar to electro-acupuncture ($p=$ non-significant); however, the effect of sham acupuncture appeared to decrease at Week 12 for pain severity (-1.7) and pain-related inference (-1.3). **Conclusions:** Electro-acupuncture significantly improved AI-related arthralgia over "usual care" with clinically important and durable changes in symptoms. Treatment effects were similar between the electro and sham groups at Week 8, suggesting that a large component of acupuncture effect is mediated through the process of acupuncture delivery rather than the specificity of needle placement or needle penetration of skin. Research is needed to evaluate the long term effects of electro-acupuncture to improve AI-related arthralgia. Clinical trial information: NCT01013337.

9640 General Poster Session (Board #40D), Mon, 1:15 PM-5:00 PM

Incidence of osteonecrosis of the jaw in patients receiving denosumab or zoledronic acid for bone metastases from solid tumors or multiple myeloma: Results from three phase III trials.

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Background: In patients with metastatic bone disease (MBD), the use of antiresorptive therapies such as denosumab or zoledronic acid (ZA) reduces the risk of skeletal-related events but is associated with a small risk of osteonecrosis of the jaw (ONJ). Two phase 3 clinical trials of denosumab vs ZA in patients with MBD showed overall cumulative ONJ incidences to be 3.8% to 4.7% at approximately 5 years of treatment with denosumab across blinded and open-label extension phases. ONJ associated with ZA was only assessed in the blinded treatment phases, as patients switched to denosumab once superior efficacy was demonstrated. Here we report incidence rates of ONJ by first vs subsequent years of exposure for the blinded treatment phase of all three phase III clinical trials. **Methods:** Patients (n = 5,677) with bone metastases from solid tumors or multiple myeloma received either SC denosumab 120 mg and IV placebo or IV ZA 4 mg (adjusted for renal function) and SC placebo Q4W in the double-blinded treatment phase of each trial. Patients who received ≥ 1 active dose during the blinded treatment phase were included in this analysis for up to 44.5 months of denosumab exposure and 41.3 months of ZA exposure. Oral assessments were conducted at baseline and every 6 months thereafter by the investigator or other qualified examiner. Potential ONJ events were independently adjudicated by a blinded committee of experts. **Results:** The median (Q1, Q3) time to onset of ONJ was similar in both treatment groups (15.6 [9.5, 20.0] months for denosumab, 15.8 [11.0, 23.6] months for ZA). Cumulative incidence rates of ONJ during the blinded treatment phases for all three trials by patient-years of follow-up are shown below (Table). **Conclusions:** The incidence of ONJ increased with longer duration of antiresorptive exposure. There were no significant differences between treatment groups in ONJ incidence at year 1 or beyond. Clinical trial information: NCT00321464; NCT00330759; NCT00321620.

N, (incidence rate)*	0–1 year	P value	> 1 year	P value	Total	P value
Denosumab (n = 2,841)	22 (1.0)	0.37	41 (3.3)	0.11	63 (1.9)	0.08
Zoledronic acid (n = 2,836)	16 (0.8)		27 (2.2)		44 (1.3)	

* Rate per 100 patient-years of follow-up.

9641 General Poster Session (Board #40E), Mon, 1:15 PM-5:00 PM

Differential protein expression profile in skin biopsies from patients with hand-foot syndrome who have benefited from topical heparin treatment.

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Background: Hand-foot syndrome (HFS) is a dose-limiting toxicity of capecitabine (CAP), leading to significant morbidity in patients receiving this agent. Interruption or dose reduction of CAP is the only effective strategy. The purpose of our study is to define the pathophysiology and risk factors predictors of CAP-induced HFS. Previously, we had conducted a clinical trial in patients who developed HFS secondary to CAP. Topical heparin was administered in palms and soles of patients four times/day for three weeks (w), evidencing clinical improvement in 99% of patients. **Methods:** Paired-skin biopsies of palms at baseline and after 3w from 21 patients were obtained. An iTRAQ (isobaric tags for relative and absolute quantitation) proteomics approach was performed to identify molecular pathways associated with HFS reversion. **Results:** Comparative analysis between baseline and post-treatment skin samples identified 1876 proteins with high confidence ($> 99\%$). The involvement of the identified proteins in biological networks served to characterize molecular pathways associated with HFS reversion. **Conclusions:** Several proteins identified in this study have a close relationship with keratinocyte terminal differentiation and keratinocyte intercellular strength. Also, we describe differential expression among proteins involved in inflammatory processes, skin immunity and cell death. In summary, our study not only served to uncover molecular mechanisms associated with HFS reversion, but also to reveal the biomarker role of several proteins in this syndrome.

Upregulated protein	Downregulated protein
Nicotinamide N-methyltransferase	Keratinocyte differentiation-associated protein
Thy-1 membrane glycoprotein	CD9 antigen
SPARC	Keratin, type II cytoskeletal 1
Serpin H1	Keratin, type I cytoskeletal 10
Dermcidin	Serpin B3
Protein S100	Interleukin-36 gamma
Collagen alpha	Keratin, type II cytoskeletal 2 epidermal
Periostin	Serpin B12
Cytochrome b-c1 complex subunit 6, mitochondrial	Filaggrin
Stathmin	Tenascin-X
Caldesmon	Plasminogen activator inhibitor 2

9642 General Poster Session (Board #40F), Mon, 1:15 PM-5:00 PM

High-dose Asian ginseng (Panax ginseng) for cancer-related fatigue (CRF): A preliminary report.

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Background: CRF is a common and severe symptom in patients with cancer. There are limited useful treatments available. The objective of this preliminary study was to assess the safety of high-dose Panax ginseng (PG) on CRF. **Methods:** In this prospective open labeled study, 30 patients with cancer and fatigue ≥4/10 (0=no fatigue, 10=worst possible fatigue) received high dose PG 800mg orally daily for 29 days. Functional Assessment of Cancer Therapy-fatigue (FACIT-F), Edmonton Symptom Assessment System (ESAS) (0=best, 10=worst), and Hospital Anxiety Depression Scale (HADS) were assessed at baseline and day 29. **Results:** 24/30 (80%) patients were evaluable. The median age was 58yrs, 50% were females, 84% were white. The most common cancer type was genitourinary cancer (31%). Table shows the changes in fatigue, anxiety, depression scores. ESAS well-being improved from 4.67 (2.04) to 3.50 (2.34) (p=0.01374), appetite improved from 4.29 (2.79) to 2.96 (2.46) (p=0.0097). 21/24 (87%) patients had an improved FACIT-F fatigue score by day 15. Global Symptom Evaluation score of PG for fatigue was better in 15/24 patients (63%) with median improvement of 5 (1=hardly any better, 7= very great deal better). No ≥ grade 3 adverse events related to the study drug were reported. **Conclusions:** 1) PG is safe and rapidly improved ESAS fatigue and FACIT-F fatigue scores; 2) Overall quality of life (FACIT-General), appetite, and sleep at night also improved. Randomized controlled trials of PG are justified in CRF. Clinical trial information: NCT01375114.

Symptom	Baseline, mean (SD)	Day 29, mean (SD)	P value
Fatigue (ESAS)	6.2 (1.82)	3.75 (1.62)	<0.0001
Drowsiness (ESAS)	3.21 (2.21)	2.42 (2.28)	0.0948
Sleep at night (ESAS)	5.38 (2.37)	3.54 (2.02)	0.0012
Depression (ESAS)	1.29 (2.22)	1.29 (2.03)	0.999
Depression (HADS)	6.50 (3.34)	6.09 (3.86)	0.6088
FACIT-F, fatigue subscale (primary outcome)	24.58 (8.9)	32.90 (11.01)	<0.0001
FACIT-G	71.42 (17.54)	77.29 (17.79)	0.0104
FACIT-F physical	17 (5.82)	19 (4.79)	0.002

9643 General Poster Session (Board #40G), Mon, 1:15 PM-5:00 PM

The efficacy of subclinical lymphedema detection in high-risk breast cancer survivors.

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Background: Lymphedema (LE) is associated with profound functional, psychosocial and medical consequences. Early intervention may decrease morbidity from LE. Bioimpedance spectroscopy (BIS) allows subclinical diagnosis by detecting subtle differences in extracellular fluid volume between the limbs. In our lymphedema program, we prospectively monitor BIS in patients (pts) undergoing axillary lymph node dissection (ALND). The aim of this study is to investigate whether early diagnosis of LE after ALND using BIS can allow early intervention. **Methods:** BIS in the "Pre-Operative Group," measurements using L-Dex U400 were obtained pre-operatively (n=123) and at 3-6 month intervals thereafter. In the "Follow-up Group" pts who had ALND previously (n=89) had baseline measurements and monitoring at the same intervals. Age, BMI, dominant hand use, side of ALND, type of breast surgery, receipt of radiation therapy, and number of LN removed were recorded. L-Dex values $>$ 10 units or increase $>$ 10 units above the initial measurement was treated with LE education, an over-the-counter compression sleeve, less intensive physical therapy sessions and daily exercise. **Results:** The mean age was 58 (27-90). The mean BMI was 28.5 (17.1-65.7)kg/m^2. ALND was on the side of the dominant hand in 56% of pts (n=119). The mean number of LNs removed was 16 (5-49). The majority of pts underwent mastectomy (59%; n=126), 73% (n=55) received RT, and 80% (n=191) received neo- or adjuvant chemotherapy. 87 pts (41%) were followed for more than 1 year from initial measurement. Since the monitoring began, 18% (n=22) in the Preoperative Group and 23% (n=20) in the Follow-up group were diagnosed with subclinical LE and received early intervention. 41 pts (97.6%) remain stable with no worsening of LE 1 yr after diagnosis. One pt advanced to stage 2 LE but declined further monitoring at 6 mo. **Conclusions:** Subclinical detection of LE with BIS and timely intervention reduced the incidence of late-stage LE among women undergoing ALND to $<$3% compared with historical incidence of $>$25%. Periodic monitoring of women at high risk for LE can minimize costly and intensive LE treatment such as custom made sleeves, pump and surgery while anticipating elimination of more advanced LE.

9644 General Poster Session (Board #40H), Mon, 1:15 PM-5:00 PM

A pilot intervention addressing sexual dysfunction after risk-reducing oophorectomy.

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Background: Women at high risk for ovarian cancer due to *BRCA1 or BRCA2* mutation or family history are recommended to undergo prophylactic bilateral salpingo-oophorectomy (PBSO) after age 35 or completion of childbearing. This potentially life-saving surgery leads to premature menopause, frequently resulting in profound sexual dysfunction. We developed and piloted the first psychoeducational intervention for managing sexual dysfunction in young women after PBSO. **Methods:** This single-arm multi-modal pilot intervention study included a single half day session with educational modules about sexual health education, relaxation training, and cognitive behavioral therapy (CBT) skills to manage symptoms, followed by tailored telephone counseling. Self-report assessments, including the 19-item Female Sexual Function Index (FSFI) and a 10-item measure of sexual knowledge after PBSO were completed at baseline and two months post-intervention. Eligible women had PBSO for risk-reduction, current age $\leq$ 49, and endorsed at least one symptom of sexual dysfunction. Study endpoints include feasibility and effectiveness. **Results:** 36 women enrolled and completed pre- and post- assessments. Median age was 44 years (range 36-49) and median time since PBSO was 3.2 years (range 0.75-12.3). FSFI scores improved significantly from baseline to post-intervention for the desire ($p = 0.003$), arousal ($p = 0.001$), and satisfaction ($p = 0.031$) domains, as well as on the full scale score ($p = 0.005$). In addition, 60% of participants demonstrated improved knowledge scores about managing sexual dysfunction after PBSO following the intervention. **Conclusions:** The current intervention builds upon recent advances in CBT and sexual health education to address this much-neglected problem after PBSO. Results from this promising pilot intervention provide compelling preliminary data to move toward conducting a randomized clinical trial. Reducing post-PBSO distress, a valuable goal in its own right, may ultimately improve uptake of this potentially life-saving procedure in a high-risk population, as loss of sexual functioning is one of the reasons mutation carriers give for rejecting surgical risk-reduction.

9645 General Poster Session (Board #41A), Mon, 1:15 PM-5:00 PM

Hepatotoxicity with chemotherapy in patients infected with hepatitis B virus.

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Background: Patients with chronic hepatitis B virus infection (HBV) are at risk for hepatotoxicity (HT) from viral reactivation during chemotherapy courses (TC). This can be minimized with antiviral prophylaxis (AV). Screening for HBV before TC remains controversial. **Methods:** A retrospective observational data only study was conducted at a Northern California integrated health care delivery system examining patients undergoing TC between 2000 and 2010. Patients were categorized as HBV positive (HBV+) if they had a positive HBsAg, HBeAg, or HBV DNA any time before and 1 year post TC. Grade 3 and 4 HT was determined using the National Cancer Institute Common Toxicity Criteria, with adaptation for those who had baseline abnormal liver function tests. We excluded patients with HIV, co-infection with both HBV and hepatitis C, and HBsAb of unclear provenance. Two control groups (CTRL1 and CTRL2) were established that had tested negative for HBV and HCV 1996 through 1 year after the last TC: CTRL1 tested negative for both before TC initiation (index TC); CTRL2 tested negative for one pre and the other post index TC or both at any time after index TC. AV prophylaxis (AVP+) was defined as anti-HBV medication given before HT; the remainder were AVP-, including those given AV after HT. Electronic medical record review was conducted on all HBV+ patients. **Results:** We identified 9,279 patients who received 15,960 TC; 57.8% were female with a mean age of 57.8 (±14.4) at TC initiation. 464 TC were given to 289 HBV+ patients; 22.8% had HT, with 7 deaths from HT, all AVP-. The rate of HT in the controls was 9.9% in CTRL1 (34/343), 12.6% in CTRL 2 (1907/15,153). **Conclusions**: These findings support the recommendation that all patients planning to receive TC should be screened for HBV. Those found positive should receive AV prophylaxis during therapy.

Rates of HT in all chemotherapy courses and by cancer types.

	AVP-	AVP+	CTRL1	CTRL2	AVP- vs AVP+	AVP- vs CTRL1	AVP- vs CTRL2
All	27.1%	14.9%	9.9%	12.6%	p=.02	p<.0001	p<.0001
Excluding cancer of liver or bile ducts	26.4%	14.2%	7.7%	12.2%	p=.02	p<.0001	p<.0001
Excluding non-Hodgkin lymphoma	22.6%	15.4%	9.7%	13.3%	p=.28	p<.0001	p<.0001
Non-Hodgkin lymphoma	69%	12%	12.1%	7.6%	p<.0001	p<.0001	p<.0001

9646 General Poster Session (Board #41B), Mon, 1:15 PM-5:00 PM

Chemotherapy-induced peripheral neuropathy in multiple myeloma patients undergoing maintenance therapy.

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Background: After 3-months autologous stem cell transplant (AuSCT), a percentage of multiple myeloma (MM) patients during maintenance therapy continue to experience a complex of symptoms related to peripheral neuropathy. This longitudinal study examined these self-reported neuropathy symptoms and identified circulating inflammatory markers associated with high neuropathy-related symptoms. **Methods:** MM patients (N=51) rated symptom severity on 0-10 scale via the M. D. Anderson symptom Inventory (MDASI) weekly from 3 to 9 months post AuSCT during maintenance therapy. Patient also rated pain on hand or foot in routine clinic visit. A panel of pro- and anti-inflammatory cytokines, receptors, chemokines was evaluated on serum samples by Luminex. Mixed effect analysis was used to describe the changes on cytokines and symptom outcomes across time. Trajectory analysis identified patients that persistently reported higher or lower symptom severity overtime. **Results:** During the study period, there was no significant reduction on pain in general or on hand/foot, or change in neuropathic symptoms such as numbness/tingling and muscle weakness. Among a third (33%) of patients who was consistently in high pain (mean 5.5), MIP-1a (p=.001) and MCP-1 (p=.032) showed significant decrease. Approximately 40 % had persistently high numbness/tingling (mean 5.2) across the observation period. Compared to low symptom group patients, this high numbness group had significantly higher IL-6 (p=.019) and TNF-alpha (p=.006). High muscle weakness (mean 3.1) was for 69% of the sample. This group had significantly higher CRP (p=.005) and TNF-alpha (p=.001). **Conclusions:** This is the first longitudinal study that tracked persistent neuropathy-related symptoms for MM patients post AuSCT. Approximately one third reported painful neuropathy, either from induction therapy or ongoing maintenance therapy. High levels of these neuropathy symptoms were associated with higher levels of specific pro-inflammatory markers. This study provided rationale for examining the effectiveness of anti-inflammation as mechanism driven intervention on peripheral neuropathy in this cohort of MM patients.

TPS9647 General Poster Session (Board #41C), Mon, 1:15 PM-5:00 PM

Cognitive function in breast cancer and lymphoma patients receiving chemotherapy: An ongoing nationwide University of Rochester Cancer Center (URCC) Community Clinical Oncology Program (CCOP) observational study with 1,200 patients and controls.

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Background: Chemotherapy-related cognitive impairment (CRCI) is a major concern for up to 75% of cancer patients that can negatively affect quality of life. Studies which have objectively assessed cognitive function (CF) in patients suggest that chemotherapy is associated with declines in multiple domains. A large, prospective longitudinal study with age- and gender- paired healthy controls is needed to confirm and expand these findings, to identify etiological mechanisms of CRCI, and to identify the best assessment methods for detecting CRCI. **Methods:** We are conducting a nationwide prospective observational study (N=1,200), conducted through the URCC CCOP Research Base and 23 CCOPs. The primary aim is to test the hypothesis that breast cancer and lymphoma patients receiving chemotherapy will have greater impairments in CRCI over time than a control comparison group. Breast cancer (stage I-IIIc) and lymphoma patients (intermediate/high grade disease) meet the following eligibility: 1) chemotherapy naïve, 2) ≥21 years of age, 3) no CNS disease, 4) scheduled to receive a standard course of chemotherapy, and 5) no concurrent radiation. Healthy control participants meet eligibility criteria 1-3 and are the same gender and age as paired patients. CF is assessed at pre-chemotherapy (Assess. 1), post-chemotherapy (Assess. 2), and 6 months post-chemotherapy in patients; their paired controls are assessed at the same time intervals. CF is measured via: 1) Computer-based CANTAB neuropsychological (NP) battery (assessing memory (primary aim), verbal memory, sustained attention, processing speed, and executive function (secondary aims)), 2) paper-based objective NP assessment (secondary aims), 3) phone-based objective NP assessment (tertiary aims), and 4) Single item, patient-reported CF (tertiary aims). Blood is collected at Assess. 1 and 2 to explore inflammatory and genetic mechanisms. 807 participants have been enrolled in 21 months. Funding: U10CA037420-26 Supp. MCJ; U10CA037420, GRM; & URCC/RPCI Grant, MCJ & CBA. Clinical trial information: NCT01382082.

TPS9648 General Poster Session (Board #41D), Mon, 1:15 PM-5:00 PM

Metabolic syndrome and breast cancer: Effects of a 16-week combined exercise intervention.

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Background: Current evidence suggests that breast cancer treatments such as chemotherapy lead to excessive weight gain, fatigue, physical inactivity, and negative alterations in components of metabolic syndrome (MetS). MetS is associated with increased risk of cancer recurrence, cardiovascular diseases and type 2 diabetes, and is defined by visceral adiposity, insulin resistance, hyperglycemia, hyperinsulinemia, low serum high-density lipoprotein cholesterol, and hypertension. MetS is highly prevalent and present in 25% of American and European adults and higher in minorities. Given that chemotherapy for breast cancer induces many of the components of MetS, an effort to offset these consequences of cancer therapy using exercise/lifestyle intervention could improve breast cancer, cardiovascular and endocrine outcomes. **Methods:** Our study seeks to determine whether a 16-week exercise intervention induces changes in prognostic components of MetS (waist circumference, blood pressure, serum levels of glucose, insulin, lipids, C-reactive protein and HbA1c) among breast cancer survivors if initiated within 3 months of completion of chemotherapy or radiation therapy. We are currently recruiting women diagnosed with Stage I-III breast cancer from the USC Norris Comprehensive Cancer Center and Los Angeles County Hospital, which cares for a high proportion of minority/underserved patients. Participants are randomized to either the Control (usual care) or the Exercise group. The Exercise group participates in aerobic and resistance exercise sessions 3 times a week for 16 weeks supervised by an exercise specialist at the USC Clinical Exercise Research Center. At baseline and following the study period, all participants are tested for MetS components, muscle strength, body composition, bone density, cardiorespiratory fitness, quality of life, fatigue and shoulder function. We will recruit an additional 85 patients (at present time n=15) over the next 3 years. It is expected that this intervention will improve components of MetS and physical fitness in breast cancer survivors when compared to the Control group, thus defining intervention and biomarker variables for more definitive trials. Clinical trial information: NCT01140282.

TPS9649 **General Poster Session (Board #41E), Mon, 1:15 PM-5:00 PM**

Phase III clinical trials with anamorelin HCl, a novel oral treatment for NSCLC cachexia.

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Background: Cancer anorexia/cachexia is a debilitating and life-threatening complication of an underlying malignancy that may develop in up to 80% of terminally ill cancer patients. Cancer cachexia has a multifactorial pathogenesis and is manifested by accelerated losses of skeletal muscle and disproportionate losses of lean body mass (LBM). Anamorelin HCl is a ghrelin receptor agonist that has demonstrated significant increases in LBM, physical strength, and body weight in Phase II trials in patients with cancer cachexia. Through its ghrelin and growth hormone secretagogue activity, it displays both anabolic and appetite stimulating properties – two aspects vital to treating cancer anorexia/cachexia. **Methods:** HT-ANAM-301 (NCT01387269) and HT-ANAM-302 (NCT01387282), also known as ROMANA 1 and ROMANA 2, are double-blind, placebo-controlled, randomized (2:1 anamorelin HCl vs. placebo) Phase III trials in patients with non-small cell lung cancer (NSCLC) cachexia. Eligible patients must have unresectable Stage III or IV NSCLC and cachexia (weight loss of $\geq$5% body weight within prior 6 months or BMI $<$20 kg/m^2). Patients receive once daily oral doses of anamorelin HCl (100 mg) or placebo for 12 weeks. Co-primary endpoints are the change from baseline in LBM as measured by DXA and in muscle strength as measured by handgrip strength. Secondary endpoints include change in body weight, overall survival, and quality of life (FACIT-F and FAACT questionnaires). For HT-ANAM-301 only, blood samples are collected at Week 6 for population pharmacokinetics. After 12 weeks of treatment, patients may continue in a separate 12-week safety extension study (HT-ANAM-303 [ROMANA 3] NCT01395914). At their last meeting (August 2012), the Independent Data Monitoring Committee suggested no safety issue and allowed the trials to continue as planned. Clinical trial information: NCT01387269, NCT01387282, NCT01395914.

TPS9650 General Poster Session (Board #41F), Mon, 1:15 PM-5:00 PM

Multimodal therapy for the treatment of fatigue in patients with prostate cancer receiving androgen deprivation therapy and radiation.

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Background: Cancer-related fatigue (CRF) is the most frequently reported symptom associated with cancer and its treatment. Unfortunately, there are limited treatment options to alleviate this distressing symptom. Preliminary data suggest that the combination of exercise, cognitive behavioral therapy (CBT), and methylphenidate (that is, multimodality therapy [MMT]) can play an important role in reducing CRF. The project's objective is to explore the effects and safety of this MMT on CRF in prostate cancer patients scheduled to receive radiotherapy with androgen deprivation therapy. We hypothesizethat the MMT is capable of reducing CRF as measured by the FACIT-F subscale in prostate cancer patients scheduled to receive radiotherapy. Specific Aims:(1) Our primary aim is to obtain preliminary estimates of the effects of various treatments (exercise, CBT, and methylphenidate) and their combinations in reducing CRF in prostate cancer patients receiving radiotherapy, as measured by the change in patients' FACIT-F subscale scores taken at baseline and on day 57 and the secondary objective is to determine the effects of the treatments and their combinations on anxiety and depressed mood (both measured by the Hospital Anxiety Depression Scale [HADS]); on physical activity and function (measured by an accelerometer and a handgrip dynamometer, respectively); on levels of inflammatory cytokines (IL-1β, IL-6, TNF-α, and IL-10) in serum and induced monocytes, before and after treatment **Methods:** For this study, we will use a randomized factorial design to assess 3 treatments (exercise, CBT, and methylphenidate) and their placebos in 8 replications. A total of 32 patients will receive each primary treatment and 32 will not. Patients will be studied for a 57-day period, during which they are scheduled undergo daily radiation treatments with androgen deprivation therapy. Fatigue, anxiety and depressed mood, and inflammatory cytokines will be determined at baseline and at 3 subsequent post-intervention assessments. After successful initiation so far 19/64 patients were enrolled. Accrual continues. Clinical trial information: NCT01410942.

TPS9651 General Poster Session (Board #41G), Mon, 1:15 PM-5:00 PM

Exercise for cancer-related fatigue and putative functional, inflammatory, and metabolic mechanisms in patients receiving chemotherapy: A URCC CCOP research base phase III RCT.

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Background: Up to 100% of cancer patients report cancer-related fatigue (CRF) during chemotherapy which co-occurs with impaired cardiopulmonary (CPF) and neuromuscular function (NMF), chronically up-regulated inflammatory responses, and low metabolic energy expenditure. CRF interferes with completion of treatment, increases cancer morbidity and mortality, and impairs quality of life (QOL). Exercise is one of the most promising treatments available for CRF, but no large multicenter phase III RCTs have confirmed these findings and little is known about the mechanisms through which exercise may impact CRF. **Methods:** We are conducting a nationwide multicenter phase III RCT (N=692) through the URCC CCOP Research Base with 23 CCOP affiliates. The primary aim is to determine if exercise will significantly improve CRF, and secondarily, CPF, NMF, inflammation, energy expenditure, and QOL compared to standard care in cancer patients receiving chemotherapy. The exercise intervention is our standardized, individually-tailored, home-based walking and progressive resistance program, "Exercise for Cancer Patients" (EXCAP, 7 days/wk, 6wks). To be eligible, patients must: 1) have a confirmed diagnosis of cancer with no leukemia or metastasis, 2) be chemotherapy naïve and scheduled to start, 3) not be receiving concurrent radiation, 4) have a KPS of >70, 5) be ≥ 21 years of age, 6) have no contraindications to exercise or functional testing, and 7) not be currently exercising. CRF and all secondary outcomes are assessed at baseline (pre-chemotherapy), 3 weeks (mid-intervention), and 6 weeks (post-intervention). Measures include: 1) CRF-Brief Fatigue Inventory, 2) CPF-6-minute walk test, 3) NMF-handgrip dynamometry, 4) inflammation-serum ELISA levels, 5) energy expenditure-actigraphy, and 6) quality of life-Functional Assessment of Chronic Illness Therapy. The DSMC reviewed the trial in October of 2012 and suggested it continue as planned. 532 participants have been enrolled in 36 months. Funding: NCI U10CA037420, U10CA37402-28, K07CA120025, K07CA132916, 1R25CA102618, ACS MRSG1300101CCE. Clinical trial information: NCT00924651.