12000 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Multisite randomized trial of integrated palliative and oncology care for patients with acute myeloid leukemia (AML). *First Author: Areej El-Jawahri, Massachusetts General Hospital, Boston, MA*

Background: Patients with AML receiving intensive chemotherapy experience substantial decline in their quality of life (QOL) and mood during their hospitalization for induction chemotherapy and often receive aggressive care at the end of life (EOL). We sought to examine the effect of integrated palliative and oncology care on QOL, mood, post-traumatic stress (PTSD) symptoms, and EOL outcomes in patients with AML. **Methods:** We conducted a multi-site randomized trial of integrated palliative and oncology care (n = 86) versus usual oncology care (n = 74) for patients with AML undergoing intensive chemotherapy. Patients assigned to the intervention were seen by palliative care clinicians at least twice per week during their hospitalization for induction chemotherapy and all subsequent hospitalizations. Patients completed the Functional Assessment of Cancer Therapy-Leukemia, the Hospital Anxiety and Depression Scale, and the PTSD Checklist to assess their QOL, mood, and PTSD symptoms at baseline, weeks 2, 4, 12, and 24. The primary endpoint was QOL at week-2. We used analysis of covariance and mixed linear effect models, controlling for baseline scores, to assess the effect of the intervention on patient-reported outcomes. **Results:** Between 1/2017 and 7/2019, we enrolled 160/235 (68.1%) of eligible patients. Compared to those receiving usual care, intervention patients reported better QOL (107.59 vs. 116.45, P = 0.039) and lower depression (7.20 vs. 5.68, P = 0.021), anxiety (5.94 vs. 4.53, P = 0.018), and PTSD symptoms (31.69 vs. 27.79, P = 0.009) at week 2. Intervention effects were sustained up to week 24 for QOL (B = 2.35, P = 0.048), depression (B = -0.42, P = 0.039), anxiety (B = -0.38, P = 0.042), and PTSD symptoms (B = -1.43, P = 0.002). Among deceased participants, those receiving the intervention were more likely to report discussing their EOL care preferences with their clinicians (75.0% vs. 40.0%, P = 0.009) and less likely to receive chemotherapy in the last 30 days of life (34.9% vs. 65.9%, P = 0.008). There was no difference in hospice utilization or hospitalization at the EOL. **Conclusions:** The integrated palliative and oncology care model for patients with AML receiving intensive chemotherapy led to substantial improvements in patients' QOL, psychological distress, and EOL care. Thus, palliative care should be considered a new standard of care for patients with AML. Clinical trial information: NCT02975869. Research Sponsor: Lymphoma and Leukemia Society.

12001 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

A randomized trial of a palliative care intervention for patients on phase I studies. *First Author: Thomas J. Smith, Johns Hopkins University School of Medicine, Baltimore, MD*

Background: The purpose of this study was to test a Palliative Care Intervention for patients with solid tumors enrolled in phase I therapeutic trials. **Methods:** This randomized trial compared patients accrued to phase I Clinical Trials in groups of Usual Care compared to a Palliative Care Intervention (PCI) in two comprehensive cancer centers. The PCI included assessment of quality of life (QOL) and symptoms, an interdisciplinary meeting to discuss the care plan, including goals of care, and two nurse-delivered teaching sessions. Subjects (n=479) were followed for 24 weeks, with 12 weeks as the primary outcome point. **Results:** Outcomes revealed that relative to Usual Care, PCI subjects showed less Psychological Distress (1.9 in Intervention and 1.2 in Control pts, p=0.03) and a trend toward improved QOL (3.7 versus 1.6, p=0.07), with differences between sites. We observed high rates of symptom-management admissions (41.3%) and low rates of Advance Directive completion (39%), and use of supportive care services including hospice (30.7%, for only1.2 months duration), despite a median survival for all patients in both groups of 10.1 months from initiating a phase 1 study until death. Patient satisfaction with oncology care was already high at baseline, and we did not see clinically significant changes in those scores by week 12. **Conclusions:** Palliative care interventions can improve QOL outcomes and distress for patients participating in phase 1 trials. Greater integration of PC is needed to provide quality care to these patients and to support transitions from treatment to supportive care, especially at the end of life. Clinical trial information: NCT01828775. Research Sponsor: U.S. National Institutes of Health.

12002 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Effect of integrating machine learning mortality estimates with behavioral nudges to increase serious illness conversions among patients with cancer: A stepped-wedge cluster randomized trial. *First Author: Chris Manz, University of Pennsylvania, Philadelphia, PA*

Background: Most patients with cancer die without a documented serious illness conversation (SIC) about prognosis and goals. Interventions that increase SICs between oncology clinicians and patients may improve goal-concordant care and end-of-life outcomes. **Methods:** In this stepped-wedge cluster randomized trial (NCT03984773), we tested the effect of an intervention delivering machine learning-based mortality estimates with behavioral nudges to oncologists to increase SICs among patients with cancer. The clinician-focused intervention consisted of 1) weekly emails providing individual SIC performance feedback (number of SICs in the past month) and peer comparisons; 2) a list of patients scheduled for the next week with a ≥10% predicted risk of 6 month mortality by a validated machine learning prognostic algorithm, and 3) automated opt-out text prompts on the patient's appointment day to consider an SIC. Eight medical oncology clinics were randomized to receive the intervention in a stepped-wedge fashion every four weeks for a total of 16 weeks. Medical oncology clinicians were included if they were trained to use the SIC Guide (Ariadne Labs, Boston MA). Patients were included if they had an outpatient encounter with an eligible clinician between June 17 and November 1, 2019. The primary outcome was the percent of patient encounters with a documented SIC. Intention to treat analyses adjusted for clinic and wedge fixed effects and clustered at the oncologist level. **Results:** The sample consisted of 78 clinicians and 14,607 patients. The mean age of patients was 61.7 years, 55.7% were female, 70.4% were white, and 19.6% were black. The percent of patient encounters with an SIC was 1.2% (106/8536) during the pre-intervention period and 4.0% (401/10,152) during the intervention period. In intention to treat adjusted analyses, the intervention led to a significant increase in SICs (adjusted odds ratio, 3.7; 95% CI, 2.5 to 5.4, *P* value < 0.0001). **Conclusions:** An intervention consisting of machine learning mortality estimates and behavioral nudges to oncology clinicians increased SICs by three-fold over 16 weeks, a significant difference.This is one of the first studies evaluating a machine learning-based behavioral intervention to improve serious illness communication in oncology. Secondary analyses (completed April 2020) will clarify whether this intervention leads to a sustained increase in SIC rates and improves goal-concordant care and end-of-life outcomes. Clinical trial information: NCT03984773. Research Sponsor: Penn Center for Precision Medicine Accelerator Grant.

12003 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

ACUFOCIN: Randomized clinical trial of ACUpuncture plus standard care versus standard care alone FOr Chemotherapy Induced peripheral Neuropathy (CIPN). *First Author: Andrew M. Wardley, The Christie NHS Foundation Trust, Manchester Academic Health Science Centre & Division of Cancer Sciences, School of Medical Sciences, Faculty of Biology Medicine & Health, University of Manchester, Manchester, United Kingdom*

Background: CIPN is a dose limiting toxicity, and a major clinical challenge. This study aims to explore the use of acupuncture with standard care (Acu +SC) against SC alone, to reduce symptoms of CIPN. **Methods:** A phase II, randomised, parallel group design was used to investigate the effectiveness of a 10 week course of acupuncture to manage CIPN. Patients experiencing CIPN ≥ Grade II (CTCAE v4.03), recording a 'Most Troublesome' CIPN symptom score of ≥ 3 using the "Measure Yourself Medical Outcome Profile" (MYMOP 2), were randomised (1:1) to either Acu+SC or SC alone. The primary end-point was a ≥ 2 point improvement in MYMOP2 score at week 10 (logistic regression adjusted for stratification factors and baseline MYMOP2 score). The necessary sample size was 100 patients;120 were randomised to allow for attrition (90% power; 10% one-sided alpha), for a hypothesised improvement in success proportions from 30% to 55%. **Results:** 120 patients were randomised to ACUFOCIN; diagnosis: breast 61 (51%), multiple myeloma 9 (8%), GI 48 (40%), gynaecological 2 (2%). MYMOP2 score for most troubling CIPN symptom at baseline: 3-4 33 (28%), 5-6 87 (73%). CTCAE CIPN at baseline; grade II 103 (86%), grade III 17 (14%). Baseline characteristics were balanced between arms. Primary outcome data were available for 108 participants with 36/54 (67%) successes in the Acu+SC arm compared to 18/55 (33%) in the SC arm. Adjusted success odds ratio was 4.3 (95% CI 1.9-9.6; p < 0.001; Acu+SC vs SC). Additionally, 27/53 (51%) participants achieved a CIPN success (grade ≤ I) in the Acu+SC arm compared to 4/56 (7%) in the SC arm with adjusted odds ratio 13.1 (95% CI 4.1-41.7; p < 0.001; Acu+SC vs SC). Significant reduction in week 10 pain score; mean difference (SC+Acu – SC alone) -1.45 with 95% CI (-2.25, -0.65) after adjustment for week 1 pain, breast cancer diagnosis and treatment complete status. (note pain on a 0-10 scale). Significant increase in the EORTC QLQ-C30 summary score; mean difference (SC+Acu – SC alone) 9.51 with 95% CI (5.01, 14.02) after adjustment for the baseline score, breast cancer diagnosis and treatment complete status. (note summary score on a 0-100 scale). Significant effects seen at week 10 are also present at week 6. The week 6 effect estimates are consistently less than the week 10 effects (but not usually statistically significantly so). **Conclusions:** In this patient cohort, a 10 week course of acupuncture significantly improved symptoms of CIPN. These results support further investigation within a phase III trial. Clinical trial information: NCT02275403. Research Sponsor: National Institute for Health Research.

12004 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Effects of electroacupuncture and auricular acupuncture for chronic pain in cancer survivors: The PEACE randomized controlled trial. *First Author: Jun J. Mao, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: The national opioid crisis has created new challenges in oncology pain management and highlighted an urgent need for non-pharmacological treatments. We evaluated the comparative effectiveness of electro-acupuncture (EA) and auricular acupuncture (AA) versus usual care (UC) for chronic musculoskeletal pain in cancer survivors. **Methods:** We conducted a randomized controlled trial of cancer survivors experiencing moderate-severe musculoskeletal pain for at least 3 months. EA used a semi-individualized protocol involving electrical stimulation of needles placed in the body. AA used the standardized Battlefield Acupuncture protocol involving up to 10 needles placed in the ears. EA and AA groups received 10 weekly treatments, whereas participants in the UC group received standard care prescribed by their providers. The primary endpoint was average pain severity change measured by the Brief Pain Inventory at week 12 compared to baseline. Functional interference and quality of life were secondary outcomes. We analyzed longitudinal mixed-effects models based on intent-to-treat principles. **Results:** Among 360 participants, mean age (SD) was 62.1 (12.7) years, 251 (69.7%) were women, and 88 (24.4%) were non-white. Compared from baseline to week 12, EA significantly reduced pain severity by 1.9 points (95% Confidence Interval 1.5-2.3, $p < 0.001$), and AA significantly reduced pain severity by 1.6 points (1.1-2.0, $p < 0.001$). AA was non-inferior to EA at reducing pain severity ($p = 0.04$). Both EA and AA also significantly improved functional interference (both $p < 0.001$), physical health (both $p < 0.001$), and mental health ($p = 0.003$, $p < 0.001$) compared to UC. Adverse events (AEs) were mild in both groups; however, 16 (11.2%) in AA stopped treatment due to AEs (mostly ear discomfort) as compared to 1 in EA (0.7%), $p = 0.001$. **Conclusions:** Among cancer survivors with chronic musculoskeletal pain, both EA and AA effectively reduced pain and improved quality of life. AA was non-inferior to EA at reducing pain but associated with higher discontinuation rates. These results will guide implementation of acupuncture in oncology care to address the unmet pain management needs of cancer survivors in the era of the opioid epidemic. Clinical trial information: NCT02979574. Research Sponsor: Department of Defense, U.S. National Institutes of Health.

12005 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Effects of YOCAS yoga, cognitive behavioral therapy, and survivorship health education on insomnia: A URCC NCORP Research Base Phase III RCT in 740 cancer survivors. *First Author: Karen Michelle Mustian, University of Rochester Medical Center, Rochester, NY*

Background: Insomnia, a prevalent and troublesome side effect experienced by cancer survivors, significantly impairs recovery and survival. We conducted a nationwide, multicenter, phase III, blinded, randomized controlled trial testing whether 1) yoga is superior to survivorship health education (SHE) and 2) yoga is non-inferior to cognitive behavioral therapy for insomnia (CBT-I) for treating insomnia in survivors. **Methods:** The trial was conducted via the University of Rochester Cancer Center NCI Community Oncology Research Program (URCC NCORP) Research Base. Participants were cancer survivors between 2-60 months post adjuvant therapy, with insomnia, no metastatic disease, and no yoga participation during the previous 3 months. Survivors were randomized into 1) YOCAS yoga (2x/wk; 75 min/sess for 4 wks with pranayama, asana, and dhyana, N = 251), 2) CBT-I (1x/wk, 90 min/sess for 8 wks with sleep hygiene, stimulus control, sleep restriction, and cognitive therapy, N = 238), or 3) SHE (2x/wk; 75 min/sess for 4 wks with ASCO-recommended survivorship education, N = 251). Insomnia was assessed pre- and post-intervention via the Insomnia Severity Index. **Results:** 740 eligible cancer survivors were enrolled (93% female, mean age = 56 + 11, 75% breast cancer). ANCOVAs with baseline values as covariates revealed YOCAS is significantly better than SHE for treating insomnia at post-intervention (CS = change score; CS mean diff = -1.43, SE = 0.42, $p < 0.01$). Yoga participants demonstrated greater improvements in insomnia from pre- to post-intervention (CS = -3.61, SE = 0.30) compared to SHE participants (CS = -2.19, SE = 0.33, all $p < 0.01$). Intent-to-treat analyses of non-inferiority (non-inferiority margin set at 1.15 a priori) showed YOCAS is inferior to CBT-I (CS mean diff = 3.52, CI = 2.55 - 4.50, $p < 0.01$). However, analyses of non-inferiority using the optimal treatment effect in fully compliant survivors were inconclusive regarding whether YOCAS is non-inferior to CBT-I for treating insomnia (CS mean diff = 2.20, CI = 0.42 - 3.98, $p = 0.09$). Significantly more survivors withdrew from CBT-I and SHE due, in part, to disliking the interventions compared to YOCAS (30%, 25%, and 16%, respectively, $p < 0.01$). **Conclusions:** YOCAS yoga is better than SHE and results are inconclusive as to whether yoga is non-inferior to CBT-I for treating insomnia among survivors. Clinicians should consider prescribing YOCAS and CBT-I for survivors reporting insomnia. Funding: NCI UG1CA189961, R01CA181064, T32CA102618. Clinical trial information: NCT02613364. Research Sponsor: U.S. National Institutes of Health.

12006 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Neuroleptic rotation for refractory agitation in cancer patients with delirium in the acute palliative care unit: A double-blind randomized clinical trial. *First Author: David Hui, University of Texas MD Anderson Cancer Center, Houston, TX*

Background: Terminal agitation commonly occurs in the last days of life and is highly distressing. The role of neuroleptics is controversial and few studies have examined agitation as a primary outcome. We assessed the effect of 3 neuroleptic strategies on refractory agitation in cancer patients with terminal delirium. **Methods:** In this single-center, double-blind, double-dummy parallel group randomized trial, patients admitted to a palliative and supportive care unit with refractory agitation despite low dose haloperidol were randomized in a 1:1:1 ratio to (1) haloperidol dose escalation, (2) neuroleptic rotation to chlorpromazine, or (3) combined haloperidol and chlorpromazine. Intravenous medications at equivalent doses were scheduled every 4 h and every 1 h as needed until discharge. The primary outcome was change in Richmond Agitation Sedation Scale (RASS) from time 0 to 24 hours. With 15 patients per group and 13 measurements over time, we had 90% power to detect an effect size of 0.2 with alpha=2.5%. One way ANOVA was used to examine within group differences. We also compared among groups with the Wilcoxon rank sum test. **Results:** 68 patients were enrolled and 45 received the blinded study interventions. The median survival was 73 h (95% CI 49, 106 h). RASS decreased significantly within 30 minutes and remained low at 24 hours in the dose escalation group (mean RASS change between 0 and 24 h [95% CI]: -3.6 [-5, -2.2]) v. rotation group (-3.3 [-4.4, -2.2]) v. combination group (-3 [-4.6, -1.4]), with no difference among groups (P=0.71). A majority of patients were perceived to be more comfortable after treatment by blinded caregivers (escalation v. rotation v. combination: 62% v. 71% v. 60%; P=0.83) and bedside nurses (64% v. 75% v. 64%; P=0.82); however, the rotation group had significantly fewer breakthrough restlessness (escalation v. rotation v. combination: 73% v. 19% v. 50%; P=0.009), required fewer upward dose titration (escalation v. rotation v. combination: 27% v. 6% v. 50%; P=0.03) and required less rescue neuroleptics in the first 24 hours (haloperidol equivalent: 4 mg vs. 2 mg vs. 6 mg, P=0.09, trend only). Hypotension was more frequently observed with chlorpromazine. Overall survival did not differ (>0.99). **Conclusions:** Preliminary data from this study supported that all 3 strategies of neuroleptics reduced agitation and improved comfort in patients with terminal delirium; however, neuroleptic rotation provided better agitation control and confirmatory studies are needed. Clinical trial information: NCT03021486. Research Sponsor: U.S. National Institutes of Health.

12007 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

A phase III randomized, double-blind placebo controlled study of armodafinil (Nuvigil) to reduce cancer-related fatigue in patients with high-grade glioma (Alliance A221101). *First Author: Alyx B. Porter, Mayo Clinic, Phoenix, AZ*

Background: Up to 96% of patients with high grade glioma (HGG) report moderate to severe fatigue. Armodafinil, the R-enantiomer of modafinil, is a psychostimulant with low potential for abuse that has shown potential for improving severe fatigue in HGG patients. **Methods:** In this phase III double blinded placebo-controlled study, adults with HGG and moderate to severe fatigue, > 4 weeks after completing radiotherapy, were randomized to receive armodafinil daily (150 mg or 250 mg) or placebo for a total of 8 weeks. The primary outcome was efficacy in treating severe fatigue. Secondary outcomes included evaluation of tolerability, neurocognitive function, and quality of life. Patients were evaluated at baseline, 4 and 8 weeks. **Results:** A total of 328 patients were enrolled between 6/3/13-3/1/19. There were 103 (150 mg arm), 97 (250 mg arm) and 97 (placebo arm) evaluable patients with primary endpoint data available. The median age was 60 years (20-85) with a median Brief Fatigue Inventory (BFI) *worst* fatigue score of 8 (6-10). 60.3% were male, 80.5% received concomitant chemotherapy, and 39.7% were on corticosteroids. The global fatigue score at end of weeks 4 and 8 were lower than at baseline ($p<0.0001$) and in the 250 mg arm than placebo ($p=0.0356$) and was higher for corticosteroid users than non-users ($p=0.0002$). There was no statistically significant difference for clinically meaningful improvement in BFI *usual* fatigue score from baseline to end of week 8 between the three arms ($p=0.9601$). Patients reported an improvement in concentration at week 4 from baseline on the 150 mg arm($P=0.0311$). There was no statistically significant difference on neurocognitive tests from baseline to end of week 4 ($p>0.05$) or week 8 ($p>0.05$) between arms. More patients reported insomnia on the 250 mg arm ($p=0.0083$). **Conclusions:** There is no meaningful benefit of the use of armodafinil to reduce moderate to severe fatigue in patients with HGG. In certain cases there may be benefit of armodafinil 150 mg to aid concentration without the risk of insomnia.Support: UG1CA189823;U10CA180868 (NRG). Clinical trial information: NCT01781468. Research Sponsor: U.S. National Institutes of Health, Other Foundation.

12008 Oral Abstract Session, Fri, 8:00 AM-11:00 AM

Results of crossover phase II component of randomized placebo-controlled trial evaluating oral THC/cannabis extract for refractory chemotherapy-induced nausea and vomiting (CINV). *First Author: Peter S. Grimison, Chris O'Brien Lifehouse, Sydney, Australia*

Background: The aim of this multi-centre, randomised, double-blinded, placebo-controlled, phase 2/3 trial is to determine efficacy of addition of oral cannabis in adults with any malignancy of any stage, experiencing CINV during moderate-highly emetogenic intravenous chemotherapy, despite guideline-consistent anti-emetic prophylaxis, requiring ≥ 2 chemotherapy cycles. Here we report the crossover phase 2 component results. **Methods:** Treatment consisted of 1 cycle of oral THC 2.5mg/CBD 2.5mg (TN-TC11M) capsules *tds* days -1 to 5 and 1 cycle matching placebo in a crossover design, then blinded patient preference for a 3rd cycle. Primary end-point is difference in proportion of patients with 'complete response' (no emesis & no use of rescue medications) during 0-120 hours from chemotherapy between cycles. 80 patients provides 80% power with 2p of 0.1 to detect a 20% difference. **Results:** 81 patients recruited (2016-9). 72 completing 2 cycles are included in efficacy analyses. 78 not withdrawing consent are included in safety analyses. Median age was 55 years (range 29-80), 78% were female, 42% report historic cannabis use, 55% were treated with curative intent. Most common regimens were AC (26%), FOLFOX (17%). All received steroids & 5-HT3 antagonist, 79% received NK-1 antagonist, 4% received olanzapine. Efficacy is shown in table. 83% preferred cannabis to placebo. Most common bothersome cannabinoid-related adverse events (cannabis, placebo) were sedation (19%,4%), dizziness (10%,1%), disorientation (3%,0%). No SAEs were attributed to THC/CBD. **Conclusions:** Addition of oral THC/CBD to standard anti-emetics was associated with less nausea & vomiting but additional side effects. Most preferred THC/CBD to placebo. Based on these positive results, the definitive parallel phase 3 trial component continues (additional n=170). Acknowledgements: Trial participants, investigators, research staff. Funding from NSW Government Dept of Health. Clinical trial information: ACTRN12616001036404. Research Sponsor: NSW Health.

ENDPOINTS	THC/CBD* %	PLACEBO* %	Difference % (90% CI)	p-value
Complete response	25	14	11 (3,19)	0.04
No emesis	69	57	12 (2,23)	0.05
No significant nausea**	21	10	11 (3,19)	0.03
No use of rescue medications	28	15	13 (3,22)	0.03

*n=72 (crossover design) ** <2 on 10-point rating scale

12009 Clinical Science Symposium, Fri, 8:00 AM-9:30 AM

A geriatric assessment (GA) intervention to reduce treatment toxicity in older patients with advanced cancer: A University of Rochester Cancer Center NCI community oncology research program cluster randomized clinical trial (CRCT). *First Author: Supriya Gupta Mohile, University of Rochester James Wilmot Cancer Institute, Rochester, NY*

Background: GA evaluates aging-related domains (e.g., function) known to be associated with cancer treatment toxicity. In this CRCT, we evaluated if providing a GA summary with management recommendations to oncologists can reduce toxicity in older patients (pts) with advanced cancer receiving chemotherapy and/or other agents with a high reported prevalence of grade 3-5 toxicity. **Methods:** Pts aged > 70 with incurable solid tumors or lymphoma and > 1 impaired GA domain starting a new treatment regimen were enrolled. Community oncology practices were randomized to intervention (oncologists received GA summary/recommendations for impairments) or usual care (none given). The primary outcome was proportion of pts who experienced any grade 3-5 toxicity (CTCAE v.4) within 3 months. Practice staff prospectively captured toxicities; blinded oncology clinicians reviewed medical records to verify. Secondary outcomes included 6 month overall survival (OS) and treatment intensity (standard vs reduced). Outcomes were analyzed using generalized linear mixed/Cox models with Arm as a fixed effect, controlling for practice. **Results:** From 2013-19, 718 pts were enrolled from 41 practices. Age (mean 77 yrs), sex (43% women), number of impaired GA domains (median 4/8), and treatment type (chemotherapy 88%) were not different by Arm. More pts in intervention were Black (12% vs 3%, p<0.01), had GI cancer (38% vs 31%, p<0.01), and had prior chemotherapy (31% vs 23%, p=0.02). Pts in intervention experienced a lower proportion of grade 3-5 toxicity (175/349; 50%) than pts in usual care (262/369; 71%). The relative risk (RR: intervention vs usual care) of grade 3-5 toxicity was 0.74 (95% CI: 0.63-0.87; p=0.0002); the difference was mostly driven by non-heme toxicities (RR 0.73; 95% CI: 0.53-1.0, p<0.05). OS was not significantly different (71% vs 74%, p=0.3). More pts in intervention received reduced intensity treatment at cycle 1 (49% vs 35%, RR 0.81, p=0.01). Dose modifications due to toxicity were lower in intervention (42% vs 58%, p<0.0001), but results were not significant after controlling for practice (RR 0.85; 95% CI: 0.67-1.08, p=0.2). **Conclusions:** Providing GA information to oncologists reduces the proportion of older pts who experience grade 3-5 toxicity from high-risk palliative cancer treatment, without compromising OS. Reduced treatment intensity at cycle 1 may explain these results. Funding: R01CA177592, U01CA233167, UG1CA189961. Clinical trial information: NCT02054741. Research Sponsor: U.S. National Institutes of Health.

12010 Clinical Science Symposium, Fri, 8:00 AM-9:30 AM

Geriatric assessment-driven intervention (GAIN) on chemotherapy toxicity in older adults with cancer: A randomized controlled trial. *First Author: Daneng Li, City of Hope National Medical Center, Duarte, CA*

Background: Geriatric assessment (GA) can predict chemotherapy (chemo) toxicity in older adults (age ≥65) with cancer. However, evidence regarding the effect of GA-driven intervention (GAIN) on the incidence of chemo toxicity has been limited. Therefore, we conducted a randomized controlled trial evaluating the impact of GAIN vs. standard of care (SOC) on chemo toxicity in older adults with cancer. **Methods:** Patients (pts) age ≥65, diagnosed with a solid malignancy, and starting a new chemo regimen at City of Hope were eligible (NCT02517034). In a 2:1 ratio, 600 pts were randomly assigned to either GAIN (n = 398) or SOC (n = 202) arms. All pts completed a baseline GA prior to chemo. In the GAIN arm, a multidisciplinary team led by a geriatric oncologist, nurse practitioner, social worker, physical/occupation therapist, nutritionist, and pharmacist, reviewed GA results and implemented interventions based on predefined triggers built into the GA's various domains. In the SOC arm, GA results were sent to treating oncologists to use at their discretion. Pts were followed until either end of chemo or 6 months after start of chemo, whichever occurred first. The primary endpoint was incidence of grade 3-5 chemo-related toxicity (NCI CTCAE v.4.0). Secondary endpoints included advance directive (AD) completion, emergency room (ER) visits, hospitalizations, and average length of stay (ALOS). Chi-square and Fisher's exact tests were used to compare the categorical outcomes, and Kruskal-Wallis test was used to compare the ALOS between arms. **Results:** Pt characteristics were balanced between arms. Median age was 71 (range 65-91). Cancer types included: 33% gastrointestinal, 23% breast, 16% lung, 15% genitourinary, and 13% other. Most (71%) had stage IV disease. The incidence of grade 3-5 chemo-related toxicity was 50.5% (95% CI: 45.6-55.4%) in the GAIN arm and 60.4% (95% CI: 53.7-67.1%) in the SOC arm (p = 0.02). Compared to SOC, the GAIN arm had a reduction of 9.9% (95% CI: 1.6-18.2%) in chemo-related toxicity. At the end of study, AD completion increased 24.1% in the GAIN arm vs. 10.4% in the SOC arm (p < 0.001). No significant differences in ER visits (27.4% vs. 30.7%), hospitalizations (22.1% vs. 19.3%), or ALOS (median 4.8 vs. 5.0 days) were observed between the GAIN and SOC arms, respectively. **Conclusions:** Integration of multidisciplinary GA-driven interventions reduced grade 3-5 chemo-related toxicity and improved AD completion in older adults with cancer. GA-driven interventions should be included as a part of cancer care for all older adults. Clinical trial information: NCT02517034. Research Sponsor: UniHealth Foundation, City of Hope's Center for Cancer and Aging.

12011 Clinical Science Symposium, Fri, 8:00 AM-9:30 AM

Integrated geriatric assessment and treatment (INTEGERATE) in older people with cancer planned for systemic anticancer therapy. *First Author: Wee-Kheng Soo, Monash University Eastern Health Clinical School, Box Hill, Australia*

Background: Older people experience significant adverse effects of cancer and anti-cancer therapy due to age-related vulnerabilities, including medical, functional, cognitive, nutritional and psychosocial issues. Comprehensive geriatric assessment and management (CGAM) provides a powerful framework to assess an older person's health status and offers a coordinated, person-centered approach to care. Despite its effectiveness, the uptake of CGAM in oncology has been limited due to a lack of randomized evidence in this setting. This study evaluated the effectiveness of CGAM in older people with cancer. **Methods:** INTEGERATE is a prospective, randomized, parallel group, open-label study in patients aged >70 years with cancer planned for chemotherapy, targeted therapy or immunotherapy. Patients were randomly assigned (1:1) to receive either geriatrician-led CGAM integrated with usual care (integrated oncogeriatric care) or usual care alone, using minimization to balance treatment intent, cancer type, age, sex and performance status. Health-related quality of life (HRQOL) was assessed using the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 and QLQ-ELD14 at 0, 12, 18 and 24 weeks. The primary outcome was HRQOL measured by the validated Elderly Functional Index (ELFI) score. Major secondary outcomes included function, mood, nutrition, health utility, treatment delivery, healthcare utilization and survival. **Results:** Of the 154 patients who underwent randomization, 13 died by week 12 and 130 (92.2% of the remaining patients) completed at least two primary outcome assessments. For the primary outcome, patients in the intervention group had significantly better ELFI score than the usual care group across all followup timepoints, with a maximal difference at week 18 (estimated marginal mean ELFI score 72.0 vs 58.7, p= 0.001). In addition, significant differences favoring the intervention group over the usual care group were seen in HRQOL (domains: physical, role and social functioning; mobility, burden of illness and future worries), unplanned hospital admissions (-1.2 admissions per person-years, p< 0.001) and early treatment discontinuation (32.9% vs 53.2%, p = 0.01). **Conclusions:** Integrated oncogeriatric care led to improvements in HRQOL, unplanned hospital admissions and treatment discontinuation in older people receiving systemic anti-cancer therapy. Older people (>70 years) planned for anti-cancer therapy should receive CGAM to optimize their clinical care and health outcomes. Clinical trial information: ACTRN12614000399695. Research Sponsor: National Health and Medical Research Council.

12012 Clinical Science Symposium, Fri, 8:00 AM-9:30 AM

Randomized trial of a perioperative geriatric intervention for older adults with cancer. *First Author: Carolyn L. Qian, Massachusetts General Hospital, Boston, MA*

Background: Older adults with gastrointestinal (GI) cancers undergoing surgery often experience poor outcomes, such as prolonged postoperative (post-op) length of stay (LOS), intensive care unit (ICU) use, and readmissions. Involvement of geriatricians in the care of older adults with cancer can improve outcomes. We conducted a randomized trial of a perioperative geriatric intervention in older adults with GI cancers undergoing surgery. **Methods:** We randomly assigned patients age ≥65 with GI cancers planning to undergo surgical resection to receive a perioperative geriatric intervention or usual care. Intervention patients met with a geriatrician preoperatively in the outpatient setting and post-op as an inpatient consultant. The geriatrician conducted a geriatric assessment and made recommendations to the surgical/oncology teams. The primary end point was post-op LOS. Secondary end points included post-op ICU use, readmission risk, and patient-reported symptom burden (Edmonton Symptom Assessment System [ESAS]) and depression symptoms (Geriatric Depression Scale). We conducted both intention-to-treat (ITT) and per protocol (PP) analyses. **Results:** From 9/13/16-4/30/19, we randomized 160 patients (72.4% enrollment rate; median age = 72 [65-92]). The ITT analyses included 137/160 patients who underwent surgery (usual care = 68/78, intervention = 69/82). The PP analyses included the 68 usual care patients and the 30/69 intervention patients who received both pre- and post-op intervention components. In ITT analyses, we found no significant differences between intervention and usual care in post-op LOS (7.2 v 8.2 days, P = .37), ICU use (23.3% v 32.4%, p = .23), and readmission rates within 90 days of surgery (21.7% v 25.0%, p = .65). Intervention patients reported lower depression symptoms (B = -1.39, P < .01) at post-op day 5 and fewer moderate/severe ESAS symptoms at post-op day 60 (B = -1.09, P = .02). In PP analyses, intervention patients had significantly shorter post-op LOS (5.9 v 8.2 days, P = .02) and lower rates of post-op ICU use (13.3% v 32.4%, p < .05), but readmission rates were not significantly different (16.7% v 25.0%, p = .36). **Conclusions:** Although this perioperative geriatric intervention did not have a significant impact on the primary end point in ITT analysis, we found encouraging results in several secondary outcomes and for the subgroup of patients who received the planned intervention. Future studies of this perioperative geriatric intervention should include efforts, such as telehealth visits, to ensure the intervention is delivered as planned. Clinical trial information: NCT02810652. Research Sponsor: NCCN Foundation Young Investigator Award.

12013 Poster Discussion Session; Displayed in Poster Session (Board #301), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Effect of early integration of specialized palliative care into standard oncologic treatment on the quality of life of patients with advanced head and neck cancers: A phase III randomized controlled trial. *First Author: Pankaj Singhai, Tata Memorial Centre, Mumbai, India*

Background: Early palliative care is an important aspect of palliative treatment but has never been evaluated in head and neck cancer. Hence we performed this study. **Methods:** This was an open-label phase 3 randomised study which enrolled adult patients with squamous cell carcinoma of the head and neck region which warranted palliative systemic therapy. They were 1:1 allocated to either systemic therapy with (EPC arm) or without the addition of early palliative care service (STD arm). Patients were administered the Edmonton Symptom Assessment Scale (ESAS-r) and FACIT HN questionnaire at baseline and 4 weekly thereafter for 12 weeks. The primary endpoint was change in the quality of life (QOL) measured using FACIT HN 12 weeks after randomization. The secondary endpoints were changed in symptom burden at 12 weeks in ESAS-r and overall survival. A repeated-measures analysis of covariance (ANCOVA) was performed to examine the effects of arm and stratum on change in QOL (or symptom score), after controlling for baseline score. **Results:** Ninety patients were randomised in each arm between 1st June 2016 to 14th August 2017. The compliance with the questionnaires was 100% at baseline. In EPC arm the 70 patients were alive at 3 months and 67 (95.7%) completed the FACIT HN and 64 (91.4%) completed ESAS-r questionnaires. While in the STD arm out of 69 alive the corresponding figures were 61(88.4%) and 59 (85.5%) respectively. There was no statistical difference in change in QOL scores and ΔESAS-r at 12 weeks between the 2 arms (Table). The median overall survival was similar between the 2 arms. (Hazard ratio for death-1.006 (95%CI 0.7347-1.346)). **Conclusion:** In this phase 3 study, integration of early palliative care in head and neck cancer patients did not result in improvement in the quality of life scores, symptom scores or overall survival. Clinical trial information: CTRI/2016/03/006693. Research Sponsor: Tata Memorial Center Research Administration Council.

Δ Scores	Early Palliative Care arm	Standard arm	P-value
FACT HN	-4.4876 (-19.5 to 12)	-1.2514 (-11.5 to 13.5)	0.9357
FACT TOI	-2.8607 (-14 to 9)	-.1803 (-12.5 to 10.5)	0.9516
FACT G	-3.8905 (-15.6667 to 9.3333)	-1.5464 (-10 to 11)	0.8392
Pain	-0.6875 (-3 to 1)	-0.8305 (-3 to 1)	0.3079
Fatigue	0.6875 (-2 to 3)	0.322 (-2 to 3)	0.7975
Drowsiness	0.125 (-2 to 3)	1.1525 (0 to 2)	0.1985
Nausea	0.9063 (0 to 2)	0.6271 (0 to 2)	0.2954
Loss of appetite	0.2656 (-1 to 2)	-.0678 (-2 to 2)	0.3813
Depression	1.0313 (-0.75 to 4)	0.0339 (-1 to 2)	0.4678

Table depicting the mean delta (Δ) scores with the interquartile range at 12 weeks.

12014 Poster Discussion Session; Displayed in Poster Session (Board #302), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Randomized trial of a symptom monitoring intervention for hospitalized patients with advanced cancer (NCT03396510). *First Author: Ryan David Nipp, Massachusetts General Hospital Cancer Center, Boston, MA*

Background: Hospitalized patients with advanced cancer experience a high symptom burden, which is associated with poor clinical outcomes and increased health care use. Symptom monitoring interventions are increasingly becoming standard of care in oncology, but studies of these interventions in the hospital setting are lacking. We evaluated the impact of a symptom monitoring intervention in hospitalized patients with advanced cancer. **Methods:** We randomly assigned hospitalized patients with advanced cancer who were admitted to the oncology service to a symptom monitoring intervention or usual care. Patients in both arms reported their symptoms (Edmonton Symptom Assessment System [ESAS] and Patient Health Questionnaire 4 [PHQ4], higher scores on both indicate greater symptom severity) daily via tablet computers. Patients assigned to the intervention had their symptom reports presented graphically with alerts for moderate/severe symptoms during daily oncology rounds. The primary endpoint was the proportion of days with improved symptoms for those who completed two or more days of symptoms. Secondary endpoints included hospital length of stay (LOS) and readmission rates. **Results:** From 2/2018-10/2019, we randomized 390 patients (76.2% enrollment rate); 320 completed two or more days of symptoms (median age=65.6 [range 18.8-93.2]; 43.8% female). The most common cancers were gastrointestinal (36.9%), lung (18.8%), and genitourinary (12.2%). Nearly half of patients (48.5%) had one or more comorbid conditions in addition to cancer. We found no significant differences between intervention and usual care regarding the proportion of days with improved ESAS total (B=-0.05, P=.17), ESAS physical (B=-0.02, P=.52), PHQ4 anxiety (B=-0.03, P=.33), and PHQ4 depression (B=-0.02, P=.44) symptoms. Intervention patients also did not differ from usual care with respect to secondary endpoints of hospital LOS (7.50 v 7.59 days, P=.88) and readmission rates within 30 days of discharge (32.5% v 25.6%, P=.18). **Conclusions:** For hospitalized patients with advanced cancer, this symptom monitoring intervention did not have a significant impact on their symptom burden and health care use. These findings do not support the routine integration of this type of symptom monitoring intervention for hospitalized patients with advanced cancer. The positive outcomes seen in previous studies of symptom monitoring interventions may not be reproduced in other patient populations and care settings. Support: UG1CA189823; Clinical trial information: NCT03396510. Research Sponsor: U.S. National Institutes of Health.

12015 Poster Discussion Session; Displayed in Poster Session (Board #303), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Impact of augmented intelligence (AI) on utilization of palliative care (PC) services in oncology. *First Author: Ajeet Gajra, Cardinal Health, Dublin, OH*

Background: Timely integration of palliative care in the management of patients with advanced cancer is a quality benchmark in oncology. However, PC is often underutilized as evidenced by delays in identification of appropriate patients, in referrals to a PC service, and in enrollment to hospice. Jvion has developed a prescriptive analytics solution, the Machine, which combines AI algorithms with machine learning techniques and applies them to clinical and exogenous datasets to identify patients with a propensity for poor outcomes. The Machine was applied to risk for patients' mortality within next 30 days, and recommended patient-specific, dynamic, and actionable insights. Use of the Machine requires no additional documentation within the electronic health record (EHR) and the insights generated can be integrated back in to any EHR to help inform the care plan. Herein, we report the results of a study evaluating the impact of AI-driven insights on PC utilization at a large community oncology practice. **Methods:** All patients were scored weekly using the Machine PC vector. The Machine risk stratified the patients and generated recommendations for the provider to consider as they developed a care plan. Patients identified as "at risk" by the Machine were assessed for a supportive care visit (PC referral) and then were referred as deemed clinically appropriate. The average monthly rates of PC consults and hospice referrals were calculated 5 months prior to and for 17 months after the launch of the Machine in the practice. **Results:** The oncology practice has 21 providers managing an average of 4329 unique patients per month (PPM). The mean rate of PC consults increased from 17.3 to 29.1 per 1000 PPM pre and post Machine deployment respectively (+168%). The mean monthly rate of hospice referrals increased by 8-fold from 0.2 to 1.6 per 1000 PPM pre and post deployment respectively. Eliminating the first 6 months of Machine deployment to account for user learning curve, the mean rates of monthly PC consults nearly doubled over baseline to 33.0, and hospice referrals rose 12-fold to 2.4 per 1000 patients in months 7-17 post Machine deployment. **Conclusions:** This oncology practice found deployment of this novel AI solution to be feasible and effective at generating actionable insights. These AI driven insights could be incorporated into workflow and improved the decision-making for whether and when a patient should be referred to PC and/or hospice services for end of life care. Further study is needed to confirm the value of AI for management of cancer patients at end of life. Research Sponsor: Jvion and Cardinal Health.

12016 Poster Discussion Session; Displayed in Poster Session (Board #304), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Risk of cardiovascular disease in women with and without a history of breast cancer: The Pathways Heart Study. *First Author: Heather Greenlee, Fred Hutchinson Cancer Research Center, Seattle, WA*

Background: Breast cancer (BC) survivors are at increased risk of cardiovascular disease (CVD) following diagnosis, as compared to women without BC. To provide a population-based estimate of CVD risk in BC survivors, we compared risk of CVD events in women with and without BC history enrolled in the Kaiser Permanente Northern California (KPNC) integrated health system. **Methods:** Data were extracted from KPNC electronic health records. All invasive BC cases diagnosed between 2005-2013 were identified and matched 1:5 with non-BC controls on birth year, race/ethnicity and KPNC membership at date of BC diagnosis. Cox regression models were used to assess differences in the hazard of four major CVD events (ischemic heart disease (IHD), heart failure (HF), cardiomyopathy, and stroke). Models were adjusted for factors known to influence risk of breast cancer or CVD.Other CVD events included arrhythmia, cardiac arrest, carotid disease, myocarditis/pericarditis, transient ischemic attack, valvular disease, and venous thromboembolism (VTE). We additionally examined subgroups of cases who received chemotherapy, radiation, and endocrine therapy, and their controls. **Results:** A total of 14,942 women with a new diagnosis of invasive BC were identified and matched to 74,702 women without BC history. On average, women were 62.0 years, 28.3 kg/m^{2}BMI, 64.9% non-Hispanic white. Among all cases and controls, there were no significant differences in hazard of developing IHD, cardiomyopathy, and stroke; there was a borderline difference in HF (HR: 1.08, 95% CI: 0.99, 1.19). Cases were more likely to have a cardiac arrest (HR: 1.39, 95% CI: 1.09, 1.78) and develop VTE (HR: 1.97, 95% CI: 1.74, 2.23). Women treated with chemotherapy were more likely than controls to develop HF (HR: 1.44, 95% CI: 1.21, 1.72), cardiomyopathy (HR: 2.01, 95% CI: 1.02, 3.98), and VTE (HR: 3.15, 95% CI: 2.62, 3.79). Women who received radiation therapy were more likely to develop carotid disease (HR: 5.49, 95% CI: 1.22, 24.66) and VTE (HR: 1.65, 95% CI: 1.35, 2.03) than controls. Women who received endocrine therapy were more likely to experience a cardiac arrest (HR: 1.49, 95% CI: 1.07, 2.09) and develop VTE (HR: 1.70, 95% CI: 1.42, 2.03) than controls. **Conclusions:** Women with BC were at increased risk of heart failure, cardiomyopathy, cardiac arrest, VTE and carotid disease. These risks varied by cancer treatment, with higher risk in those who received chemotherapy. Future studies should explore the effects of chemotherapy class and radiation dose exposure on diverse CVD endpoints in BC survivors. Research Sponsor: U.S. National Institutes of Health.

12017 Poster Discussion Session; Displayed in Poster Session (Board #305), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Onset of cardiovascular disease risk factors in women with and without a history of breast cancer: The Pathways Heart Study. *First Author: Marilyn L. Kwan, Kaiser Permanente, Oakland, CA*

Background: Women with a history of breast cancer (BC) are at increased long-term risk of dying from cardiovascular disease (CVD). However, the onset of CVD risk factors in women with BC has not been well-described. We compared risk of incident CVD risk factors in women with and without BC enrolled in the Kaiser Permanente Northern California (KPNC) integrated health system. **Methods:** Data were extracted from KPNC electronic health records. All invasive BC cases diagnosed between 2005-2013 were identified and matched 1:5 with controls on birth year, race/ethnicity and KPNC membership at the date of BC diagnosis. Cox regression models assessed the hazard of incident hypertension (based on diagnosis codes and filled prescriptions), dyslipidemia (based on diagnosis codes, filled prescriptions, and lab values), and diabetes (KPNC Diabetes Registry). Models were adjusted for baseline BMI, menopausal status, smoking status, neighborhood median household income, education, prevalent CVD conditions, and other baseline CVD risk factors. Subgroups of women who received chemotherapy, radiation therapy, and endocrine therapy were compared with controls. **Results:** A total of 14,942 women with a new diagnosis of invasive BC were identified and matched to 74,702 controls. On average, women were 62.0 years, 28.3 kg/m^{2}BMI, 64.9% non-Hispanic white. Overall, cases were more likely to develop hypertension (HR: 1.18, 95% CI: 1.13, 1.24) and diabetes (HR: 1.23, 95% CI: 1.16, 1.31). Across the board, receipt of any of the three therapies (chemotherapy, radiation therapy and endocrine therapy) was associated with increased risk of hypertension and diabetes, compared to controls. Risk-factor specific hazard ratios for receipt of chemotherapy were (HR 1.18, 95% CI: 1.10, 1.27) and (HR 1.38, 95% CI: 1.26, 1.51), for hypertension and diabetes, respectively. For receipt of radiation therapy, risk-factor specific hazard ratios were (HR: 1.17, 95% CI: 1.09, 1.26) and (HR: 1.15, 95% CI: 1.04, 1.27), for hypertension and diabetes, respectively. Risk-factor specific hazard ratios for receipt of endocrine therapy were (HR: 1.22, 95% CI: 1.14, 1.30) and (HR: 1.16, 95% CI: 1.06, 1.27), for hypertension and diabetes, respectively. **Conclusions:** The risk of developing hypertension and diabetes is increased in women with BC who received chemotherapy, radiation therapy, and/or endocrine therapy. Future studies should examine the roles of CVD risk factor diagnosis and management on cardiometabolic risk in women with a BC history. Research Sponsor: U.S. National Institutes of Health.

12018 Poster Discussion Session; Displayed in Poster Session (Board #306), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Effect of a tailored exercise intervention during or after chemotherapy on cardiovascular morbidity in cancer patients. *First Author: Gabriela G.F. Giovanna Femma van der Schoot, Department of Medical Oncology, University Medical Center Groningen, Groningen, Netherlands*

Background: Cancer treatment outcome may be impaired due to treatment-related adverse effects like decreased cardiorespiratory fitness. Evidence on exercise during or after chemotherapy shows positive effects on cardiorespiratory fitness, fatigue and quality of life (QoL) in cancer patients. However, optimal timing of starting exercise is unknown. This study aimed to investigate if an exercise intervention that starts during chemotherapy (early group) is superior to a program starting after completion of chemotherapy (late group) to reduce cardiovascular morbidity. **Methods:** In this multicenter randomized controlled trial, 266 patients (testicular-, (n = 95), breast-, (n = 139), and colon cancer (n = 30) or non-Hodgkin lymphoma (NHL) (n = 2)), treated with curative chemotherapy were randomized to a 24 week aerobic and resistance exercise intervention starting either early, i.e. during chemotherapy (n = 131) or late, i.e. at completion of chemotherapy (n = 135) (NCT01642680). Effect on VO_2 peak was evaluated with intention-to-treat linear mixed-effect models, adjusted for baseline values (T0) and diagnosis at post-chemotherapy (T1), post-exercise intervention (T2) and 1-year post-exercise intervention (T3, i.e., primary endpoint). Here we report T0, T1 and T2 data. Secondary endpoints were QoL (EORTC-QLQ-C30) and fatigue (MFI-20), with higher scores indicating more fatigue. **Results:** Median age was 33 yrs for testicular-, 52 yrs for breast- and 64 yrs for colon cancer and NHL patients. Patients in the early group declined significantly less in VO_2 peak and QoL at T1 compared to the late group (adjusted between-group differences were 3.2 ml/min/kg (95% confidence interval CI 2.3 to 4.1, $P < 0.0001$) and 5.8 (95% CI 0.6 to 10.9, P = 0.028). Patients in the early group experienced reduced general and physical fatigue at T1 (adjusted between-group differences were -2.0 (95% CI -3.3 to -0.8, P = 0.002) and -2.9 (95% CI -4.3 to -1.5, $P < 0.0001$). At T2, VO_2 peak, QoL, general and physical fatigue were comparable and regained baseline levels (adjusted between-group differences - 0.08 ml/min/kg (P = 0.9), -1.4 (P = 0.7), 0.7 (P = 0.3) and 0.2 (P = 0.7), respectively. **Conclusions:** A supervised exercise program for patients with testicular-, breast- and colon cancer that is initiated at start of curative chemotherapy effectively reduces a decline in VO_2 peak and QoL and reduces fatigue. After completion of the exercise intervention, initiated both during and after chemotherapy, patients regained their baseline VO_2 peak, levels of fatigue and QoL. Clinical trial information: NCT01642680. Research Sponsor: Dutch Cancer Society. Grant: DCS 2011-5265.

12019 Poster Discussion Session; Displayed in Poster Session (Board #307), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Predictive model of aromatase inhibitor non-adherence using patient-reported outcomes in women with breast cancer (SWOG S1105). *First Author: Dawn L. Hershman, Columbia University Medical Center, New York, NY*

Background: Non-adherence to aromatase inhibitors (AIs) for breast cancer is common and increases risk of recurrence. Few prospective studies have systematically evaluated factors associated with non-adherence. We analyzed baseline sociodemographic, prescription, and patient reported outcome (PRO) symptoms and quality-of-life to identify factors associated with non-adherence prospectively over 3-years. **Methods:** Patients enrolled in SWOG S1105 were required to have been on an AI for ≥30 days. Patients were assessed for non-adherence to AIs every 3 months for 36 months, with non-adherence defined as urine AI metabolite assay results satisfying any of the following: < 10 ng/mL, undetectable, specimen submitted outside of the ± 21 day follow-up appointment window, or no submitted specimen. At baseline patients were asked about insurance, pill number dispensed and medication cost, and they completed PROs focused on pain and endocrine symptoms (BPI (Brief Pain Inventory), FACT-ES (Endocrine Symptoms)), as well as their beliefs about medications (TSQM (Treatment Satisfaction Questionnaire for Medicine) and BMQ (Brief Medication Questionnaire)). PRO scales were split at the median creating high vs low binary predictors. We determined the association of baseline factors and non-adherence at 36 months. We also evaluated an adverse risk model for AI non-adherence by summing the number of statistically significant adverse factors associated with non-adherence. Logistic regression was used. **Results:** In total, 724 patients were registered from 40 institutions between May, 2012 and September, 2013. The median age was 60.9 years, and 64.5% were on AI < 12 months prior to registration. Overall, 35.9% were non-adherent at 36 months. Younger patients (< 65 years) were less adherent (39% vs. 29% non-adherence, OR = 1.51, p = 0.02). Baseline scores on the BPI, FACT-ES, BMQ and TSQM were each statistically significantly associated with AI adherence. Non-adherence was significantly higher among patients scoring poorly on all 4 PRO instruments (65%) compared to those scoring poorly 0 or 1 PRO instruments (27%; OR, 4.68 [2.84-7.73], p < .0001). For each increase in the number of adverse risk PRO scores, the risk of non-adherence increased by 45% (OR = 1.45, p < .0001). Similar results were found when age was included in the score. **Conclusions:** Presence of multiple baseline risk factors identified through PRO instruments increases non-adherence to AI's 4-fold. Use of PROs can identify patients for targeted interventions to improve adherence. Research Sponsor: U.S. National Institutes of Health, Conquer Cancer Foundation of the American Society of Clinical Oncology.

12020 Poster Discussion Session; Displayed in Poster Session (Board #308), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Impact of baseline symptom burden as assessed by patient-reported outcomes (PROs) on overall survival (OS) of patients with metastatic cancer. *First Author: Atul Batra, Tom Baker Cancer Center, Calgary, AB, Canada*

Background: Patients with metastatic cancer experience variable symptom burden, but serial symptom assessments using PROs may be challenging to implement in routine clinical practices. We aimed to determine if a single measurement of symptom burden at the time of metastatic diagnosis is associated with survival. **Methods:** We examined prospectively collected baseline PROs of patients newly diagnosed with metastatic breast, lung, colorectal, or prostate cancer using the revised Edmonton Symptom Assessment System (ESASr) questionnaire from a large province (Alberta, Canada) between 2016 and 2019. The ESASr was categorized into physical (PH), psychosocial (PS), and total symptom (TS) domains whereby scores were classified as mild (0-3), moderate (4-6), or severe (7-10). Multivariable Cox proportional hazards models were constructed to evaluate the effect of baseline symptom scores on OS. **Results:** We identified 1,315 patients, of whom 57% were men and median age was 66 (IQR, 27-93) years. There were 180, 601, 240, and 294 patients with breast, lung, colorectal, and prostate cancer, respectively. Approximately one-quarter of all patients reported moderate to severe PH, PS, and TS scores, with lung cancer patients experiencing the highest symptom intensity across all domains ($P<0.0001$). While age did not affect symptom scores, women were more likely to report severe PH, PS, and TS scores as compared to men ($P=0.02$, 0.002, and 0.007, respectively). On multivariable Cox regression analysis, older age (HR 1.02, 95% CI, 1.02-1.03, $P<0.0001$) and female sex (HR 1.67, 95% CI, 1.39-1.99, $P<0.0001$) were predictive of worse OS as were severe baseline PH and TS scores (see Table) . However, baseline PS scores were not related to OS. **Conclusions:** A single assessment of baseline symptom burden using the ESASr in patients with metastatic cancer has significant prognostic value. This may represent a feasible first step toward routine collection of PROs in real-world settings where serial symptom measurements can be challenging to implement. Research Sponsor: None.

OS by symptom burden.

Group (n)	Median OS, in months (95% CI)	HR (95% CI)	*P* value
PH			
Mild (885)	33.5 (30.2-36.4)	-	-
Moderate (368)	12.2 (10.1-15.1)	1.68 (1.32-2.13)	<0.0001
Severe (62)	10.8 (4.9-17.7)	1.89 (1.26-2.83)	0.002
PS			
Mild (946)	29.1 (25.5-33.3)	-	-
Moderate (243)	16.1 (12.4-20.8)	1.15 (0.94-1.41)	0.17
Severe (117)	10.7 (8.1-16.9)	1.13 (0.85-1.52)	0.39
TS			
Mild (924)	32.5 (28.6-35.1)	-	-
Moderate (350)	12.2 (10.1-15.1)	1.27 (0.96-1.68)	0.09
Severe (41)	7.9 (3.5-16.9)	1.71 (1.01-2.91)	0.04

12021 Poster Discussion Session; Displayed in Poster Session (Board #309), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Integrating PROs with prognostic value into oncologic care: High ESAS global distress score associated with lower overall survival in advanced cancer patients. *First Author: Ishwaria Mohan Subbiah, The University of Texas MD Anderson Cancer Center, Houston, TX*

Background: Despite compelling data supporting their use, patient reported outcomes (PROs) are not widely integrated into routine cancer care. In our Palliative Care (PC) practice, all patients complete the Edmonton Symptom Assessment Scale (ESAS), a simple, validated 10-item PRO tool which uses a 0 to 10 rating of 10 common symptoms (pain, fatigue, nausea, drowsiness, appetite, sleep, dyspnea, well-being, anxiety & depression). Our team has previously validated the Global Distress Score (GDS), a sum of 9 physical + psychosocial ESAS items. Here, we studied the implementation of the GDS as a streamlined way to capture the overall symptom burden while providing prognostic value. **Methods:** We queried a PC database for patients w metastatic cancer at time of 1st PC visit. GDS was calculated & grouped into 3 cohorts based on previous work & clinical experience: high (GDS of 35+), Moderate (16-34) or Low (0-15). Overall Survival was defined as time from 1st PC visit date to death. Regression analysis, ANOVA and t-tests were conducted. **Results:** 333 patients met the inclusion criteria: median age 62.4y (range 20.5-88.4y), 25 AYA (15-39y), 169 mid age (35-64y), 140 seniors (65y+); 190 female 143 male; median prior therapies 2 (range 0-11), 227 patients were in 2nd line + above therapy. Median ECOG PS 2; 124 patients w ECOG PS 3 & 33 w ECOG PS 4. 262 patients had died at time of analysis. Lower OS was associated w higher GDS (r 0.21, $P < 0.001$). OS in Low, Mod, High GDS cohorts was 13.1m, 7.9m, & 3.7m, respectively ($p < 0.001$). There were no sig OS difference between 3 age cohorts (AYA 5.2m, mid age 6m, seniors 5.4m, p0.56). **Conclusions:** Higher GDS score was associated with a clinically significant decrease in overall survival highlighting the potential of the ESAS as a PRO tool in prognostication and clinical decision making for patients with advanced cancers with a high symptom burden. In the realm of increasingly complex PRO instruments, the ESAS represents a simple, well-validated tool which, in our studies and 25 years of clinical experience, takes the patient less than a minute to complete, with subscores such as the GDS which carry a highly prognostic utility for patients with advanced cancers. Research Sponsor: None.

12022 Poster Discussion Session; Displayed in Poster Session (Board #310), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Temporal trends in opioid prescribing patterns among oncologists in the Medicare population. *First Author: Vikram Jairam, Department of Therapeutic Radiology, Yale School of Medicine, New Haven, CT*

Background: In the wake of the United States (U.S.) opioid epidemic, there have been significant governmental and societal efforts to curb opioid prescribing. However, it is unknown whether these efforts have affected prescribing among oncologists, whose patient population often requires narcotics for symptom management. We investigated temporal patterns in opioid prescribing for Medicare patients among oncologists. **Methods:** We queried the Centers for Medicare and Medicaid Services Part D prescriber dataset to identify independently practicing physicians between January 1, 2013 and December 31, 2017. We used population-averaged multivariable negative binomial regression to estimate the association between time and per-provider opioid prescribing rate, defined as number of opioid claims (original prescriptions and refills) per 100 patients, among oncologists and non-oncologists on both a national and statewide level. All models were adjusted for provider characteristics and annual total patient count per provider. **Results:** The final study sample included 20,513 oncologists and 711,636 non-oncologists. From 2013 to 2017, the national opioid prescribing rate declined by 19.3% (68.8 to 55.5 opioid prescriptions per 100 patients; $P< 0.001$) among oncologists and 20.4% (50.7 to 40.3 prescriptions per 100 patients; $P< 0.001$) among non-oncologists. During this timeframe, 40 U.S. states experienced a significant ($P< 0.05$) decrease in opioid prescribing among oncologists, most notably in Vermont (-43.2%), Idaho (-34.5%), and Maine (-32.8%). In comparison, all 50 states exhibited a significant decline ($P< 0.05$) in opioid prescribing among non-oncologists. In 5 states, opioid prescribing decreased more among oncologists than non-oncologists, including Oklahoma (-24.6% vs. -7.1%), Idaho (-34.5% vs. -17.8%), Utah (-31.7% vs. -18.7%), Texas (-19.9% vs. -14.7%), and New York (-24.0% vs. -19.7%) (all $P< 0.05$). **Conclusions:** Between 2013 and 2017, the opioid prescribing rate decreased by approximately 20% nationwide among both oncologists and non-oncologists. These findings raise concerns about whether opioid prescribing legislation and guidelines intended for the non-cancer population are being applied inappropriately to patients with cancer and survivors. Research Sponsor: None.

12023 Poster Discussion Session; Displayed in Poster Session (Board #311), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

Prevalence and temporal trends of prescription drug use in cancer survivors: A population study, 2001 to 2016. *First Author: Elisa Liu, NYU School of Medicine, New York, NY*

Background: The burden of prescription drug use is higher in cancer survivors than the general population. We examined the prevalence and temporal trends of prescription drug use among cancer survivors, with an emphasis on central nervous system (CNS) active medications used to manage long-term cancer sequelae. **Methods:** Adult respondents with (n=3207) and without (n=40,440) a prior cancer diagnosis from 8 cycles (2001-2016) of the National Health and Nutritional Examinational Survey (NHANES) were evaluated for prescription drug usage. Cross-sectional analyses and temporal trends across cycles were evaluated and weighted to represent the US adult population. **Results:** Cancer survivors report higher rates of prescription drug usage (85.1% vs 54.3%, p<0.001, and 75.8%, p<0.001) and polypharmacy (27.8% vs 10.7%, p<0.001, and 22.7%, p<0.001) than both unadjusted and age-adjusted controls. Younger survivors report greater usage of CNS (36.8% vs 13.1%, p<0.001), psychotherapeutic (18.4% vs 7.7%, p<0.001), hormonal agents (19.1% vs 10.1%, p=0.003), and gastrointestinal (10.7% vs 4.7%, p=0.02) than controls, while differences are attenuated in older cohorts. Among broad drug categories, the usage of cardiovascular (p-trend<0.001), metabolic (p-trend<0.001), and immunologic agents (p-trend=0.01) has increased. Among CNS active subclasses, the usage of anticonvulsants (p-trend<0.001), anxiolytics (p-trend =0.02), narcotics (p-trend=0.02) and GABA analogs (p-trend<0.001) has increased. When comparing respondents with and without a history of cancer, the increased usage of anti-depressant prescription medications (18.3% vs 1.5% p<0.001), including SSRIs (11.2% vs 1.0%, p<0.001), SSNRIs (3.5% vs 0.3%, p<0.001), tricyclics (2.8% vs 0.1%, p<0.001), among cancer survivors was disproportionate compared to the increased proportion of positive depression screens (9.2% vs 7.0%, p=0.006). **Conclusions:** Cancer survivors report higher prescription drug use for both chronic conditions and late effects of cancer. The usage of CNS active medications, many of which are used on and off label for their pain management properties, has increased. The higher rates of pharmaceutical use may result in unanticipated long-term toxicities and financial burdens. Research Sponsor: None.

12024 Poster Discussion Session; Displayed in Poster Session (Board #312), Fri, 8:00 AM-11:00 AM, Discussed in Poster Discussion Session, Fri, 8:00 AM-11:00 AM

FDA analysis of ECOG performance status and safety outcomes. *First Author: Harpreet Singh, U.S. Food and Drug Administration, Silver Spring, MD*

Background: Patients with poor performance status are often excluded from clinical trials. The FDA has published several guidances on modernizing oncology clinical trial eligibility criteria to more accurately reflect the patient population. Many patients receiving novel oncology therapeutics are heavily pretreated, and often have comorbidities, organ dysfunction, and frailty syndromes. Little is known about the safety of novel therapeutics in patients with poor performance status. **Methods:** Data from six randomized trials (n=4465) leading to registration for several solid tumor and malignant hematologic cancers, including multiple therapeutic mechanisms of action, such as EGFR TKI's, immune checkpoint inhibitors (ICI), and chemotherapy, were pooled. Cumulative incidence of Grade 3-5 adverse events and serious adverse events at Days 30, 90, and 180 were evaluated based on ECOG 0-2. Rates of treatment discontinuation by ECOG was also examined. **Results:** Cumulative incidence of toxicity events at days 30, 90, and 180 are shown in Table. Patient dropout rates due to death were 3.9%, 6.7%, and 10.9%; dropout rates due to disease progression were 66.5%, 66.6% and 56.9%; and dropout rates due to reasons other than progression or death were 29.7%, 26.7% and 32.1% for ECOG PS 0, 1 and 2, respectively. **Conclusions:** This FDA exploratory analysis of safety outcomes in registration trials based on ECOG suggests increasing rates of adverse events and rates of treatment discontinuation due to death with worsening performance status. Discontinuation rates due to disease progression and other reasons did not appear to be worse for ECOG 2 compared to 0-1. These findings were consistent across therapies (targeted therapy, ICI, chemotherapy). All trials in the analysis led to FDA approval, thus inclusion of patients with ECOG 2 did not adversely affect the trial outcome for this set of FDA approved agents. ECOG performance status eligibility criteria should be evaluated and modified on a frequent basis during drug development. Additional analysis of trials which enroll patients with ECOG 2 is needed. Research Sponsor: None.

Cumulative incidence of AEs at days 30, 90, and 180.

	ECOG 0 (n= 1260)	ECOG 1 (n= 2402)	ECOG 2-3 (n=803)
Serious Adverse Events			
Day 30	14.6%	19.3%	29.1%
Day 90	24.9%	33.8%	44.3%
Day 180	30.2%	40.4%	50.6%
Grade 3-5 Adverse Events			
Day 30	32.3%	36.5%	47.8%
Day 90	49.5%	55.5%	63.1%
Day 180	56.2%	63.1%	68.1%

12025 Poster Session (Board #313), Fri, 8:00 AM-11:00 AM

Aggressive care at end-of-life in the Veteran's Health Administration versus fee-for-service Medicare among patients with advanced lung cancer. *First Author: Carolyn J Presley, The Ohio State University, Columbus, OH*

Background: The Veteran's Health Administration (VHA) allows simultaneous receipt of cancer treatment and hospice care, termed concurrent care, while fee-for-service Medicare does not. Although many physicians who care for patients in the VHA also care for private sector patients, it is unclear whether there is a "spillover" relation between end of life (EOL) care in the VHA and Medicare systems at the regional level. We examined temporal trends, as well as regional-level associations between Medicare and VHA EOL practice for patients with advanced lung cancer. **Methods:** We conducted a retrospective study on VHA and SEER-Medicare (SM) decedents from 2006-2012 with stage IV non-small cell lung cancer (NSCLC) who received any lung cancer care. Aggressive care (AC) at EOL was defined as any of the following within 30 days of death– intensive care unit (ICU) admission, no-hospice care, cardiopulmonary resuscitation(CPR), mechanical ventilation (MV), > 1 inpatient admission and receipt of chemotherapy. Descriptive statistics were used to compare outcomes. We also analyzed the association between Medicare hospital referral region (HRR) hospice admissions, Medicare HRR EOL spending, and VHA AC use adjusted for patient's characteristics using a random intercept mixed effect logistic regression model after matching VHA facilities with Medicare facilities in a particular HRR. **Results:** AC use significantly decreased during the study period, from 46% to 31% among 18,371 Veterans and from 42% to 38% among 25,283 in the SM cohort, (t-test $P < .05$). Hospice use significantly increased within both cohorts ($p < .001$). The receipt of chemotherapy at EOL was similar for both cohorts throughout the study period. Veterans who received care in regions with higher hospice admissions among Medicare beneficiaries were significantly less likely to receive AC at EOL (adjusted Odds Ratio (aOR): 0.13 95%CI: 0.08-0.23, $P < .001$) than veterans in regions with lower Medicare hospice use. Medicare HRR spending at the EOL was not associated with receipt of AC among Medicare beneficiaries (aOR): 1.004 95%CI: 1.00-1.009, P = 0.07). **Conclusions:** Perhaps due to availability of concurrent care, VHA patients received less aggressive care at EOL as compared to SM patients. At the regional level, greater hospice use among Medicare beneficiaries was significantly associated with reduced AC within the VHA. Research Sponsor: REDCap project and The Ohio State University Center for Clinical and Translational Science grant support(National Center for Advancing Translational Sciences, Grant UL1TR002733),Carolyn Presley is a Paul Calabresi Scholar supported by the OSU K12 Training, Other Foundation.

12026 Poster Session (Board #314), Fri, 8:00 AM-11:00 AM

Impact of palliative care on end-of-life outcomes in hematologic malignancies. *First Author: Ari Pelcovits, Brown University, Providence, RI*

Background: Patients (pts) with hematologic malignancies (HMs) receive more aggressive end-of-life (EOL) care and often die in the hospital. The impact of palliative care (PC) on EOL quality outcomes in HMs has not been well described. In 2017 we embedded a PC specialist within our inpatient malignant hematology team to facilitate the use of early PC. We sought to determine if this practice was accompanied by a shift in EOL outcomes. **Methods:** We conducted a retrospective review of pts diagnosed with acute myeloid leukemia (AML) at our institution in the 2 years before (Cohort A) and after (Cohort B) implementation of embedded PC. We identified pts who received PC and if it was early (during initial inpatient stay) or late (sometime after). We then examined EOL quality outcomes: hospitalizations and intensive care (ICU) admissions in the last 30 days of life, chemotherapy use in the last 14 days of life, and use of hospice and death out of hospital (DOH), using Fisher's exact test to compare proportions. **Results:** Among 139 AML pts, 46 in Cohort A, 93 in Cohort B, we identified 34 and 47 decedents in each cohort respectively. The use of PC was significantly higher in Cohort B (75% vs 43%, $P= 0.0006$), with a significant increase in early PC (52% vs 11%, $P < 0.0001$). There was no significant improvement in EOL quality outcomes between Cohort A and B, or uniquely among pts receiving early PC ($P > 0.05$); however, PC use in general across all cohorts was associated with significant increase in hospice use and fewer ICU admissions (P =0.016 and 0.0043, respectively). Among pts not receiving PC, a numerical improvement was noted in EOL metrics between Cohorts A and B ($P > 0.05$; see table). **Conclusions:** PC for pts with AML was associated with significantly better EOL quality outcomes. We also observed improvement in EOL metrics over time among pts not receiving PC, which may indicate a culture shift with the embedded PC service, whose benefit extended to pts not directly receiving PC. Embedding a PC specialist and early PC in AML, however, was not significantly associated directly with EOL care improvements. The value of these interventions in HMs may be better measured using patient-reported outcomes and quality of life measures rather than strict EOL outcomes. Further research should consider potential differential role of PC among pts with HM undergoing aggressive/curative, or non-intense/palliative therapy. Research Sponsor: None.

	Overall				No PC	
	Cohort A	Cohort B	PC	No PC	Cohort A	Cohort B
Hospice Use	59%	63%	72%	43%	31%	58%
DOH	55%	56%	65%	39%	29%	55%
Hospitalization	81%	85%	84%	83%	94%	69%
ICU Admission	32%	26%	17%	48%	59%	33%
Chemotherapy	32%	24%	25%	31%	35%	25%

12027 Poster Session (Board #315), Fri, 8:00 AM-11:00 AM

The adoption of immune checkpoint inhibitors and patterns of care at the end of life. *First Author: Fauzia Riaz, Stanford School of Medicine, Stanford, CA*

Background: As immune checkpoint inhibitors (ICIs) have transformed the care of patients with cancer, it is unclear whether treatment at end of life (EOL) has changed. Because aggressive therapy at EOL is associated with increased costs and patient distress, we explored the association between the FDA approvals of ICIs and treatment patterns at EOL. **Methods:** We conducted a retrospective, observational study using patient-level data from the Flatiron health EHR-derived de-identified database. Patients had advanced melanoma, non-small cell lung cancer (NSCLC) (cancer types with an ICI indication) or microsatellite stable (MSS) colon cancer (a cancer type without an ICI indication) and died between 2013 and 2017. We calculated annual proportions of decedents who received systemic cancer therapy in the final 30 days of life and used logistic regression to model the association between the post-ICI Federal Drug Administration (FDA) approval time period and use of systemic therapy at EOL, adjusting for patient characteristics. We also assessed the use of chemotherapy or targeted/biologic therapies at EOL, before and after FDA approval of ICIs using Pearson Chi Square test. **Results:** There was an increase in use of EOL systemic cancer therapy in the post-ICI approval period for both melanoma (33.9% to 43.2%, p-value < 0.001) and NSCLC (37.4% to 40.3%, p-value < 0.001). In contrast, the control group of decedents with MSS colon cancer demonstrated no significant increase in use of systemic therapy at EOL. After controlling for patient characteristics, there was a significantly higher odds of receiving systemic treatment at EOL in the post-ICI time period compared to the pre-ICI time period in melanoma (OR 1.42, 95% CI 1.09-1.86, p-value < 0.001) and NSCLC (OR 1.13, 95% CI 1.06-1.20, p value < 0.001), with no significant difference in receipt of systemic therapy in patients with MSS colon cancer. After FDA approval of ICIs, patients with NSCLC and melanoma had a decrease in the use of chemotherapy, with a concomitant increase in use of ICIs at EOL. Decedents with MSS colon cancer did not have a statistically significant change in use of chemotherapy or targeted/biologic therapies during the study period. **Conclusions:** The adoption of ICIs was associated with a substantive increase in the use of systemic therapy at EOL in melanoma, and a smaller yet significant increase in NSCLC. Research Sponsor: U.S. National Institutes of Health.

12028 Poster Session (Board #316), Fri, 8:00 AM-11:00 AM

Impact of performance status on response and survival among patients receiving checkpoint inhibitors for advanced solid tumors. *First Author: Mridula Krishnan, University of Nebraska Medical Center, Omaha, NE*

Background: Clinical trials leading to the approval of immune checkpoint inhibition (ICI) have almost exclusively been performed in patients with good performance status (ECOG PS of 0-1). However, ICI remains an attractive option for patients with advanced tumors and poor performance status, considering their overall tolerability. While use of ICI in patients with poor PS (ECOG PS of 2 or greater) has been rapidly adopted, whether these patients derive the same benefits as expected in the studied populations is largely unknown. We therefore performed an institutional retrospective analysis of all patients treated with palliative single agent anti-PD1 or anti-PDL1 to determine response and survival for those with poor performance status. **Methods:** We retrospectively identified patients with advanced solid tumor malignancies who were treated with ICI monotherapy with palliative intent at our institution between 2015-2019. The primary objective was to compare overall survival (OS) for patients with good PS (ECOG PS 0-1) with those with poor PS (ECOG PS 2 or 3-4). The log-rank test compared the survival among patients with different ECOG PS. In addition, we used a proportional hazards model to assess association between ECOG PS and the OS with adjustment for age, gender, and smoking status. A secondary objective was to compare overall response rates (ORR) of the three ECOG PS groups which were evaluated with a binary rate model. **Results:** We identified 266 patients treated with ICI, 87 with NSCLC, 34 with melanoma, 33 with RCC, 24 with bladder cancer, 22 with head/neck cancer, and the rest with other histologies. 187 (70%) were ECOG PS 0-1, 62 (23%) were ECOG PS 2, and 17 (7%) were ECOG PS 3-4. 89 of these patients (33%) were still alive at time of last follow-up. Across all tumor types, patients with ECOG PS 0-1 had superior survival compared to ECOG PS 2 (median survival 12.4 months vs 4.6 months, HR 0.41, $p < 0.001$). Median survival for ECOG PS 3-4 was lower at 2.3 months. The ORR for ECOG PS 0-1 (23%) was significantly higher to that of ECOG PS 2 (6%, $p = 0.02$). ORR for ECOG PS 3-4 was 12%. **Conclusions:** Despite the appeal of ICI for patients with advanced malignancy and poor performance status, outcomes were poor. Survival and objective response rates for patients with ECOG PS 2 and higher were significantly worse than those with ECOG PS 0-1. ICI treatment comes with cost, including potentially forgoing early hospice referral or optimal support at the end of life. Prospective trials defining the activity and role of ICI in poor PS are urgently needed. Research Sponsor: None.

12029 Poster Session (Board #317), Fri, 8:00 AM-11:00 AM

Prospective study comparing self-administered geriatric assessment to provider's routine clinical assessment of older patients with metastatic breast cancer treated at community oncology practices. *First Author: Rino S. Seedor, Fox Chase Cancer Center, Philadelphia, PA*

Background: Geriatric Assessment (GA) is recommended for evaluating an older cancer patient's (pt) fitness for treatment. We conducted a prospective study evaluating the current gaps that exist in the assessment of older pts with metastatic breast cancer (MBC) in community practices (CP). **Methods:** Self-administered validated GA was compared to provider assessment (PA) of MBC pts $\geq$ 65-years-old treated at CP in the US. Providers were blinded to the GA results until their evaluation was completed. Differences in PA vs GA detected abnormalities were assessed using McNemar's test. The effect of patient/provider factors on the rate of abnormalities not identified was assessed using regression models, clustering by provider and adjusting for the number of prior pts seen. **Results:** 100 pts were enrolled across 9 CP (median age 73.9, (65-90)). GA detected a total of 356 abnormalities in 96/100 (96%) pts, of which 223 required immediate interventions. African American and widowed/single pts were more likely to have abnormalities identified by GA. On average PA did not identify abnormalities detected by validated GA in 2 of 8 domains. 73% of functional status, 86% of social support, 44% of nutritional, and 96% of cognitive abnormalities detected by GA were not identified by PA (all $P < 0.0001$). Providers with more years of clinical experience were more likely to identify abnormalities (compared to < 5 years (y) in practice: 5-10 y in practice, $p = 0.149$; 11-15 y in practice, $p = 0.028$; > 15 y in practice, $p = 0.017$). GA had the most significant impact on pts with decreased ECOG PS ($p = 0.045$). Pts found to have an abnormal Timed Up and Go (TUG) test were more likely to have additional abnormalities in other domains (mean 4.3 vs 2.1, Wilcoxon $p < 0.001$), and more abnormalities not identified by the PA ($p < 0.001$). Providers were "surprised" by GA results in 33% of cases, mainly with cognitive or social support findings, and reported plans for management change for 40% of pts based on GA findings. **Conclusions:** Including a GA in the care of older pts with MBC in CP is beneficial as validated GA has a high detection rate of abnormalities not detected by PA. Research Sponsor: NCCN and Pfizer Independent Grants for Learning & Change Metastatic Breast Cancer.

12030 Poster Session (Board #318), Fri, 8:00 AM-11:00 AM

Development and validation of an early death risk score for older patients treated with chemotherapy for cancer. *First Author: Jaime Feliu Batlle, Medical Oncology Department, Hospital Universitario La Paz, Madrid, Spain*

Background: Determining life expectancy in older patients is needed to select the best treatment strategy. We aimed to develop and validate a score to predict early death risk (< 6 months) in elderly patients with cancer that are planned to initiate chemotherapy treatment. **Methods:** Patients over 70 years starting new chemotherapy regimens were prospectively included in a multicenter study. A pre-chemotherapy assessment that included sociodemographics, tumor/treatment variables, and geriatric assessment variables, was performed. Association between these factors and early death was examined by using multivariate logistic regression. Score points were assigned to each risk factor based on their b coefficient. We validated the risk score with an external validation cohort of 206 patients. **Results:** Three hundred forty two patients were included in the training cohort. The independent predictors for early death were metastasic cancers (odds ratio [OR] 4.8, 95% confidence interval [CI], [2.4-9.6]), ECOG performance status (OR 2.3, 95% CI:1.084-5.232), ADL (OR 1.7, 95% CI:1.08-3.5), serum albumin levels (3.3, 95% CI: 1.6-6.6), BMI (OR 2.4, 95% CI:1,2-4.8), serum GGT levels (OR 1.5, 95% CI:1.05-1.8) and hemoglobin levels (OR 2.3, 95% CI:1.2-4.6). With these results, a score was to stratify patients regarding their risk of early death: low (0 to 2 points; 5%), intermediate (3 to 5 points; 19%) or high (6 to 14 points; 50%) ($p < 0.001$). The area under the curve of the receiver-operating characteristic (ROC) curve was 0.79 for the training cohort (95% CI, 0.74 to 0.85), and 0.70 (95% CI: 0.60-0.80) for the validation cohort (difference between cohorts not statistically different). **Conclusions:** We developed a highly accurate tool that uses basic clinical and analytical information to predict the probability of early death in elderly patients with cancer that are planned to initiate chemotherapy treatment. This tool can help physicians in decision making for this population of patients. Research Sponsor: None.

12031 Poster Session (Board #319), Fri, 8:00 AM-11:00 AM

Is there a benefit of immune checkpoint inhibitors for patients over 75 years of age with advanced cancer in first and second line setting: A meta-analysis. *First Author: Thierry Landre, UCOG-HUPSSD-APHP, Paris, France*

Background: The impact of aging on Immune Checkpoint Inhibitors (ICIs) effectiveness is controversial. Currently, data from clinical studies do not show any difference between patients over 65 years and those under 65 years. We propose to compare the clinical benefit of ICIs in those over 75 and in those under 75. **Methods:** We performed a meta-analysis of published randomized control trials (RCTs) concerning ICIs versus standard therapy in patients with advanced solid tumours. Overall Survival (OS) among the older ($\geq$75 years) was compared with that of younger patients (< 75 years) in first and second line setting. Hazard ratios (HRs) with their 95% confidence interval (CI) were collected from the studies and pooled. **Results:** Fifteen phase III studies evaluating anti-PD-1 (nivolumab or pembrolizumab), anti-PD-L1 (atezolizumab or avelumab) or anti-CTLA-4 (ipilimumab) were included. Patients were enrolled for Non-Small-Cell-Lung-Cancer, Renal-Cell-Carcinoma, Melanoma, Head-and-Neck-Squamous-Cell-Carcinoma or Gastric-Cancer. Eight studies assessed treatment in first line setting and seven in second line. The median age was 64 years, with 906 patients over 75 years of age and 5233 younger. In first line setting, HRs for death were 0.78 (95% CI: 0.61-0.99) in patients $\geq$75 years versus 0.84 (95% CI: 0.71-1.00) in younger. In second line setting, HRs for death were 1.02 (95% CI: 0.77-1.36) in patients $\geq$75 years versus 0.68 (95% CI: 0.61-0.75) in younger with a statistically significant difference observed between subgroups (p interaction = 0.009). **Conclusions:** ICIs appears to be effective in patients over 75 years of age. However, the survival benefit comes mainly from the first line of treatment. This result encourages the use of ICIs early in the therapeutic management of patients over 75 years of age. Research Sponsor: None.

12032 Poster Session (Board #320), Fri, 8:00 AM-11:00 AM

Omission of adjuvant chemotherapy in elderly patients with early stage breast cancer. *First Author: Sung Jun Ma, Department of Radiation Medicine, Roswell Park Comprehensive Cancer Center, Buffalo, NY*

Background: Breast cancer incidence in elderly population over 70 years is anticipated to grow up to 35% by 2030. However, this elderly population is under-represented in the TAILORx (Trial Assigning Individualized Options for Treatment) with less than 5% of the entire study cohort. As the omission of radiation therapy among the elderly with favorable prognosis is a reasonable alternative option, omission of chemotherapy has not been prospectively investigated. To address this knowledge gap, we conducted an observational cohort study to evaluate the omission of chemotherapy in elderly patients with early breast cancer. **Methods:** The National Cancer Database (NCDB) was queried for patients above the age of 70 diagnosed with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, pT1-2N0 breast cancer who underwent hormone therapy with or without chemotherapy (2010-2015). Kaplan-Meier method and Cox multivariable analysis (MVA) were performed for survival analysis. Propensity score matching in a 1:1 ratio without any replacement was used to address selection bias. Sensitivity analysis was performed on a subgroup of those with a high 21-gene recurrence score (RS) $>$ 25. **Results:** A total of 12004 patients were identified, including 10802 and 1202 patients with and without adjuvant chemotherapy, respectively. The median follow up was 38.2 months (IQR 22.5-57.2). On univariate analysis, chemotherapy was not associated with improved overall survival (HR 0.96, p = 0.71), ineligible for inclusion in the final MVA model. On interaction analysis, the use of chemotherapy had no interaction with RS (p = 0.46), age (p = 0.08), tumor size (p = 0.23), tumor grade (p = 0.42), and comorbidity score (p = 0.22). On 1030 and 689 matched pairs for all RS and RS $>$ 25, respectively, there was no association of overall survival with chemotherapy (all RS: HR 0.76, p = 0.08; RS $>$ 25: HR 0.74, p = 0.10). **Conclusions:** For elderly patients with early stage breast cancer, the addition of adjuvant chemotherapy may not be associated with improved survival even in the setting of high RS $>$ 25. Given the toxicity profile of systemic therapy, shared decision making between clinicians and elderly patients is needed to individualize treatment options. Research Sponsor: None.

12034 Poster Session (Board #322), Fri, 8:00 AM-11:00 AM

Factors associated with referral for perioperative geriatric comanagement (GERI-CO) program in 12,398 older adults with cancer. *First Author: Armin Shahrokni, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: At ASCO 2019, we showed that the Memorial Sloan Kettering (MSK) Geriatric Co-management (GERI-CO) program was associated with improvement in 90-day postoperative mortality rate. Now, we present factors associated with the use of such program. **Methods:** At MSK, patients aged 75+ can be referred for perioperative GERI-CO. We retrospectively reviewed the available data of patients aged 75+ who underwent surgery within two months of their initial visit with the surgeon (2011 to 2019). Patients that were referred for GERI-CO were compared with those who were not: sociodemographic, frailty, comorbid conditions, and surgery characteristics. Frailty level was determined using the MSK Frailty Index (score ranges from 0-11, higher scores suggest more frailty). Multivariable regression analysis was used to assess factors associated with the use of the GERI-CO Program. **Results:** In total 12,398 patients (4422, 35.7% GERI-CO) were included. Average time from surgical consult to geriatric visit was 9 days. Patients in the GERI-CO program were older (80.7 vs. 79.6), less likely to be non-Hispanic White (87% vs. 91%), have English as primary language (84% vs. 89%), and be fit (12% vs. 17% with MSK-FI 0). They were more likely to have stroke history (5% vs. 4%), have diabetes (DM) (25% vs.20%), hypertension (78% vs. 71%), and peripheral vascular disease (14% vs. 12%), but less likely to have cardiac disease (22% vs. 26%), myocardial infarction (MI) (7% vs. 10%), pulmonary disease (13% vs. 16%). Patients referred for GERI-CO were more likely to undergo 3+ hours surgeries (25% vs. 8%), with 100+ cc intraoperative blood loss (41% vs. 22%), and hospital length of stay (LOS) of 3+ days (42% vs. 19%). In multivariable analysis, being frail (OR = 1.3 and 1.6 for MSK-FI 1-2 and 3+), longer surgery (OR = 2.6 and 3.6 for operation time 1.5-3 and 3+ hours), longer LOS (OR = 1.3 and 1.5 for LOS 1-2 and 3+ days), older age (OR = 1.06), having DM (OR = 1.15) were associated with higher likelihood of GERI-CO while having history of cardiac disease (OR = 0.55), MI (OR = 0.84), pulmonary disease (OR = 0.69) were associated with less likelihood of referral for GERI-CO. **Conclusions:** Our result shows the unique characteristics of patients managed in the GERI-CO program. This has implications for both implementation of GERI-CO program in other institutions and assessing outcomes of these patients. Research Sponsor: U.S. National Institutes of Health.

12035 Poster Session (Board #323), Fri, 8:00 AM-11:00 AM

Abbreviated geriatric assessment (GA) in new oncology patients and its association with early death. *First Author: Michael Maranzano, University of Chicago Medical Center, Chicago, IL*

Background: The ASCO 2018 Geriatric Oncology Guidelines support the broad application of GA to risk-stratify patients age ≥65 undergoing cancer-directed therapy. Despite this, GA has not been widely adopted due largely to perceived time and resource constraints. We administered an abbreviated GA by medical assistants (MAs) in an outpatient oncology clinic to explore its feasibility and correlation with adverse events. **Methods:** This is a single-institution, retrospective study of adults establishing oncology care at an academic medical center from 11/2016-4/2017. MAs completed an abbreviated GA of well-validated tests. Cognitive function was screened by the Mini-Cog (score $<$ 4) and physical function by the Five Times Sit-to-Stand Test (FTSST ≥ 15 seconds). Patient-reported Outcomes (PRO) screened for malnutrition by the Malnutrition Screening Test (MST ≥ 2), for vulnerability by Vulnerable Elders Survey (VES-13 ≥ 3) and for depression by Patient Health Questionnaire-4 (PHQ-4 $>$ 2). The first result within 3 months of the initial visit was used for analysis. ED visits, inpatient admissions and early death, defined as within the first 6 months from the initial visit, were collected from the electronic medical record. GA results and baseline characteristics were modeled for these events using univariate logistic regression. Multivariable regression was performed when univariate regression revealed at least 2 factors with p$<$ 0.1. **Results:** New patients 65+ years (n=304, median age 72) established care in our practice during this six-month period. Nearly all patients (n=285, 94%) completed at least one GA test. Fewer patients completed the Mini-Cog and FTSST (60% completed) compared to the PRO screenings (83-90% completed). Those with any positive GA screening test were nearly 3 times as likely to die within 6 months of their initial outpatient visit compared with those with no deficits (OR 2.95, 95% CI 1.11-9.30). Those with FTSST ≥ 15 sec or unable to complete were more likely to have an ED visit within 6 months (OR 2.40, 95%CI 1.04-5.46).No other individual screening test had a statistically significant association with adverse events. **Conclusions:** An abbreviated version of GA completed by MAs can be incorporated into new oncology patient visits for all older adults, and those with any abnormalities on screening tests had a higher likelihood of early death. Research Sponsor: None.

Adverse events by abbreviated GA.

	At Least 1 Positive Screening Test n = 143	All Negative Screening Tests n = 131
Death	15 (11%)	5 (4%)*
ED Visit	33 (23%)	28 (21%)
Admission	53 (37%)	52 (40%)

*p $<$ 0.05

12036 Poster Session (Board #324), Fri, 8:00 AM-11:00 AM

Association of geriatric comanagement with reduction in adverse surgical outcomes among patients 75 or older with cancer with prolonged hospital stay. *First Author: Armin Shahrokni, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: Patients with prolonged hospital stay following surgery are at higher risk of readmission, emergency room visits, and mortality. In our study, we assessed the relationship between Geriatric Comanagement (GERI-CO) and adverse outcomes among these patients. **Methods:** In a retrospective study, patients aged 75+ with cancer who had hospital length of stay longer than 75% of cohort (8 days or longer) postoperatively at Memorial Sloan Kettering Cancer Center from 2011-18 were studied. GERI-CO status was obtained from medical records. Differences in sociodemographic, frailty, surgery, and comorbid conditions between GERI-CO and non-GERI-CO patients were assessed. Frailty was assessed by Memorial Sloan Kettering Frailty Index, score 0 to 11, higher score reflective of more frailty. Composite adverse outcome is a composite score of 30-day readmission, or emergency room visit, or 90 day mortality. Multivariable regression analysis was used to assess the relationship between GERI-CO and postoperative adverse outcome. **Results:** In total 1118 patients (634, 56.7% in the GERI-CO) were included. Patients in GERI-CO were older (80.8 vs. 79.9), more likely to undergo 3+ hours of surgery (66% vs. 43%), have 100+ cc intraoperative blood loss (78% vs. 72%), and have liver disease (16% vs. 10%), but were less likely to have kidney disease (19% vs. 25%), cardiac disease (28% vs. 35%), myocardial infarction (8% vs. 12%), pulmonary disease (15% vs. 20%), ASA-PS 4+ (11% vs. 21%) compared to non-GERI-CO patients. Gender, Frailty and the rest of comorbid conditions, and average length of stay (15 days) did not differ between groups. GERI-CO patients were less likely to have 30-day hospital admission (11% vs. 18%), emergency room visit (14% vs. 22%), or 90 day mortality (6% vs. 15%), and composite adverse outcome (20% vs. 37%) compared to non-GERI-CO patients. In the multivariable analysis, after adjustment for age, frailty, ASA-PS, operation time, intraoperative blood loss, kidney, cardiac and pulmonary disease, patients in GERI-CO were less likely to have composite adverse outcome (OR = 0.57, p = 0.002). **Conclusions:** GERI-CO program for patients with prolonged length of stay following surgery is associated with reduced 30-day hospital readmission, emergency room use, and 90-day mortality. Research Sponsor: U.S. National Institutes of Health.

12037 Poster Session (Board #325), Fri, 8:00 AM-11:00 AM

Treatment patterns and outcomes by age in metastatic melanoma: A study of the National Cancer Database. *First Author: Justin Moyers, Loma Linda University Medical Center, Loma Linda, CA*

Background: Metastatic melanoma carries poor prognosis and traditional chemotherapy has limited efficacy. Immune checkpoint inhibitors (ICI) have drastically improved disease outcomes since first approved in 2011. Elderly patients were underrepresented in landmark early trials of ICI leading to limited clinical trial data on efficacy and treatment patterns in this population. We aimed to examine the real-world IO outcomes and demographics of elderly patients in the National Cancer Database. **Methods:** We queried the database for patients with stage IV melanoma diagnosed between 2011-2015 with survival data available. Patients were divided into receipt of immunotherapy (IO) or no receipt of IO; those without documentation were excluded. Cases were separated into 3 cohorts of age at diagnosis (60 years-old or younger, 61-74 years-old, and 75 years-old and greater). Descriptive variables were compared by Chi-squared analysis and survival analyses were performed by Kaplan-Meier method and log-rank test. **Results:** 11,265 cases met inclusion criteria: 4,117 aged 60 or less, 3,940 aged 61-74, and 3,208 aged 75 or older. Those receiving immuno-oncologic agents (IO) in all age groups showed a longer median OS (mOS) than those who did not receive IO (mOS overall 17.28 v 7.49; $p<0.01$). Survival was longer in all age cohorts when IO was received compared to not received; ages less than 60 (mOS 20.3 v 9.2m; $p<0.01$), ages 61-74 (mOS 15.5 v 7.8m; $p<0.01$), and ages 75 or greater (mOS 14.4 v 5.8m; $p<0.01$). A greater percentage of patients received IO in younger than older cohorts, 20.1% in $\geq$ 75, 37.6% in 61-74, and 42.3% in $\leq$ 60; $p<0.01$. Additional descriptive variables shown in the table were compared between the cohorts include care at academic or integrated cancer network, uninsured, Charlson-Deyo Comorbidity Index (CDCI) of 2 or greater, and documented inclusion of palliative care treatment. **Conclusions:** Substantial survival benefit is realized with IO in all age cohorts although elderly cohorts did not receive IO as often as younger cohort. Elderly patients experienced lower rates of care at academic/network cancer programs, lower uninsured rate, and higher CDCI. Research Sponsor: None.

Variable	Age Category ≤60 years	61-74 years	≥ 75 years	p-value
Patients (n)	4117	3940	3208	
Received Immunotherapy (%)	42.3	37.6	20.1	<0.01
Treated in Academic or Network Cancer Programs (%)	59.0	55.9	48.9	<0.01
Uninsured (%)	8.7	3.0	0.5	<0.01
CDCI of 2 or greater (%)	4.2	8.3	10.5	<0.01
Palliative care included in treatment (%)	4.2	3.2	4.2	0.14

12038 Poster Session (Board #326), Fri, 8:00 AM-11:00 AM

Metastasis free survival in older men with nonmetastatic castration-resistant prostate cancer treated with androgen receptor inhibitors: An FDA-pooled analysis. *First Author: Harpreet Singh, U.S. Food and Drug Administration, Silver Spring, MD*

Background: The FDA has approved three androgen receptor (AR) inhibitors for nonmetastatic castration-resistant prostate cancer (nmCRPC) based on improvements in metastasis-free survival (MFS). MFS is an earlier endpoint, defined as the time from randomization to either imaging-detectable distant disease or death. This pooled analysis examines MFS, time to initiation of cytotoxic chemotherapy (TTCyto), and safety outcomes in men over 80 treated with AR inhibitors. **Methods:** Data was pooled from three randomized controlled studies (n=4117) of AR inhibitors for nmCRPC. The treatment effect of AR inhibitors on MFS and TTCyto across age groups was evaluated using Kaplan-Meier estimates and a Cox proportional hazards regression model. Hazard Ratios for MFS and TTCyto were adjusted for baseline ECOG, total Gleason score, PSA doubling time, and prior bone-targeting therapy. **Results:** For patients age 80 years or older (n=675) who were treated with AR inhibitors, the hazard ratio was 0.38 (95% CI 0.29, 0.49) with an estimated median MFS of 40 months (95% CI 36, 41) versus 22 months (95% CI 18, 29) for those treated with placebo (n=348). For patients <80 (n=2019) treated with AR inhibitors, the HR was 0.31 (95% CI 0.27, 0.36) with an estimated median MFS of 41 months (95% CI 36, NR) versus 16 months (95% CI 15, 18) for those treated with placebo (n=1075). Patients over 80 also derived similar improvements in time to initiation of cytotoxic chemotherapy (HR 0.43 95% CI 0.23, 0.82), compared to their younger counterparts (HR 0.41 95% CI 0.33, 0.50). See Table for selected safety outcomes. **Conclusions:** In an exploratory subgroup analysis, older men (≥80) with nmCRPC derived similar benefit in MFS and time to initiation of cytotoxic chemotherapy with AR inhibitors compared with younger patients. Men age 80 and above experienced higher rates of Grade 3-4 adverse events, serious adverse events, falls, and fractures. This trend towards increased toxicity was observed regardless of treatment arm. Analysis of patient reported outcomes is ongoing. Research Sponsor: None.

Toxicity and selected adverse events of AR inhibitors by age.

	Androgen Receptor Inhibitors		Placebo	
	Age < 80 (n=2015)	Age ≥ 80 (n=672)	Age < 80 (n= 1073)	Age ≥ 80 (n=344)
Grade 1-2	1123 (55.7)	323 (48.1)	608 (56.7)	177 (51.5)
Grade 3-4	603 (29.9)	249 (37.1)	244 (22.7)	106 (30.8)
Serious Adverse Events	461 (22.9)	206 (30.7)	190 (17.7)	99 (28.8)
Falls	166 (8.2)	101 (15)	51 (4.8)	27 (7.8)
Fractures	157 (7.8)	70 (10.4)	41 (3.8)	35 (10.2)

12039 Poster Session (Board #327), Fri, 8:00 AM-11:00 AM

Hospitalizations following cancer diagnosis: National values for frequency, duration, and charges. *First Author: Michael T. Halpern, National Cancer Institute at the National Institutes of Health, Bethesda, MD*

Background: US medical care costs for cancer are projected to be $158 billion in 2020. Hospitalization is a substantial component of these costs; however, little is known about national patterns of hospitalization among individuals with cancer. This study used Medicare data to determine national rates and charges for hospitalizations among older cancer patients. **Methods:** We used data from 100% of individuals diagnosed with cancer in SEER-Medicare in the most recent 5 years available, 2011-2015. Analyses determined proportion of patients hospitalized, number/duration of hospitalizations, and charges by patient clinical and sociodemographic characteristics within 12 months of diagnosis. **Results:** Among 307,944 unique patients, 65% were hospitalized in the first year following diagnosis. Rates ranged from 34% for patients with in situ disease to 82%-84% for patients with advanced disease; 31% had 2 or more hospitalizations. Hospitalization rates were lowest among skin melanoma (25%) and breast (42%) cancer patients, highest for brain/nervous system (97%) and ovarian (96%) cancer patients. Hospitalized patients had a mean of 2.1 hospitalizations; mean days per hospitalization within 12 months was 8.8 (median 4). Duration of hospitalization varied little by stage at diagnosis. Mean days per hospitalization was shortest for thyroid and prostate cancer patients (5.7 & 6.0 days), longest for colorectal cancer and leukemia patients (10.6 & 11.3 days). DRGs varied substantially by cancer type; DRG for chemotherapy administration was more frequent among hospitalizations for patients with hematologic malignancies or distant stage disease. Mean Medicare charge (2016 $) per hospitalization was $67,368 (median $41,973), and was lowest for breast cancer patients ($48,021), highest for leukemia patients ($91,799). Patient charges per hospitalization averaged $1107 (median $1317) and showed little variation by cancer type or stage. **Conclusions:** Most older individuals experience at least one hospitalization within 12 months of cancer diagnosis. Frequency, duration, and charges of hospitalizations vary by cancer type and stage. This nationally representative information will aid in projecting cancer care costs and potential economic impacts of new therapies and treatment program. Research Sponsor: None.

12040 Poster Session (Board #328), Fri, 8:00 AM-11:00 AM

Communication about comorbidities among 527 older patients with advanced cancer and their oncologists and caregivers: A multisite cluster-randomized controlled trial. *First Author: Amber Kleckner, University of Rochester Medical Center, Rochester, NY*

Background: Older patients with advanced cancer often have comorbidities that increase the risk of toxicity from neoplastic therapy but are not always considered in treatment planning. We assessed the utility of a geriatric assessment (GA) intervention to increase the number and quality of discussions about comorbidities among oncologists, older patients, and caregivers. **Methods:** This multi-site trial enrolled patients who were ≥70 years, had advanced solid tumors or lymphoma, had ≥1 GA impairment, and who were considering or receiving cancer treatment. All patients received the GA and completed an Older Americans Resources and Services Comorbidity survey, which evaluated 15 conditions and interference with activities (clinical impairment = ≥3 comorbidities or ≥1 highly interfering). Oncology practices were randomized to intervention (GA with a summary with management recommendations provided to oncologists) or usual care (GA only). The clinic visit after GA was audio-recorded, transcribed, and coded for GA topics including comorbidity. Generalized linear mixed models adjusting for site (random effect) were used to assess the effect of the intervention. **Results:** Patients (n=527 evaluable, 76.6±5.2 years, 49% female) and oncologists (n=131, 63 in intervention) were enrolled from 31 sites. In total, 94.5% of patients had ≥1 comorbidity with an average of 3.2±1.9; 64% were clinically impaired by comorbidity (p=0.76 between arms). The intervention arm had twice the number of conversations about comorbidities (1.02 vs. 0.52 conversations per patient, difference 0.50, 95% CI 0.18-0.81, p=0.004) and conversations were more likely to be initiated by the oncologist ($p<0.001$, Table). Moreover, among patients who had conversations about comorbidities, more patients in the intervention arm had discussions specifically addressing comorbidities (e.g., cancer treatment modification, communication with the primary care physician; 24.3% vs. 7.5%, p=0.003). **Conclusions:** Providing oncologists with a GA summary and recommendations encouraged them to engage in more discussions about their patients' comorbidities with the goal of addressing interactions between comorbidities, cancer, and its treatments. Funds: PCORI CD4634, NCI UG1CA189961 Clinical trial information: NCT02107443. Research Sponsor: U.S. National Institutes of Health, Patient-Centered Outcomes Research Institute.

No. of comorbidity-related discussions during a clinic visit (unadjusted).

Conversation initiator	Usual care (n=14 sites 243 patients)	Intervention (n=17 sites 284 patients)
Oncologist	71	243
Patient	45	42
Caregiver	6	17
Other	4	3
Total	126	305

12041 Poster Session (Board #329), Fri, 8:00 AM-11:00 AM

Gait speed and recommended treatment intensity among older adults with blood cancers. *First Author: Andrew Hantel, Dana-Farber Cancer Institute, Boston, MA*

Background: Gait speed identifies frailty and predicts survival among older adults with hematologic malignancies (Liu, *Blood*, 2019). It is not known if gait speed correlates with the intensity of oncologists' recommended treatment in this population. **Methods:** From 2/2015-11/2019, patients ≥75 years presenting for an initial hematologic malignancy consultation at the Dana-Farber Cancer Institute were approached for a screening frailty assessment including a 4-meter gait speed test, reported as <0.4, 0.4-0.6, 0.6-0.8, or >0.8 meters/second (m/s). Faster gait speed is associated with less frailty and predicts better survival. Gait speed was not reported to the oncologist. Treatment recommendations were categorized into standard, reduced, or no therapy based on NCCN guidelines, as applicable. Gait/treatment intensity "mismatches" were characterized as patients with lowest quartile gait speed recommended standard intensity and highest quartile not recommended standard intensity. Multivariable regression was performed to assess if gait speed predicted treatment intensity (controlling for age, sex, ECOG performance status [PS], and disease type). **Results:** Of 786 patients enrolled, 408 required active treatment where NCCN guidelines vary by fitness. Mismatches were seen in 26.7% of patients (Table: column percentages with 95% CI, mismatches starred): 10 (21.3%) with lowest quartile gait speed recommended standard intensity and 99 (55.0%) with highest quartile recommended reduced or no therapy. In multivariable analysis, PS was predictive of no therapy as compared to standard intensity (all $p<0.02$) and age was predictive of reduced as compared to standard intensity ($p<0.01$); gait speed was not reliably predictive in either case. **Conclusions:** In this large cohort of older adults with hematologic malignancies, gait/treatment intensity mismatches occurred in over one-quarter of patients. Oncologists' recommendations were predicted by age and PS but not gait speed. Given that gait speed is a strong predictor of survival in this population, oncologists should integrate it to minimize over- and under-treatment when making treatment recommendations. Research Sponsor: None.

		Gait Speed (m/s)			
		<0.4 (N=47)	0.4-0.6 (N=52)	0.6-0.8 (N=129)	>0.8 (N=180)
Recommended Treatment Intensity	No Therapy	10	7	13	4*
		21.3%	13.5%	10.1%	2.2%
		[11.8,35.3]	[6.5,25.7]	[5.9,16.6]	[8.3,5.8]
	Reduced Intensity	27	35	67	95*
		57.5%	67.3%	51.9%	52.8%
		[43.0,70.7]	[53.5,78.7]	[43.3,60.5]	[45.5,60.0]
	Standard Intensity	10*	10	49	81
		21.3%	19.2%	38.0%	45.0%
		[11.8,35.3]	[10.6,32.3]	[30.0,46.68]	[37.9,52.4]

12044 Poster Session (Board #332), Fri, 8:00 AM-11:00 AM

Investigating the disparate enrollment of older adults on phase I clinical trials: Evolving participation patterns of patients 65 years and older w advanced cancer on phase I trials. *First Author: Ishwaria Mohan Subbiah, The University of Texas MD Anderson Cancer Center, Houston, TX*

Background: While safety and dose-finding remain the primary objective of Phase 1 trials, the potential for clinical benefit has taken a greater meaning in the last decade with the novel therapies. With data from phase I trials being submitted for regulatory approval, the finer details of these studies are under even more scrutiny: in particular, do the trial participants reflect the general patient population for whom the drug may be indicated? To that end, we investigated age-based enrollment on phase I clinical trials over time. **Methods:** We queried a prospectively maintained database at a major phase I trials center to identify eligible patients and demographic + clinical variables including phase I trial characteristics, age at date of enrollment into 3 age-based cohorts: AYA ages 15-39y, mid-age 40-64y, older adults aged 65y+. We calculated descriptive statistics, and explored correlations (Pearson/Spearman) and associations (linear regression) between age and independent variables. **Results:** Over a 3-year period (1/1/17 to 12/31/19), we identified 6267 pts enrolled on 338 phase I trials. Median overall age 58.4y (range 15.5-95.1y). 729 (12%, median age 34.8y) were AYA, 3652 (58%, median age 55.4y) mid-age and 1886 (30%, median 70y) older adults, of whom 870 pts were aged 70-79y and 76 pts aged 80y+ (18 being >85y). There was no association b/w senior participation and year of enrollment (2017 31%, 2018 29%, 2019 30%, b/w age and type of therapy (i.e. targeted vs immunotherapy, etc.) or b/w age and # of drugs given on trial (single agent vs combo) (all $p > 0.05$). **Conclusions:** Older adults remain underrepresented on phase I trials esp. when compared to incidence of cancer in that age group (30% enrollment vs 60% incidence), a discordance more staggering in the oldest old pts (85y+; only 18 pts enrolled over 3 yrs when compared to 140,690 pts 85y+ w a new cancer dx in just 2019). Once enrolled, older adults received similar types of phase I therapies with comparable number of drugs as compared to middle age patients, i.e. older adults were just as likely to get immunotherapy or targeted therapy as well mono- vs combo therapy as mid-age pts. Research Sponsor: None.

Types of Therapy	Older adult	%	Midage	%
Immunotherapy agent(s)	**662**	**35%**	**1292**	**35%**
Single Agent IO	286	43%	585	45%
Combo IO	376	57%	707	55%
Chemotherapy	**49**	**3%**	**79**	**2%**
Single Agent	47	96%	77	97%
Combo	2	4%	2	3%
Targeted	**801**	**42%**	**1566**	**43%**
Single Agent	633	79%	1260	80%
Combo	168	21%	306	20%
Immuno+Targeted	**259**	**14%**	**463**	**13%**
Targeted+Chemo	**85**	**5%**	**171**	**5%**
Other (biologics, combo)	**30**	**2%**	**81**	**2%**

12045 Poster Session (Board #333), Fri, 8:00 AM-11:00 AM

Association of geriatric conditions with survival and health care use in older adults with colon cancer living in long-term care facilities. *First Author: Daniel E Lage, Harvard Medical School, Boston, MA*

Background: Older adults with colon cancer residing in nursing homes are at risk for experiencing geriatric conditions such as cognitive decline, limitations in activities of daily living (ADLs), needing pain medications, and incontinence, due to cancer and its treatment. We sought to investigate these factors pre- and post-diagnosis and explored their relationship with health care use and survival. **Methods:** We identified 483 patients age 65+ with colon cancer from 2011-2015 in SEER-Medicare with linked quarterly nursing home assessments from the Minimum Data Set both pre- and post-cancer diagnosis. We determined the number of geriatric conditions (cognitive functioning, limitation in any ADL, pain medication use, bowel/urinary incontinence) at the pre- and post-cancer diagnosis assessment. We created four groups based on changes in these factors from pre- to post- assessment: improved (n = 105), worsened (n = 25), remained limited (n = 240), never limited (n = 113). Regression models estimated how changes from pre- to post-cancer diagnosis were associated with number of emergency department (ED) visits, hospitalizations, and survival, adjusted for age, sex, race/ethnicity, insurance status, cancer stage, number of pre-cancer comorbidities, urban/rural status, and time from diagnosis. **Results:** Overall, 55.3% of patients were age > 80 at diagnosis, with 64.8% female; 73.3% non-Hispanic white; and 9.9% Stage IV. Pre- versus post-diagnosis, 20.7% vs. 34.8% of patients were limited in cognitive functioning, and 75.4% vs. 77.8% were limited in ADLs. About a third of patients required pain medication, and about half of patients had urinary incontinence, which did not change pre- and post-diagnosis. Patients who remained limited had higher rates of ED visits (Risk ratio [RR] 1.05, $p < .01$) compared to those never limited. Those who worsened had higher rate of hospitalization (RR 1.44, $p < .01$) and ED visits (RR 1.63, $p < .01$). 12-month and 5-year survival was 46.7% and 6.1%, respectively. Factors associated with worse survival in a multivariable model included: remaining limited at both assessments (OR 1.52, $p < .01$), worsening from prior (OR 2.00, $p = .01$), as well as older age and higher cancer stage. **Conclusions:** Older adults with colon cancer residing in nursing homes have high prevalence of geriatric conditions and differential health care use and survival based on the presence of geriatric conditions, highlighting the need to consider geriatric conditions when providing cancer care to this population. Research Sponsor: American Cancer Society.

12046 Poster Session (Board #334), Fri, 8:00 AM-11:00 AM

Use of self-rated health to identify frailty and predict mortality in older adults with cancer. Results from the care study. *First Author: Mustafa Al Obaidi, University of Alabama at Birmingham, Birmingham, AL*

Background: Poor self-rated health (SRH) is a known predictor of mortality in the general adult population, but little is known about its use in older adults with cancer. The purpose of this study was to examine the association and ability of SRH to identify frail older adults and assess its ability to predict mortality in older adults with cancer. **Methods:** Using participants from the Cancer & Aging Resilience Evaluation (CARE) Registry who had undergone a geriatric assessment, we examined SRH using a single-item from the Patient-Reported Outcomes Measurement Information System (PROMIS) global health scale. SRH scores were dichotomized into Poor (poor and fair) and Good (good, very good, and excellent). Multivariable logistic regression analyses were used to examine associations between SRH and frailty (based on frailty index) and specific geriatric impairments adjusting for age, sex, comorbidity, cancer type and stage. Finally, the impact of SRH on all-cause mortality was assessed with a multivariable cox regression model. **Results:** A total of 708 participants with malignancy were included, median age was 68y, 41.5% male, and 74.6% White. Colorectal cancer was the most common cancer (27.1%) and 48.2% of the participants had Stage IV disease. Poor SRH was reported by 42% of participants and was associated with significantly higher odds of frailty (adjusted Odds Ratio [aOR] = 21.8; 95%CI 13.7-34.8). Similarly, poor SRH was independently associated with higher odds of impairments in Activities of Daily Living (ADL) (aOR = 5.6, 95%CI, 3.6-8.9), independent ADL (aOR = 8.4, 95%CI, 5.8-12.4), cognition (aOR = 4.6, 95%CI 2.3-9.3), malnutrition (aOR = 4.5, 95%CI 3.2-6.4), falls (aOR = 3.6, 95%CI 2.4-5.4), anxiety (aOR = 4.6, 95%CI 2.9-7.3), and depression (aOR = 5.4, 95%CI 3.0-9.7). The SRH demonstrated high sensitivity (84.3%) and specificity (78.4%) for identifying frailty, with a positive predictive value of 67% and negative predictive value of 90.6%. The 1y survival rate in those with Poor SRH was significantly worse (64.7% *vs* 84.3%, log rank p value < 0.001). In a multivariate cox regression analysis, poor SRH remained an independent predictor of worse survival (adjusted Hazard Ratio 2.29 [1.6-3.2], $p< 0.01$) after adjusting for age, sex, race, cancer type, stage, comorbidity, and planned treatment. **Conclusions:** Poor SRH is highly associated with frailty and could be a simple tool to identify frail older patients with cancer at risk for adverse events and increased mortality. Research Sponsor: U.S. National Institutes of Health.

12047 Poster Session (Board #335), Fri, 8:00 AM-11:00 AM

Geriatric assessment (GA) predictors of 1y mortality in older adults with gastrointestinal (GI) malignancies: Results from the CARE study. *First Author: Grant Richard Williams, University of Alabama Birmingham, Birmingham, AL*

Background: Chronologic age is an imperfect predictor of morbidity and mortality in older patients with newly-diagnosed GI malignancies. Identifying patients with GI malignancies that are at increased risk of mortality within the 1st year remains challenging given no prior studies have focused on this population, yet is critical to developing personalized treatment plans. To fill this gap, we examined predictors of 1y mortality using variables from a patient-reported GA in a prospective cohort of older adults with GI malignancies. **Methods:** Cancer and Aging Resilience Evaluation (CARE) is a prospective registry of older adults (≥60y) with cancer seen at UAB (J Geri Onc 2019; PMID 31005648). Patients with GI malignancies with GA completed within the timeframe of 3 mo. before and up to 6 mo. after diagnosis were included. Vital status (up to 12/7/2019) was ascertained by linking participants to LexisNexis. Multivariable Cox regression analysis was used to estimate associations between GA variables and 1y mortality, adjusting for age at cancer diagnosis, race, cancer stage (IV *vs.* I-III), cancer group (high risk: pancreatic, hepatobiliary, esophageal *vs.* low risk: colorectal, GIST, neuroendocrine, etc.), and planned chemotherapy (yes/no). **Results:** A total of 356 participants met eligibility criteria. Mean age at enrollment was 70y; 56.4% were females; 25% black; 47.1% had high-risk cancers. In unadjusted analysis, high-risk cancers, cancer stage, malnutrition, impaired performance status, limitations in social activities, impaired instrumental activities of daily living (IADL), physical health, mental health, anxiety, and ≥3 comorbidities were associated with higher 1y mortality. Our base model (demographic and clinical variables) demonstrated good discrimination (c statistic 0.758), but was improved with the addition of all significant GA variables (c-statistic 0.810). Fatigue and malnutrition were identified as the strongest predictors among the GA variables, and a model adding those to the base model retained high discrimination (c-statistic 0.804). The estimated 1yr survival was 53.1% for those with both fatigue and malnutrition compared to 88.1% in those with neither. **Conclusions:** Among older adults with GI malignancies, malnutrition and fatigue were the strongest GA predictors of 1yr mortality after adjusting for age and clinical factors. These findings provide evidence for developing targeted interventions in older patients with newly-diagnosed GI malignancies to reduce 1y mortality. Research Sponsor: U.S. National Institutes of Health.

12048 Poster Session (Board #336), Fri, 8:00 AM-11:00 AM

Association between chronological age and geriatric assessment (GA) to identify deficits in elderly adults with cancer: Findings from the Care Registry. *First Author: Grant Richard Williams, University of Alabama Birmingham, Birmingham, AL*

Background: Although ASCO and NCCN guidelines recommend that adults with cancer diagnosed at age ≥65y undergo a GA, the association between chronologic age and GA identified deficits remains understudied, and thus, the appropriate age cut-off for employing GA in clinical settings remains unknown. We addressed this gap by examining the association between chronologic age and GA deficits in older adults with cancer. **Methods:** The Cancer and Aging Resilience Evaluation (CARE) is an ongoing prospective registry of older adults (≥60y) with cancer at a single site. Eligible patients underwent a patient-reported GA adapted from the Cancer and Aging Research Group. The association between age categories (10y increments) and presence of GA deficits was tested using chi-squared tests of trend. Linear association between age and GA deficits was examined using Pearson correlation. **Results:** The median age at enrollment was 70y (60-96) for 08 participants; 58% were male. Most common cancer types were colorectal (27%), pancreatic (17%), and hepatobiliary (12%). No significant correlation was found between chronologic age and the number of GA deficits (r = 0.03). There was no association between the youngest (60-70y) vs. the oldest age groups (≥80y) with respect to the prevalence of GA deficits: frailty (33% *vs.* 33%, *p*= 0.97); impairment of activities of daily living (ADL) (20% *vs.* 16%, *p*= 0.7);impairment of instrumental ADL (50% vs 60%, *p*= 0.3); malnutrition (42% *vs.* 33%, *p* =0.4), cognitive impairment (8% *vs.* 6%, *p*= 0.6), falls (19% *vs.* 30%, *p* 0.1), anxiety (19% *vs.* 11%, *p*= 0.1) and depression (13.4% *vs.* 13.7%, *p*= 0.2) (Table). Prevalence of 3+ comorbidities was higher in the older patients (45% *vs.* 59%, *p*= 0.03). **Conclusions:** In our cohort of older adults with mostly gastrointestinal malignancies, age was not associated with GA identified deficits and the prevalence of most impairments was similar across age-groups. The use of chronologic age alone to identify which patients may benefit from GA is problematic, and adults 60yrs and above, or perhaps even younger, may derive benefits from a GA. Research Sponsor: U.S. National Institutes of Health.

	Age 60-70	Age 70-79	Age ≥80	*p* value
No. of patients	**422**	**223**	**63**	
Frail	140 (33%)	76 (34%)	21 (33%)	0.97
Comorbidity > = 3	180 (45%)	114 (54%)	34 (59%)	**0.03**
Any IADL impairment	210 (50%)	112 (50%)	38 (60%)	0.29
Any ADL impairment	85 (20%)	44 (20%)	10 (16%)	0.73
Malnutrition	178 (42%)	90 (40%)	21 (33%)	0.41
Falls > = 1	81 (19%)	45 (20%)	19 (30%)	0.13
Cognitive Impairment	33 (8%)	13 (6%)	4 (6%)	0.63
Anxiety	81 (19%)	30 (13%)	7 (11%)	0.08
Depression	54 (13%)	19 (9%)	8 (13%)	0.25

12049 Poster Session (Board #337), Fri, 8:00 AM-11:00 AM

An international cohort study investigating the impact of age on clinical outcome in patients with hepatocellular carcinoma treated with sorafenib. *First Author: Rohini Sharma, Imperial College London, London, United Kingdom*

Background: There is no consensus on the effect of sorafenib dosing on efficacy and toxicity in elderly patients with hepatocellular carcinoma (HCC). Older patients are often empirically started on low dose therapy with the aim to avoid toxicities whilst maximising clinical efficacy. We aimed to verify whether age impacts on overall survival (OS) of patients with HCC, and whether a reduced starting dose of sorafenib impacts on OS or rates of toxicity experienced by the elderly. **Methods:** In this international, multicentre cohort study, patients with a confirmed diagnosis of advanced-stage HCC receiving sorafenib were recruited from seven specialist centres. Demographic and clinical data including development and grade of sorafenib toxicity and sorafenib starting dose were collected prospectively. Survival time (months) was recorded prospectively. Outcomes for those < or > 75 years were determined **Results:** A total of 5598 patients were recruited; 792 (14.1%) were over the age of 75. The elderly were more likely to have larger tumours (> 7cm)(39 vs 33%, p = 0.07) with Child-Pugh A liver function(67 vs 57.7%) and less portal vein thrombosis compared to those < 75years(22.1 vs 29.4)(p < 0.001). They were more likely to be commenced on lower starting dose of sorafenib i.e 400mg/200mg (38.7 vs 37.2%, P < 0.01). In terms of OS, there was no difference in the median OS of those >75 years and patients < 75 (7.3months vs 7.2months; HR 0.98 (95% CI 0.90–1.06), p = 0.63). There was no relationship between starting dose of sorafenib, 800mg vs 400mg/200mg, and OS between those < or > 75years. The elderly experienced a similar incidence of grade 2-4 sorafenib-related toxicity compared to < 75years(74.3 vs 61.7%, p = 0.051)(except for anorexia (14.0 vs 7.2%, p < 0.01) and rash (3.1 vs 6.3%, p < 0.05), irrespective of the dose prescribed. The elderly were more likely to discontinue sorafenib due to toxicity (27.0 vs 21.6%, p < 0.01). This did not vary between different starting doses of sorafenib. The mean duration of treatment was similar between those < and > 75 and, again, the starting dose of sorafenib did not affect treatment duration in the elderly. **Conclusions:** The median OS in the elderly is the same for that of patients under 75 years and is independent of the dose of sorafenib prescribed. Therefore, sorafenib should be offered to elderly patients and they should not be excluded from therapy Research Sponsor: None.

12050 Poster Session (Board #338), Fri, 8:00 AM-11:00 AM

External validation of two predictive scores of chemotherapy toxicities among older patients with solid cancer, from ELCAPA prospective cohort. *First Author: Maxime Frelaut, Institut Curie, Paris, France*

Background: Severe chemotherapy toxicities are frequent among older patients, and may have a major impact on mortality, comorbidities, and quality of life. Two scores were developed to predict severe toxicities: Chemotherapy Risk Assessment Scale for High-age patients (CRASH) score, and Cancer and Aging Research Group Study (CARG) score. The main objective of the present study was to evaluate the predictive value of both scores on an external cohort. Secondary objective was to identify individual predictive factors of severe chemotherapy toxicities. **Methods:** The Elderly Cancer Patients (ELCAPA) survey consists in a prospective cohort including patients aged 70 years or older referred for a geriatric assessment (GA) before anticancer treatment, such as chemotherapy for solid cancer. CARG and CRASH score were retrospectively collected. Main endpoint was grade 3/4/5 toxicities for CARG-score, hematologic grade 4/5 and non-hematologic grade 3/4/5 toxicities for CRASH-score. Calibration and discrimination (Area Under ROC Curve, AUC) were evaluated. **Results:** From July 2010 to March 2017, 248 patients were included. Among them, 150 (61%) experienced severe toxicity as defined in CARG study, and 126 (51%) as defined in CRASH study. There was no increased risk of toxicity in intermediate and high risk groups of CARG-score compared to low risk group (OR = 0.3, $IC_{95\%}$ [0.1 – 1.4], *p*= 0.1; and OR = 0.4, $IC_{95\%}$[0.1 – 1.7], *p*= 0.2 respectively, AUC-ROC = 0.55). Similarly, there was no more risk of severe toxicities in intermediate low, intermediate high, and high risk groups compared to low risk groups of CRASH combined score (respectively OR = 1, $IC_{95\%}$ [0.3 – 3.6], *p*= 0.99; OR = 1, $IC_{95\%}$ [0.3 – 3.4], *p*= 0.9; OR = 1.5, $IC_{95\%}$ [0.3 – 8.1], *p*= 0.67; AUC-ROC = 0.52). A multivariate predictive model including cancer type, performance status (PS 0 *vs.* PS 1-2), number of severe comorbidities (Cumulative Illness Rating Scale for Geriatrics, CIRS-G, ≥1 grade 3 or 4 comorbidity), body mass index (BMI > 25 kg/m² protective *vs.* normal BMI), and Chemotox score (1 *vs.* 0) had an AUC of 0.78. **Conclusions:** Neither CARG nor CRASH score was predictive of severe chemotherapy toxicities in the ELCAPA cohort. There is a need to identify new predictors of chemotherapy toxicity in older patients with solid cancers. Research Sponsor: INCA (Institut national du Cancer), Canceropôle Ile de France and Gérontopôle Ile de France.

12051 Poster Session (Board #339), Fri, 8:00 AM-11:00 AM

Regaining a satisfactory quality of life and predicting functional decline after major cancer surgery in older adults: The Geriatric Oncology Surgical Assessment and Functional rEcovery after Surgery (GOSAFE) study. *First Author: Isacco Montroni, Degli Infermi Hospital, Faenza, Italy, Faenza, Italy*

Background: Older cancer patients value quality of life (QoL) and functional outcomes as much as survival but surgical studies lack specific data. The international, multicenter GOSAFE study (ClinicalTrials.gov NCT03299270) aims to evaluate patients' QoL and functional recovery (FR) after cancer surgery and to assess predictors of FR **Methods:** GOSAFE prospectively collected functional and clinical data before and after major elective cancer surgery on senior adults (≥70 years). Surgical outcomes were recorded (30, 90, and 180 days post-operatively) with QoL (EQ-5D-3L) and FR (Activities of Daily Living (ADL), Timed Up and Go (TUG) and MiniCog), 26 centers enrolled patients from February 2017 to April 2019. **Results:** 942 patients underwent a major cancer resection. Median age was 78 (range 70-95); 52.2% males, ASA III-IV 49%. 934 (99%) lived at home, 51% lived alone, and 87% were able to go out. Patients dependent (ADL $<$ 5) were 8%. Frailty was detected by means of G8 ≤14 in 68.8% and fTRST ≥2 in 37% of patients. Major comorbidities (CCI $>$ 6) were reported in 36% and 21% had cognitive impairment according to MiniCog (2.2% self-reported). 25% had $>$ 3 kg weight loss, 27% were hospitalized in the last 90 days, 54% had ≥3 medications (6% none). Postoperative overall morbidity was 39.1% (30 day) and 22.5% (90 day), but Clavien-Dindo III-IV complications were only 13.4% and 6.9% respectively. 30/90/180-day mortality was 3.6/6/8.9% (10/30/33% in patients with severe functional disability). At 3 months after surgery, QoL was stable/improved (mean EQ-5D index 0.78 was equivalent before vs. after surgery, while the EQ-5D VAS score $>$ 60 raised from 74.3% at baseline to 80.2%, $p < 0.01$). 76.6% experienced postoperative FR/stability. Logistic regression analysis showed that ASA 3-4, CCI≥7 and CD III-IV complications are significantly associated with functional decline while a G8 $>$ 14 has a positive association with functional recovery. Age is not associated with functional outcomes. **Conclusions:** The largest prospective study on older patients undergoing structured frailty assessment before and after major elective cancer surgery has shown that QoL remains stable/improves after cancer surgery. The majority of patients return to independence and G8 can predict functional recovery. Older patients with multiple comorbidities, high ASA score or postoperative severe complications are likely to functionally deteriorate after oncologic surgery Clinical trial information: NCT03299270. Research Sponsor: None.

12052 Poster Session (Board #340), Fri, 8:00 AM-11:00 AM

Living life post cancer treatment (LLPCT): An assessment of a 12-week multidimensional wellness intervention to improve quality of life and physical activity in cancer survivors. *First Author: Christopher C. Marino, University of Pittsburgh Medical Center, Pittsburgh, PA*

Background: Cancer survivors face unique health challenges with implications on health-related quality of life (HRQoL) and physical, social, and emotional well-being. With advancements in cancer treatment and aging populations, the prevalence of cancer survivors is expected to grow prompting the need for improved survivorship care delivery and comprehensive rehabilitative services. Living Life Post Cancer Treatment (LLPCT) is a community-based 12-week program that provides multidimensional support to patients of any cancer diagnosis transitioning from active treatment to post-treatment life. This single-arm intervention study aims to assess the program's impact on HRQoL and physical activity in cancer survivors. **Methods:** A total of 125 participants within 2 years of treatment completion were enrolled in a 12-week program comprised of 9 sessions of engaging workshops, personalized exercise training, and nutrition and psychosocial counseling with an interprofessional team of oncology providers, social workers, exercise trainers, and dietitians. The program consisted of 8 consecutive weekly sessions followed by a 1-month follow-up session at week 12. Ninety-six (77%) participants completed the eighth or ninth session of the program and were included in the analysis. A series of questionnaires were administered at baseline and weeks 8 and 12. Primary outcomes assessed were HRQoL using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire and physical activity using average daily steps by pedometer and 2-minute step test performance. **Results:** Among the 96 participants (mean age 60.4 ± 11.7) who completed the program, the majority were female, white, and married. Post-intervention median FACT-G scores significantly increased from baseline at weeks 8 (+8.8, $p = 0.002$) and 12 (+7.3, $p < 0.001$). Average daily steps by pedometer increased by 1063 ($p = 0.003$) and 1233 ($p = 0.015$) and 2-minute step test performance increased by 18 ($p < 0.001$) and 21 ($p < 0.001$) steps at weeks 8 and 12, respectively. Participants reported high levels of satisfaction and improved self-efficacy to incorporate lifestyle modifications. **Conclusions:** These findings suggest that this 12-week intervention improves HRQoL and step-based physical activity levels in cancer survivors and could serve as a multidimensional model for post-treatment support. Further research is needed to determine if these benefits are sustained long-term. Research Sponsor: Our Clubhouse is a community-based non-profit organization funded primarily by individual contributions and partnerships with regional healthcare systems, specifically University of Pittsburgh Medical Center, Allegheny Health Network, and Excela Health.

12053 Poster Session (Board #341), Fri, 8:00 AM-11:00 AM

The impact of weight loss on physical function in overweight or obese breast cancer survivors. *First Author: Jennifer Y. Sheng, Johns Hopkins Hospital, Baltimore, MD*

Background: In the prospective POWER-remote trial, 51% and 12% of overweight/obese breast cancer survivors randomized to either a remotely delivered behavioral intervention or self-directed approach, respectively, lost ≥5% of baseline weight. We collected patient-reported outcomes (PROs) to examine the impact of >5% weight loss on symptoms, physical function (PF), and wellbeing. We hypothesized *a priori* that, regardless of study arm, those with ≥5% weight loss would have improved PF at 6 months v. those who did not. **Methods:** Women with stage 0-III breast cancer, who completed local therapy and chemotherapy, with a BMI ≥25 kg/m^2 were randomized to the 12-month intervention or self-directed weight loss. POWER-remote consists of telephone coaching and online tracking of diet, activity and weight. Women in the self-directed arm received a lifestyle booklet. All women completed PROs at baseline, 6 and 12 months: PROMIS PF, pain, fatigue, anxiety, depression, sleep; FACT-endocrine symptoms; MOS-sexual function. PROs were summarized descriptively and changes within and between groups were tested with multivariable mixed effects models, adjusted for age and baseline weight. **Results:** From 2013-2015, 96 women enrolled; 83 were evaluable at 6 months. At 6 months, PF scores improved in those with ≥5% weight loss v. not. While endocrine symptoms, fatigue, and anxiety improved in the group who lost ≥5%, differences between groups were not statistically significant. There was no significant change in sexual function, depression, or sleep within or between groups. Similar findings were seen across domains at 12 months, except pain improved in the group losing ≥5%. **Conclusions:** For overweight/obese breast cancer survivors, PF and other PROs improved among patients who lost ≥5%. These results support the patient-centered benefits of weight loss in this population. Clinical trial information: NCT01871116. Research Sponsor: U.S. National Institutes of Health, Other Foundation, Other Government Agency.

Changes (Δ) in PROs at 6 months from baseline (BL) by weight loss (WL).

	6 month follow up		
	≥5% WL n=28	<5% WL n=55	P, between groups
Physical function			
BL, Mean (SD)	49.3 (6.6)	49.8 (8.1)	.02
Δ from BL, Mean (SD)	4.4 (5.4)	.3 (8.2)	
P, within group	.009	.99	
Endocrine symptoms			
BL, Mean (SD)	42.4 (8.9)	39.4 (11.2)	.43
Δ from BL, Mean (SD)	2.9 (5.3)	.7 (9.3)	
P, within group	.02	.47	
Fatigue			
BL, Mean (SD)	48.7 (7.7)	51.4 (7.8)	.28
Δ from BL, Mean (SD)	-3 (5.2)	-.4 (7.9)	
P, within group	.09	.91	
Anxiety			
BL, Mean (SD)	48.9 (7.9)	49.2 (8.6)	.16
Δ from BL, Mean (SD)	-2.3 (6.5)	-.2 (8)	
P, within group	.05	.72	

12054 Poster Session (Board #342), Fri, 8:00 AM-11:00 AM

Moving toward precision: Understanding the heterogeneity of obesity. *First Author: Kin Wai (Tony) Hung, Olive View UCLA Medical Center, Sylmar, CA*

Background: Obesity is a global health epidemic and has been linked to detrimental impact on cancer incidence, recurrence, and mortality. Growing evidence have recognized the complex biopsychosocial relationship including microbial phenotypes that undermines the carcinogenic potential and heterogeneity of obesity. A precision understanding on obesity while at its infancy is necessary to accelerate reduction of its impact on cancer outcomes. **Methods:** With our aim to better understand the biopsychosocial relationship on obesity, we conducted a cross sectional study in healthy and obese individuals. Univariate and multivariate logistic regression models were used to examine obesity and its association with sociodemographic (age, gender, ethnicity, education, income, and marital status), clinical (waist to hip ratio), dietary-behavioral (daily calorie, fat, carbohydrate, protein consumption, and preference on cultural diet), and biological factors (gut microbiome). Parameters were controlled and corrected for multiple hypothesis testing. Gut microbial data using 16S rRNA sequencing were analyzed for alpha diversity, beta diversity, and association of taxa abundance. **Results:** Among 171 participants between July 2013 and August 2018, individuals were found to have a higher BMI if they were Hispanic [Adjusted Odds Ratio (AOR) 3.36, 95% CI 1.27-8.90], had an obese waist to hip ratio (AOR 8.51, 95% CI 3.45-21.02), and consumed an American diet (AOR 4.82, 95% CI 1.74-13.34). Multivariate permutation analysis controlling for BMI, sociodemographic, clinical, and dietary parameters found that Hispanic have a significantly different microbiome profile than non-Hispanic ($p = 0.042$). While microbial species richness (Chao1) were similar ($p = 0.22$), Hispanic had a lower microbial species evenness (Shannon) compared to non-Hispanic ($p = 0.029$). Differential expression of microbial species revealed a positive correlation of Firmicutes:Bacteroidetes ratio in individuals with higher BMI and consumed an American diet whereas a negative correlation to Hispanic ethnicity. **Conclusions:** Obesity association to Hispanic ethnicity uniquely expressed through microbial signature despite sociodemographic, clinical, and dietary differences. Microbial characterization as an emerging predictive marker for oncology therapeutics may also serve as selection biomarker in onco-obesity practices and clinical trials. Addressing ethnic disparities guided by microbial phenotypes may unlock novel understanding of obesity heterogeneity and transform its impact on cancer care. Research Sponsor: NIH/NIDDKK23 DK106528 (PI: Gupta), NIH/NCATS UL1TR001881 (CURE/CTSI funds to Gupta: PI), NIH/NIDDK DK 041301 (CURE/CTSI funds to Gupta: PI).

12055 Poster Session (Board #343), Fri, 8:00 AM-11:00 AM

Randomized clinical trial on the effect of a supervised exercise program on quality of life, fatigue, and fitness following esophageal cancer treatment (PERFECT study). *First Author: Anne Maria May, Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, Utrecht University, Utrecht, Netherlands*

Background: Patients with potentially curable esophageal cancer are often treated with chemoradiotherapy followed by surgery. This treatment might have a negative impact on physical fitness, fatigue and quality of life (QoL). In patients with other types of cancer, evidence suggests that physical exercise reduces treatment related side effects. We investigated whether a supervised exercise program also beneficially affects QoL, fatigue and cardiorespiratory fitness (CRF) in patients after treatment for esophageal cancer. **Methods:** The multicenter PERFECT study randomly assigned patients in the first year after esophagectomy to an exercise intervention (EX) or usual care (UC) group. EX patients participated in a 12-week moderate to high intensity aerobic and resistance exercise program supervised by a physiotherapist. UC patients were advised to maintain their physical activity levels. Attendance and compliance with the exercise intervention protocol were retrieved from exercise logs. QoL (primary outcome, EORTC-QLQ-30, range 0-100), fatigue (MFI-20, range 4-20) and CRF (cardiopulmonary exercise testing) were assessed at baseline and after 12 weeks (post-intervention). The outcomes were analyzed as between-group differences using either linear mixed effects models or ANCOVA adjusted for baseline and stratification factors (i.e. sex, time since surgery, center), according to the intention-to-treat principle. **Results:** A total of 120 patients (age 64±8) were included and randomized to EX (n = 61) or UC (n = 59). Patients in the EX group participated in 96% (IQR:92-100%) of the supervised exercise sessions and compliance with all parts of the exercise program was high (> 90%). Post-intervention, global QoL was not statistically different between groups, but significant ($p < 0.05$) beneficial EX effects were found for QoL-Summary scores (between-group difference 3.5, 95% CI 0.2;6.8) and QoL-role functioning (9.4, 1.3;17.5). Physical fatigue wat non-significantly lower in the EX group (-1.2; -2.6;0.1, p = 0.08). CRF was significantly higher (VO_{2peak} (1.8 mL/min/kg, 0.6;3.0) following the EX intervention. **Conclusions:** Patients were well capable to complete an intensive supervised exercise program after esophageal cancer treatment, which led to small but significant improvements in several aspects of QoL and cardiorespiratory fitness. Our results suggest that supervised exercise is a beneficial addition to routine care of patients with esophageal cancer. Clinical trial information: NTR5045. Research Sponsor: World Cancer Research Fund The Netherlands (WCRF NL, project number 2013/997).

12056 Poster Session (Board #344), Fri, 8:00 AM-11:00 AM

Effect of evidence-based nutrition educational intervention on adherence to dietary guidelines (ADG) and weight management among early-stage breast cancer (EBC) patients (pts): A prospective trial. *First Author: Ilaria Trestini, Department of Oncology, University of Verona Hospital Trust, Verona, Italy*

Background: Excess adiposity is linked to an increased risk of worse outcome among EBC pts. Pts undergoing EBC treatment are susceptible to change in nutrition status. However, implementation and assessment of the adherence to lifestyle interventions have been limited. This prospective trial aimed to evaluate the impact of an evidence-based nutrition intervention, according to the ADG, in terms of body composition changes in EBC pts. **Methods:** Entry criteria: EBC pts candidate to neoadjuvant/adjuvant therapy. At study entry, pts received a nutrition evidence-based tailored intervention. Dietary and anthropometric assessments were evaluated at baseline and after 12-months nutritional intervention. Waist circumference (WC) was assessed as a surrogate measure of fat distribution. ADG was estimated by Med-Diet 14-item questionnaire. Health-Related Quality of Life was analysed with EORTC QLQ-C30. Descriptive statistics was adopted. Associations between variables and groups according to nutritional variables were analysed (Chi-square test). **Results:** From February 2016 to December 2019, 243 pts were enrolled (median age 49 years): 27.6%/48.6% neoadjuvant/adjuvant treatment. At baseline, 38.3% of pts were overweight and 23.9% were obese. Notably, tumor size was significantly correlated with WC in the whole population (p = 0.003). Moreover, pts with central obesity were more likely to present HER2-negative tumors (57.4% vs. 42.5%, p = 0.03). Most pts reported relevant nutrition impact symptoms and symptoms affected QoL. Particularly, dyspepsia and constipation were more prevalent in overweight and obese pts ($p < 0.0001$ and p = 0.009, respectively), as well as in pts who gained ≥5% of weight (p = 0.04 and p = 0.02, respectively). At baseline, there was low ADG. After the 12-months intervention, ADG significantly increased (median Med-Diet score: 6 vs.12, $p < 0.0001$). A high ADG (defines as a Med-Diet score ≥10) significantly correlated with: 1) loss of weight ≥5% from the baseline weight (p = 0.003); 2) change in terms of BMI; 3) prevalence of central obesity. **Conclusions:** A tailored evidence-based nutritional intervention for EBC pts represents a tool to improve their ADG, weight management and, thus, to potentially influence the disease outcome. Research Sponsor: None.

Variables	At baseline	After 12-months	p-value
BMI			p = 0.003
underweight	5 (3.3)	0 (0)	
normal weight	73 (48.0)	126 (82.9)	
overweight	60 (39.5)	21 (13.8)	
obese	14 (9.2)	5 (3.3)	
WC			p = 0.01
central obesity	58 (38.2)	11 (7.2)	

12057 Poster Session (Board #345), Fri, 8:00 AM-11:00 AM

The impact of high intensity interval training on functional performance, body composition and quality of life in a diverse group of cancer survivors. *First Author: Jennifer Lynn Beebe-Dimmer, Wayne State University School of Medicine, Karmanos Cancer Institute, Detroit, MI*

Background: Given the well-documented benefits of regular exercise to cancer survivors, in 2012, an expert panel assembled by the American Cancer Society recommended that patients engage in at least 150 minutes per week of moderate-to-vigorous physical activity. However, few patients meet this goal. We have also observed racial differences in reported participation in regular exercise among cancer survivors living in Metropolitan Detroit, Michigan. **Methods:** The CAPABLE study is a 12- week pilot exercise intervention that introduces cancer survivors to the sport of CrossFit. We evaluated the impact of this unique, high-intensity interval training method on functional performance, cardiovascular endurance, body composition and health-related quality of life (HRQOL) as measured by the Functional Assessment of Cancer Therapy (FACT) instrument. All measures were summarized at baseline and program exit. Paired signed rank tests were used to assess change in each of these measures over time. **Results:** Of the 48 participants enrolled in the pilot, 37 (77%) were considered adherent to the program (attending at least 75% of sessions over the 12-week period). The mean age of participants was 58.5 years, 73% identified as African American and the majority of participants were breast cancer survivors (N = 20). The mean body mass index (BMI) at baseline was 32.8 kg/m^2 decreasing to a mean of 31.7 kg/m^2 at exit (BMI change -1.1, $p < 0.001$). Similar changes were observed in % body fat measured by bioelectrical impedance. There were significant improvements in all measures of functional performance over 12-weeks (all $p < 0.001$). We observed significant and meaningful improvements in reported HRQOL measured by the FACT survey, overall (FACTG total change +9.5 ($p < 0.001$)) and in each one of the individual domains (physical, social, emotional, and functional well-being). **Conclusions:** We observed significant improvements in performance, body composition and quality of life among cancer survivors introduced to a high-intensity interval training program. Understanding and eliminating barriers to programs like these are critical to improving outcomes and reducing cancer health disparities. Clinical trial information: NCT03750981. Research Sponsor: Karmanos Cancer Institute.

12058 Poster Session (Board #346), Fri, 8:00 AM-11:00 AM

The impact of tobacco retail density on overall survival (OS) in lung cancer survivors. *First Author: Lawson Eng, Division of Medical Oncology and Hematology, Princess Margaret Cancer Centre, Toronto, ON, Canada*

Background: Continued smoking after a cancer diagnosis is associated with poorer outcomes. We previously identified that tobacco retail outlet density is negatively associated with cessation in lung cancer survivors (ASCO 2019). However, the impact of tobacco retail density on survival has not been evaluated. We evaluated the impact of tobacco retail density on OS in lung cancer patients (pts). **Methods:** Lung cancer pts diagnosed from 2009-2012 were recruited at diagnosis and completed a baseline questionnaire on their sociodemographics, ECOG and smoking history. Clinicopathologic data including stage, histology and OS data were collected. Validated tobacco retail location data obtained from Ministry of Health and pt home addresses were geocoded using ArcGIS 10.6.1, which calculated tobacco outlet density within 250 meters (m) and 500m from pts. Multivariable Cox proportional hazard models evaluated the impact of tobacco outlet density on OS adjusted for significant clinicodemographic covariates. **Results:** Among 1411 pts, median age 66, 53% female, 8% small cell/56% adenocarcinoma/17% squamous/19% other, 28% stage 1/9% stage 2/20% stage 3/35% stage 4, 38% were current smokers at diagnosis and 40% were ex-smokers; median OS was 24 months. On average, there was one vendor (range 0-23) within 250m and four vendors (range 0-44) within 500m from pts; 33% and 60% of pts lived within 250m and 500m from at least one vendor respectively. The final baseline multivariable model consisted of age, gender, stage, smoking status, ECOG and neighbourhood marginalization index ($P< 0.05$). Among all pts, not living within 250m to an outlet improved OS (aHR 0.84 [0.72-0.97] P= 0.02). Living near more outlets within 250 m (aHR 1.03 per outlet [1.00-1.05] P= 0.03) or 500 m (aHR 1.01 per outlet [1.00-1.02] P= 0.04) worsened OS. Subgroup analysis based on smoking status at diagnosis, identified that among current smokers, not living within 250m to an outlet improved OS (aHR 0.76 [0.60-0.97] P= 0.03), and among ex-smokers, living near more outlets within 500 m worsened OS (aHR 1.02 per outlet [0.99-1.03] P= 0.07); other associations showed similar directionality. Among 135 current smokers at diagnosis with follow-up smoking status, not living within 250m to an outlet continued to show a trend towards improved OS (aHR 0.57 [0.31-1.03] P= 0.06), after also adjusting for follow-up smoking status. **Conclusions:** Living near a greater density of tobacco outlets is associated with poorer OS among lung cancer pts. Reducing the density of tobacco outlets may be a strategy that can help improve lung cancer pt outcomes. Research Sponsor: Cancer Care Ontario - ON-PROST.

12059 Poster Session (Board #347), Fri, 8:00 AM-11:00 AM

Panel-based methodology for assessing the impact of public policies on cancer patients and survivors. *First Author: Amy Farner, American Cancer Society Cancer Action Network, Washington, DC*

Background: Cancer interventions are subject to a range of regulations, but data from large, nationally representative surveys are not always available in time to inform the policy process and do not always address issues specific to cancer patients and survivors. Understanding their experiences is critical to achieving policy solutions to issues such as access to effective pain relief, reducing unexpected medical bills, and reducing the impact of high prescription drug costs on treatment for lower income cancer patients. This research intended to better understand patient experiences and opinions in a statistically valid manner specifically targeted to the policy process. **Methods:** 3057 panelists were identified from ACS contacts, health systems, and social media advertising through ACS/ACS CAN pages and paid Facebook ads, to participate in a series of surveys across a year. The panel included diverse survivors across age, gender, race, ethnicity, economic status, and cancer type. Online surveys deployed semi-monthly on cancer survivorship topics impacted by current policy, including access to/affordability of care, pain treatment, and prescription drug costs. Responses were analyzed for the entire population and across subgroups of cancer survivors. **Results:** Each survey achieved a response rate between 35% and 50% of all panel members, resulting in a margin of error +/- 3% and 95% confidence level. Insights from cancer patient and survivor experiences helped support public policies through findings such as (but not limited to): 41% of those prescribed opioids had trouble getting their medicine, creating difficulty participating in work, family, or social events; extra trips to the doctor or pharmacy; negative impact on treatment, and trips to the Emergency Room due to uncontrolled pain; 24% received a surprise medical bill, increasing their anxiety, reducing likelihood to see a specialist, and reducing likelihood to seek emergency care during a serious health issue; and 31% of those with household income less than $30,000 report trouble affording prescription drugs and 17% have delayed or not filled a prescription due to cost. Findings supported the policy process by helping craft policy positions aligned with cancer patient preferences, raising public awareness, and communicating to policymakers the impact of policies on cancer. **Conclusions:** The panel methodology illustrates the impact of policy decisions on cancer patients and survivors. Findings provide an unprecedented level of input to the policy process for cancer patients and survivors. Research Sponsor: Bristol Meyers Squibb.

12060 Poster Session (Board #348), Fri, 8:00 AM-11:00 AM

Patterns of the risk for subsequent primary cancer among survivors of adult-onset cancers in the United States. *First Author: Hyuna Sung, American Cancer Society, Atlanta, GA*

Background: The number of cancer survivors who develop new cancers is projected to grow in the US. Few studies, however, have provided a comprehensive overview of the contemporary pattern in the risk of subsequent primary cancer (SPC) among survivors of adult-onset cancers. Herein, we evaluate overall and type-specific risks of SPCs among adult-onset cancer survivors by first primary cancer types and sex. **Methods:** We assessed the excess risk of SPCs among 1,442,374 persons aged 20-84 years who were diagnosed with first primary cancers from 1992-2010 and survived ≥5 years in the 12 Surveillance, Epidemiology, and End Results registries. We expressed the risks using excess absolute risk (EAR) per 10,000 person-years and standardized incidence ratio (SIR) by first primary cancer types and sex, compared to those expected in the general population. We also estimated percent contributions of each specific type of SPCs to the total EAR for all first primary cancers combined by sex. **Results:** The overall risk of SPCs was higher than expected for 24 of the 34 first primary types among male survivors and for 28 of the 35 first primary types among female survivors. The greatest SIR and EAR were estimated after laryngeal cancer in both men (SIR = 1.74, 95%CI = 1.67-1.82; EAR = 159.3, 95%CI = 143.6-175.5) and women (SIR = 2.48, 95% CI = 2.26-2.73; EAR = 202.7; 95%CI = 171.8-236). There were 290 type-specific associations with significantly higher risk of SPC, 36% of which being reciprocal, predominantly among smoking-associated, HPV-associated, and hematologic cancers. The SIRs in men ranged from 1.05 (95%CI = 1.00-1.10; EAR = 1.69) for lung/bronchus cancer after colorectal cancer to 73.9 (95%CI = 58.3-92.3; EAR = 23.3) for anal cancer after Kaposi sarcoma; and in women the SIRs ranged from 1.08 (95%CI = 1.02-1.15; EAR = 0.36) for pancreatic cancer after breast cancer to 19.9 (95%CI = 15.0-26.0; EAR = 39.5) for oral cavity/pharyngeal cancer after laryngeal cancer. For all first primary cancers combined, lung/bronchus cancer comprised the greatest proportion of the total EAR of SPCs, 34.6% in men and 29.1% in women, followed by urinary bladder (11.8%) and oral cavity/pharynx (7.5%) in men and by corpus uterus (12.9%) and colorectum (7.6%) in women. **Conclusions:** Despite the substantial heterogeneity in the risk of SPCs across the first primary types, only a few cancers comprised a considerable proportion of the total excess risk among survivors. Better understanding of contributing factors to these patterns will inform survivorship care plans and care delivery. Research Sponsor: None.

12061 Poster Session (Board #349), Fri, 8:00 AM-11:00 AM

Impact of immune checkpoint and BRAF inhibitors on the incidence of second primary malignancies (SPM) in melanoma. *First Author: Nibash Budhathoki, NYU Winthrop Hospital, Mineola, NY*

Background: Prior studies have shown an increased risk of SPM in melanoma, however there is limited data on the incidence of SPM following the 2011 approvals of immune checkpoint (ipilimumab) and BRAF (vemurafenib) inhibitors, which have become standard of care. We present data comparing SPM rates before and after introduction of these agents for advanced cutaneous melanoma. **Methods:** Adult melanoma patients with regional or distant metastases were identified from SEER-18 database and divided into cohorts: 2005-2010 and 2011-2016. SPM was defined as tumors diagnosed ≥6 months from diagnosis of the primary cancer. SEER*stat was used to calculate SPM by multiple primary standardized incidence ratio based on observed (O) and expected (E) cases. The expected numbers of new cancers of specific types were estimated by assuming that incidence rates for new primary tumors corresponded to sex, age, and calendar time–specific SEER rates for similar invasive primary cancers and applying those rates to the accumulated person-years (PYR) of observation. Excess absolute risk (EAR) of malignancy per 10,000 PYR at risk was calculated as $([O - E]/PYR) \times 10{,}000$. **Results:** As shown in the table, from before 2005-2010, 421 of 7991 patients (5.2%) with advanced melanoma had 444 SPM (O/E ratio 2.2, 95% CI 1.9-2.4, $P < 0.0001$, EAR 157). In comparison, from 2011-2016, 527 of 9341 patients (5.6%) developed 584 SPM (O/E ratio 2.5, 95% CI 2.3-2.7, $P < 0.0001$, EAR 193). Incidence of AML, myeloma, and pancreatic cancer increased in 2005-2010, while soft tissue malignancies increased from 2011-2016. The incidence of thyroid, brain, and small bowel tumors increased in both groups from 2005-2016. **Conclusions:** There is a distinct pattern as well as increased latency of SPM in patients with advanced melanoma in the era of immune checkpoint and BRAF inhibitors. We speculate that reduction in chemotherapy use, augmentation of immunosurveillance, and inhibition of oncogenic pathways may impact the pathogenesis of SPM. Research Sponsor: None.

Summary	2005-2010	2011-2016
Total number of patients	7991	9341
Male	5096 (63.7%)	5996 (64%)
Female	2895 (36.3%)	3345 (36%)
White	7683 (96.1%)	8987 (96%)
Black	122 (1.5%)	127 (1.4%)
Other races	186 (2.3%)	127 (1.4%)
Total number of SPMs	444	584
Total patients with SPM	421 (5.3%)	527 (5.6%)
Patients with 1 SPM	400 (5.0%)	431 (4.6%)
Patients with 2 SPM	19 (0.23%)	35 (0.4%)
Patients with 3 SPM	2 (0.02%)	11 (0.1%)
Median years of age at diagnosis of SPM (range)	66 (20-94)	69 (23-101)
Median latency time to development of SPM (range)	18 months (6-64)	41 months (6-200)

12062 Poster Session (Board #350), Fri, 8:00 AM-11:00 AM

Effects of radiation therapy on clonal hematopoiesis. *First Author: Leslie Ann Modlin, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: Clonal hematopoiesis (CH), characterized by recurrent somatic mutations in blood, is a common age-associated condition that portends an increased risk of myeloid neoplasms and cardiac disease. Oncologic therapies appear to promote CH, including ionizing radiation therapy (RT) (OR = 1.4, $p < 10^{-6}$) and systemic DNA-damaging agents (OR = 1.2, $p = 8 \times 10^{-4}$). How various RT parameters (e.g. target site, dose, fractionation, modality) may influence CH is unknown. **Methods:** CH mutations were identified via targeted, deep-coverage next-generation sequencing from paired peripheral blood and tumor samples (MSK-IMPACT). CH was defined as a somatic blood mutation with a minimum variant allele frequency of 2%. Putative driver mutations (CH-PD) were identified from OncoKB and other published sources. Clinical and RT characteristics were abstracted from medical records. To account for differences in RT dose and fractionation, equivalent radiation dose in 2 Gy fractions (EQD_2) with an α/β ratio of 3 for late effects was calculated. Univariate and logistic regression modeling for associations between clinical and treatment parameters and CH were performed. **Results:** We identified 2,195 patients who received RT before blood draw and 7,832 who did not, encompassing 57 histologies. A median of 267 days elapsed between the end of RT and blood draw. After RT, 22% of patients had at least one CH-PD mutation (n = 486). The most common single anatomic sites radiated were pelvis, chest wall/breast, and head and neck. Conventional RT was used in 2% (n = 46), 3D-conformal in 14% (n = 308), intensity modulated RT in 36% (n = 787), volumetric modulated arc RT in 12% (n = 263), multiple techniques in 26% (n = 560), and unknown in 11% (n = 231). There was no association between RT modality and presence of CH-PD ($p > 0.05$ for all between group comparisons of modality). On multivariate regression after controlling for age, race, time from diagnosis to blood draw, smoking status, and for chemotherapy class, cytotoxic, immune, or targeted therapies in the entire cohort, EQD_2 was associated with CH-PD ($p = 0.012 \times 10^{-3}$). Evaluating EQD_2 by irradiated anatomic site, total pelvic dose by EQD_2 in 10 Gy increments remained significantly associated with CH-PD (OR = 1.07, p = 0.0046), as was head and neck EQD_2 (OR = 1.046, p = 0.032). **Conclusions:** CH-PD was associated with higher radiation dose for pelvic or head and neck RT, but not other anatomic sites after controlling for systemic therapies. RT modality was not associated with CH-PD. Ongoing work will directly evaluate the bone marrow dosimetry of various treatment approaches using phantom-based modeling. Research Sponsor: U.S. National Institutes of Health.

12063 Poster Session (Board #351), Fri, 8:00 AM-11:00 AM

Impact of preexisting cardiovascular disease (CVD) on treatments and outcomes of patients with breast or lung cancer. *First Author: Atul Batra, Tom Baker Cancer Center, Calgary, AB, Canada*

Background: Prior cardio-oncology and geriatric oncology research has mainly focused on cancer treatments and their late effects on cardiac health, but little information is known about how cardiac health may influence subsequent cancer treatments. This real-world study aimed to evaluate the associations of pre-existing CVD on treatment adherence and survival in patients with breast or lung cancer. **Methods:** We linked administrative data from the population-based cancer registry, electronic medical records, and billing claims in a large province (Alberta, Canada) over a 10-year time period (2006-2015). Multivariable logistic regression analyses were performed to identify associations of CVD with cancer treatments. Multivariable Cox proportional hazards models were constructed to determine the effect of CVD on overall survival (OS), while adjusting for receipt of cancer treatments. **Results:** We identified 46,227 patients with breast or lung cancer, of whom 77% were women and median age was 65 years. While 82% of patients with breast cancer were early stage, 50% with lung cancer had metastasis. The prevalence of pre-existing CVD was 20% where congestive heart failure was most frequent. In logistic regression, CVD was associated with lower odds of receiving appropriate chemotherapy (OR, 0.60, 95% CI, 0.56-0.65, *P*<.0001), radiotherapy (OR, 0.76, 95% CI, 0.72-0.81, *P*<.0001), and surgery (OR, 0.60, 95% CI, 0.54-0.66, *P* <.0001), irrespective of tumor site (Table). The 5-year OS was lower in patients with baseline CVD as compared to those without (46% vs 58%, *P<0.0001*). Upon adjusting for stage and treatment, CVD continued to correlate with worse OS (HR, 1.23, 95% CI, 1.19-1.26; *P*<.0001). **Conclusions:** Cancer patients with prior CVD were less likely to receive standard cancer therapy. Even among those who underwent cancer treatments, worse outcomes were observed in those with CVD. Early cardio-oncology and geriatric oncology engagement may reduce treatment bias and ensure that carefully selected patients with a cardiac history are still offered appropriate cancer therapy. Research Sponsor: None.

Odds of receiving appropriate cancer therapy in patients with pre-existing CVD (vs. those without CVD).

	Breast Cancer (n=25,527)	Lung Cancer (n=20,700)	Total (n=46,227)
Chemotherapy			
OR	0.56	0.59	0.60
95% CI	0.49-0.65	0.54-0.64	0.56-0.65
***P*-value**	<0.0001	<0.0001	<0.0001
Surgery			
OR	0.66	0.55	0.60
95% CI	0.60-0.72	0.48-0.63	0.54-0.66
***P*-value**	<0.0001	<0.0001	<0.0001
Radiation			
OR	0.69	0.81	0.76
95% CI	0.57-0.83	0.76-0.87	0.72-0.81
***P*-value**	<0.0001	<0.0001	<0.0001

12065 Poster Session (Board #353), Fri, 8:00 AM-11:00 AM

Fatigue in long-term survivors with ovarian cancer: Results of Expression VI – Carolin meets HANNA – Holistic analysis of Long-term survival with ovarian cancer—The international NOGGO, ENGOT and GCIG survey. *First Author: Hannah Woopen, NOGGO and Department of Gynecology, European Competence Center for Ovarian Cancer, Charité, University Medicine of Berlin, Campus Virchow Klinikum, Berlin, Germany*

Background: Long-term survivors (LTS) with ovarian cancer may be cured from cancer but frequently experience long-term toxicities such as fatigue with a huge impact on quality of life. Aim of this study was to evaluate factors associated with fatigue in LTS. **Methods:** Within the study "Carolin meets HANNA" (www.carolinmeetshanna.com) long-term survivors with ovarian cancer (LTS) were recruited since 11/2016. Long-term survival was defined as an ovarian cancer diagnosis more than eight years ago. **Results:** Until 12/2019 473 LTS could be recruited. 211 LTS (44.5%) have experienced fatigue. At the time point of recruitment in 23.4% (111 LTS) fatigue was still present. LTS with fatigue were not more frequently under current treatment compared to LTS without fatigue (p = 0.348). LTS with fatigue were not younger at initial diagnosis (50.4 vs. 51.9 years, p = 0.228). 58.6% of LTS with fatigue compared to 41.5% without fatigue have developed recurrent disease (p = 0.002) and LTS had more frequently more than one recurrence (66.1% vs. 51.7%, p = 0.055). Fatigue was associated with worse health status (2.9 vs. 2.2 on a scale from 1-5, p < 0.001). Fatigue was associated with medical complaints in general (82.0% vs. 43.0%, p < 0.001). Symptoms such as nausea and vomiting (p < 0.001), loss of appetite (p < 0.001), constipation (p < 0.001), diarrhea (p < 0.001), weight loss (p = 0.001) and bloating (p < 0.001) were more frequent in LTS with fatigue. This also accounts for cognitive disorders (39.6% vs. 10.5%, p < 0.001), depression (23.4% vs. 7.4%, p < 0.001), polyneuropathy (39.6% vs. 13.2%, p < 0.001) and cardiovascular disease (11.7% vs. 3.6%, p = 0.002). LTS with fatigue regard themselves more frequently as cancer patient (73.9% vs. 40.8%), p < 0.001). **Conclusions:** Fatigue is still very common in LTS despite the long survival time. Fatigue is associated with worsened health status and other long-term side effects underlining the impact on LTS. There is a high need for survivorship clinics that should ask for and, if necessary, should address still existing side effects such as fatigue. Research Sponsor: German Ovarian Cancer Foundation, Pharmaceutical/Biotech Company.

12066 Poster Session (Board #354), Fri, 8:00 AM-11:00 AM

Efficacy of ear acupuncture on sleep quality in breast cancer survivors: A randomized controlled trial. *First Author: Melanie Désirée Hoextermann, Department of Internal and Integrative Medicine, Evang. Kliniken Essen-Mitte, Faculty of Medicine, University of Duisburg-Essen, Essen, Germany, Essen, Germany*

Background: Among females, breast cancer is the most commonly diagnosed cancer worldwide. Sleep problems impair 40 to 70 % of breast cancer survivors. The aim of this randomized controlled trial was to evaluate the effect of ear acupuncture on sleep quality in breast cancer survivors. **Methods:** Fifty-two female breast cancer survivors (mean age 55.73 ± 8.10) were randomized to either 10 treatments of ear acupuncture within five weeks (N = 26) or to a single session of psycho-education and given an advice booklet concerning insomnia (N = 26). Both interventions were delivered in a group setting. Primary outcome was sleep quality (measured by the Pittsburgh Sleep Quality Index) at week 5 corrected for treatment expectancies. Secondary outcomes were inflammation parameters (interleukin-6) at week 5, sleep quality at week 17, and stress, anxiety, depressive symptoms, quality of life and fatigue 5 weeks and 17 weeks after randomization. **Results:** Intention-to-treat analysis showed a significantly stronger increase of sleep quality in the ear acupuncture group compared to the psycho-education group (p= .031; d = 0.64) at week 5. Furthermore, ear acupuncture improved stress (p= .030; d = 0.64), anxiety (p = .001; d = 0.97), and fatigue (p = .012; d = 0.75) at week 5 compared to psycho-education. No significant group difference was found on any outcome at week 17. No serious adverse events occurred during the study period. **Conclusions:** Group ear acupuncture may be a helpful intervention in tackling sleep problems in breast cancer survivors in the short term and may reduce stress, anxiety and fatigue as well. Long-term effects remain questionable. Clinical trial information: NCT03874598. Research Sponsor: Karl and Veronica Carstens-Foundation.

12068 Poster Session (Board #356), Fri, 8:00 AM-11:00 AM

Lifelong disease burden of chemotherapy in Hodgkin lymphoma (HL): A simulation study from the St. Jude Lifetime (SJLIFE) Cohort and HL International Study for Individual Care (HoLISTIC). *First Author: Susan K. Parsons, Tufts Medical Center, Boston, MA*

Background: Current emphasis for childhood and young adults with HL is to maintain high cure rates while concurrently identifying regimens to reduce excess long-term mortality/morbidity. Thus, understanding the late effects (LE) of contemporary clinical trials (CCT) for HL is critical. **Methods:** We used simulation to estimate the projected life expectancy (LExp), quality adjusted life-expectancy (QALE) & cause of death (COD) in a large cohort of HL CCT patients (pts) in the recently established HoLISTIC consortium by linking long-term risk models from the SJLIFE cohort. Individual patient data (IPD) on bleomycin, alkylating agents and anthracycline were extracted & harmonized for 982 HL pts in 5 prospective CCT (mean diagnosis age 19y, range 3-30y; 51% male; all treated with chemotherapy only; progression-free survival [PFS] >5y) in the HoLISTIC database. LExp, QALE & COD were projected using a previously developed microsimulation model (Bhakta, *Blood [Supplement]*, 2019) that incorporated mortality & incidence of LEs by diagnosis age, sex, race, treatment exposures & attained age estimated from 5,522 adult 10-y survivors of childhood cancers in the SJLIFE cohort (56% male; mean age at last follow-up 35y, range 19-68). Microsimulation was applied to 10,000 randomly selected survivors of HL CCT cohort, from 10y after HL diagnosis until death to project the LExp, QALE & COD. **Results:** Assuming 10-y PFS, LExp and QALEs projected for the HL CCT cohort using adjusted US general population rates linked with the SJLIFE microsimulation model, COD and trial-specific exposures are shown in the Table. **Conclusions:** A novel lifetime simulation approach was used to project LExp, QALE & COD by linking together IPD from CCTs with the long-term risk model of the SJLIFE survivorship cohort. Despite differences in PFS, reflecting in part the variation in risk/stage status, the projected long-term outcomes were similar. Our approach highlights a new opportunity to inform future clinical trial design and aid provider & patient decision-making. Research Sponsor: None.

		Trial				
	US Population	COG AHOD0431	EORTC/LYSA/FIL H10	COG AHOD0031	ECOG2496	Italian HD0607
Number		**139**	**266**	**304**	**73**	**200**
Risk/Stage		**Low**	**Early**	**Intermediate**	**Advanced**	**Advanced**
5-y PFS (%)		90	87	85	77	80
Exposures						
Bleomycin (Yes/No)		N	Y	Y	Y	Y
Alkylators (mg/m^2)		3600	6218	3200	6600	8850
Anthracyclines (mg/m^2)		150	244	200	275	305
Outcomes (y, mean)						
LExp	79	72	71	71	70	70
QALE	69	58	57	58	57	56
COD (%)						
Cardiac		19	20	19	21	22
Pulmonary		1	1	1	1	1
Second Malignancy		7	12	12	13	14
Other		73	67	68	65	64

12069 Poster Session (Board #357), Fri, 8:00 AM-11:00 AM

Long-term follow-up assessment of cardiac safety in SAFE-HEaRt, a clinical trial evaluating the use of HER2-targeted therapies in patients with HER2-positive breast cancer and compromised heart function. *First Author: Katia Khoury, Georgetown Lombardi Cancer Center, Washington, DC*

Background: HER2-targeted therapies are associated with cardiotoxicity, mostly asymptomatic and reversible. The impact of withholding these therapies on breast cancer outcomes is unknown. SAFE-HEaRt trial was the first study to evaluate the safety of HER2-targeted agents in patients with reduced left ventricular ejection fraction (LVEF) receiving concomitant cardioprotective medications and close cardiac monitoring. We report the 3-year follow-up (f/u) results. **Methods:** Thirty patients with stage I-IV HER2-positive breast cancer receiving trastuzumab, pertuzumab or ado-trastuzumab emtansine (TDM-1), with asymptomatic LVEF 40-49%, were started on beta blockers (ß-blockers) and/or ACE inhibitors/ARBs, with the primary endpoint being completion of HER2-targeted therapy without cardiac events (CE) or protocol-defined asymptomatic worsening of LVEF. **Results:** Patients were accrued from 10/2013 to 12/2017 and median f/u as of 2/7/20 is 37 months. The study met its primary endpoint with 27 patients (90%) completing their HER2-targeted therapies without cardiac issues. 24 patients were reconsented for long-term f/u. There were 23 evaluable patients (1 lost for f/u). Off study, 2 patients continued treatment with trastuzumab, 3 with trastuzumab and pertuzumab, and 3 with TDM-1 for metastatic disease. 1 of the 2 patients who had developed a CE with symptomatic heart failure (HF) died of progressive oncological disease, and the second had LVEF recovery on cardiac medications after completion of adjuvant HER2-targeted therapy. Almost 5 years later, she had an asymptomatic decline in her LVEF to 35% after deciding to stop her ß-blocker and ARB. Of the remaining 21 patients, 15 had recovery of their LVEF to $\geq$50%, 9 of whom remain on cardiac medications. 5 patients had stable LVEF 40-49% and remain asymptomatic on cardiac medications. Only 1 patient had symptoms suggestive of HF, with last documented LVEF stable at 45-50%, but she has not sought medical care for the last 15 months since relocating to another country. There were no new CE and no cardiac deaths. Mean LVEF was 45% at baseline, 46% at end of treatment, and 51.5% at long term f/u. **Conclusions:** Long-term f/u of the SAFE-HEaRt study continues to provide safety data of HER2-targeted therapy use in patients with compromised heart function. The late development of cardiac dysfunction is uncommon and continued multi-disciplinary oncologic and cardiac care of patients is essential for improved patient outcomes. Clinical trial information: NCT04143594. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology, Pharmaceutical/Biotech Company, U.S. National Institutes of Health.

12070 Poster Session (Board #358), Fri, 8:00 AM-11:00 AM

Assessing the roles of inflammation and blood brain barrier permeability in cognitive impairment: A nationwide longitudinal study of patients receiving chemotherapy and non-cancer controls. *First Author: Elizabeth Belcher, University of Rochester Medical Center, Rochester, NY*

Background: Cognitive impairment is a prevalent side effect of chemotherapy. We have previously shown that chemotherapy treatment is associated with worse performance on the Rapid Visual Processing test (RVP), an objective measure of sustained attention, over time compared to non-cancer controls. Better understanding of the biologic mechanisms underlying cognitive impairment in cancer patients is needed. The pro-inflammatory cytokine tumor necrosis factor alpha (TNFα) has been implicated in increasing blood brain barrier (BBB) permeability, which in turn is associated with cognitive impairment. This study assessed the relationships of TNFα and S100β, a biomarker of BBB permeability, to each other and to RVP performance over time. **Methods:** We analyzed a subset of participants (n = 89 patients, n = 52 controls, mean age = 60) from a prospective longitudinal study of women with breast cancer receiving chemotherapy and non-cancer controls. TNFα and S100β were measured in serum pre-chemotherapy (T1, $\leq$7 days before first treatment) and post-chemotherapy (T2, $\leq$1 month after last treatment) and at corresponding times for controls. Sustained attention was assessed by total correct rejections on the RVP test at T1 and T2. Separate linear regression models including all participants were used to relate 1) baseline TNFα and S100β levels to change in RVP performance over time, 2) change in TNFα and S100β to change in RVP performance over time, and 3) change in TNFα to change in S100β. Models were adjusted for age. 4) T-tests were used to compare the TNFα and S100β change scores (T1 to T2) of patients vs controls. **Results:** Greater increase (T1 to T2) in the pro-inflammatory cytokine TNFα was associated with worse cognition, measured by performance on RVP over time ($p = 0.02$). Higher baseline S100β, a biomarker of BBB permeability, was associated with worse performance on RVP over time ($p = 0.09$). Increase in TNFα was associated with increase in S100β ($p = 0.11$). S100β increased from T1 to T2 in patients relative to controls ($p = 0.09$). **Conclusions:** These results suggest that higher TNFα may be related to increases in blood brain barrier permeability and worse cognition. Future studies will further define the link between inflammation, blood brain barrier permeability and chemotherapy-related cognitive decline, with the goal of informing the development of new interventions. Funding: R01CA231014, T32CA102618, DP2CA195765, UG1CA189961. Research Sponsor: U.S. National Institutes of Health.

12071 Poster Session (Board #359), Fri, 8:00 AM-11:00 AM

Effects of GC4419 (avasopasem manganese) on chronic kidney disease in head and neck cancer patients treated with radiation and cisplatin. *First Author: Emily J. Steinbach, University of Iowa, Iowa City, IA*

Background: Nephrotoxicity is a major complication of platinum-based chemotherapy and ranges in incidence from 31-68%. The effects of platinum-based chemotherapeutics on long-term renal outcomes (chronic kidney disease, CKD) profoundly affect morbidity and mortality. Concurrent chemoradiotherapy (CRT) including cisplatin is standard for locally advanced squamous cell head and neck cancer (HNC) but is accompanied by the risk of CKD. In a randomized, multi-center, placebo-controlled Phase 2b trial (NCT02508389) of GC4419 (avasopasem manganese) in HNC patients receiving CRT, avasopasem reduced the duration, incidence, and severity of severe oral mucositis (Anderson et al, JCO 2019). Avasopasem did not appear to alter the safety profile of CRT in that trial, including incidence of adverse events of kidney injury or azotemia. **Methods:** Pre- and post-treatment markers of kidney function including blood urea nitrogen (BUN), serum creatinine (sCr), and estimated glomerular filtration rate (eGFR) were retrospectively evaluated for a subset of 52 of the trial patients who received 3 cycles x 100 mg/m^2 cisplatin plus placebo or 30 or 90 mg of avasopasem intravenously prior to RT, and 7 comparator patients who received the same CRT outside the study. Kidney function was evaluated between 3- and 24-months post-completion of cisplatin-radiation therapy by two-way analysis of variance (-ANOVA) as defined by the Kidney Disease Improving Global Outcomes (KDIGO) CKD staging. **Results:** Baseline patient characteristics were skewed towards a male population but were balanced across all treatment arms with regards to baseline kidney function (comparator + placebo, n = 19; 30 mg GC4419, n = 18; 90 mg GC4419, n = 15). Treatment with 90 mg GC4419 demonstrated normal BUN values (10-20 mg/dL) at 3, 6, and 18 months and normal sCr values (0.6-1.2 mg/dL) between 3 and 24 months as compared to the placebo arm + comparator group, which exhibited statistically elevated BUN and sCr ($p < 0.05$). Treatment with 90 mg GC4419 also demonstrated significantly higher eGFR between 3 and 24 months post-chemoradiation ($p < 0.05$) compared to the placebo arm + comparator group. 90 mg GC4419 treatment significantly reduced the incidence of CKD compared to the placebo arm and comparator group, as determined by fold change in sCr values and eGFR measurements $<$ 60 mL/min (stage G3a/b, G4, or G5 CKD). **Conclusions:** Avasopasem has the potential to reduce the incidence and severity of CKD in patients receiving cisplatin therapy. Clinical trial information: NCT02508389. Research Sponsor: Galera Therapeutics, Inc.

12072 Poster Session (Board #360), Fri, 8:00 AM-11:00 AM

Patient reported outcomes in older breast cancer survivors. *First Author: Sharon H. Giordano, The University of Texas MD Anderson Cancer Center, Houston, TX*

Background: The majority of breast cancer patients are age 66 years or older at diagnosis, yet little is known about the symptom burden of older breast cancer survivors. **Methods:** Using the same process as for SEER-Medicare, data from the Texas Cancer Registry (TCR) and Medicare claims were linked. From this TCR-Medicare dataset, patients age 65 years and older at diagnosis, with localized or regional breast cancer, diagnosed in 2012 and 2013, and still alive in 2018 were identified. To assess long-term outcomes, a mailed survey, which included selected questions from the NCI's PRO-CTCAE question bank, was sent to 4591 eligible patients along with a $10 gift card. Non-responders were sent a follow-up questionnaire at 4-6 weeks and 8-10 weeks after initial mailing. The percentage reporting symptoms, overall and by treatment received, are described. **Results:** 1594 survivors completed the questionnaire (35% response rate). Median time from diagnosis to survey completion was 67 months. 70% of responders were age 65-74, 26% age 75-84, and 3% age 85+ at diagnosis. 84% were non-Hispanic white, 6% black, and 9% Hispanic. 77% had localized stage disease and 23% had regional disease at diagnosis. 58% had lumpectomy, 36% had mastectomy, and 2% reported no surgery. 77% had ER+ breast cancer. 28% received adjuvant chemotherapy. 48% had Part D claims for adjuvant endocrine therapy. PROs are reported in Table, overall and by use of chemotherapy and endocrine therapy. **Conclusions:** Older breast cancer survivors, particularly those who were treated with chemotherapy, experience a high symptom burden. Research Sponsor: CPRIT, Other Foundation.

PRO-CTCAE	Overall % Reporting in Past 7 Days N = 1594	% Among Chemotherapy Treated N = 454	% Among Endocrine Therapy Treated N = 774
Arm/leg swelling	32	40	33
Any hair loss	36	53	33
Numbness/tingling in hands or feet	40	58	39
Problems with concentration	37	49	37
Problems with memory	49	61	50
Aching muscles	69	77	70
Aching joints	69	76	69
Fatigue/tiredness/lack of energy	72	84	73
Hot flashes	43	49	45

12073 Poster Session (Board #361), Fri, 8:00 AM-11:00 AM

Financial toxicity among breast cancer survivors with health insurance. *First Author: Wendy Landier, University of Alabama at Birmingham, Birmingham, AL*

Background: Cancer treatment and its sequelae have been associated with financial toxicity in breast cancer survivors, particularly those who have no health insurance. However, the prevalence of financial toxicity in the insured survivors, and the underlying factors are not well understood. **Methods:** Breast cancer survivors attending a survivorship clinic (University of Alabama at Birmingham) completed a survey assessing demographics, financial toxicity (i.e., material resources; food/housing/energy insecurity), and health-related quality of life (HRQL: SF-36). Clinical characteristics were abstracted from medical records. A multivariable logistic regression model was developed to understand factors associated with financial toxicity; the model included survivor age, race, socioeconomic status, insurance type, marital status, cancer stage, time since diagnosis, current medications, and physical and mental domains of HRQL. **Results:** The 368 participants (1% male; 67% white, 25% African American, 8% other) were a median of 61y of age (range, 33-86y) and 4.3y post-diagnosis (1-34y) at survey completion; 90% had stage 0-II disease; 34% were single (not currently married/partnered); type of health insurance included private/military (57%), Medicare (39%), and Medicaid/self-pay (4%). Overall, 31% reported financial toxicity; 26% endorsed not being able to live at current standard of living $>$ 2 mo. if they lost all current sources of income; 6% endorsed energy insecurity, 5% endorsed food insecurity, and 4% endorsed housing insecurity. In a multivariable model, financial toxicity was associated with age $\leq$60y at survey (Odds Ratio [OR] 5.1; 95% confidence interval [CI] 2.0-13.3); household income $<$ $50K/y (OR 5.3; 95%CI 2.5-11.2); being single (OR 2.6; 95%CI 1.3-5.4); and lower physical (OR 2.6; 95%CI 1.2-5.4) and mental (OR 2.2; 95%CI 1.2-4.3) HRQL. Cancer stage, race, time from diagnosis, and insurance type were not associated with financial toxicity. The prevalence of financial toxicity among survivors who were single, $\leq$60y at survey, and with household income $<$ $50k/y was 79.3%, compared with 6.7% among those who were older, married/partnered, and with higher income. **Conclusions:** Financial toxicity is prevalent among insured breast cancer survivors several years after cancer diagnosis, and is exacerbated among the younger survivors who are single, with low household income, and endorse poorer physical and mental quality of life. These findings inform the need to develop interventions to mitigate financial toxicity among at-risk breast cancer survivors. Research Sponsor: Breast Cancer Research Foundation of Alabama.

12074 Poster Session (Board #362), Fri, 8:00 AM-11:00 AM

Cutaneous pigmentary changes related to anticancer therapy in African Americans. *First Author: Dulce M. Barrios M.S, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: Pigmentary disorders are known to disproportionately affect individuals with darker skin, including African Americans (AAs)— a historically underrepresented population in oncology research. However, reports on the prevalence and characterization of anticancer-therapy related cutaneous pigmentary changes in this population are lacking. **Methods:** A retrospective analysis of AA cancer patients that ever received a hematopoietic stem cell transplantation (HSCT) and/or systemic oncologic therapy within six months prior to diagnosis of cutaneous hypo- or hyperpigmentation at our institution between 4/18/2012 and 8/26/2019 was conducted. Clinical and management characteristics were summarized; severity of pigmentary changes was assessed using the Common Terminology Criteria for Adverse Events version 5.0 (CTCAE v.5.0). **Results:** From a total of 1342 AA patients evaluated by oncodermatologists during the study period, 121 (9%) met inclusion criteria. Average age in this cohort was 52, and 102 (84%) were women. Breast (63, 52%), gastrointestinal (14, 12%), and hematologic malignancies (13, 11%) comprised the majority of cancer diagnoses. Most (93, 77%) patients had skin hyperpigmentation (84, 69%) or hypopigmentation (9, 7%) as a primary CTCAE diagnosis; the rest had secondary post-inflammatory hyperpigmentation (28, 23%). A higher proportion (105, 87%) of pigmentary alterations was attributed to single agents [i.e. chemo- (55, 46%), radiation (16, 13%), targeted (12, 10%), endocrine (9, 7%), and supportive oncologic (6, 5%) therapy] versus combination treatment (16, 13%). Five (4%) patients had graft versus host disease associated with allogeneic HSCT, four (80%) of which presented as cutaneous hypopigmentation. Hand foot syndrome (24, 20%), acneiform rash (24, 20%), and radiation dermatitis (16, 13%) were commonly diagnosed dermatologic adverse events (dAEs), generally classified as mild/grade 1 (67, 55%) in severity. For management, skin lightening agents +/- emollients (36, 30%) or emollients alone (25, 21%) were highly recommended. Topical corticosteroids +/- emollients were prescribed just as frequently as reassurance and/or avoidance of sun exposure (22, 18%). **Conclusions:** Cutaneous pigmentary changes related to cytotoxic chemotherapy, radiation and/or targeted oncologic therapy are common in AA cancer patients. Undertreatment of these dAEs, possibly due to under-recognition in darker skin, warrants further investigation to assess impact on quality of life and help improve management in this population. Research Sponsor: Conquer Cancer Foundation of the American Society of Clinical Oncology.

12075 Poster Session (Board #363), Fri, 8:00 AM-11:00 AM

Long-term cancer survival in cohorts of U.S. health professionals. *First Author: En Cheng, Yale University, New Haven, CT*

Background: Few studies have investigated long-term survival and causes of death among men and women diagnosed with major cancers. **Methods:** We estimated overall and cause-specific mortality rates for men diagnosed with prostate, lung and bronchus, colon and rectum, bladder, and melanoma cancer in the Health Professionals Follow-up Study between 1986-2010+, and women with breast, lung and bronchus, colon and rectum, uterine corpus, thyroid, and ovarian cancer in the Nurses' Health Study (NHS) between 1976-2010+ and NHS II between 1989-2010+. Kaplan-Meier curves were used to calculate cumulative mortality rates at 5, 10, 15, 20, and 30 years and competing risk methods were used to calculate cumulative cancer-specific mortality rates of major causes at 5, 10, 15, 20, and 30 years. Additionally, among women 40-year mortality rates were calculated. **Results:** Except for lung and ovarian, most major cancer patients are more likely to die from other causes than the index cancer. We observed two basic patterns for cumulative cancer-specific mortality rates. The first pattern is greatly diminished risk of index cancer-specific mortality 10 years or more following diagnosis - for colorectal cancer, cancer-specific mortality rate increased by less than 3% between 10 to 30- or 40-year following diagnosis (among men, from 35.1% to 36.7%; among women, from 34.8% to 37.7%), and this pattern also applied to bladder, melanoma, or uterine corpus cancer. The second one is sustained, but nevertheless low, excess risk - prostate cancer-specific mortality rate increased gradually and almost linearly from 5.3% to 15.1% after diagnosis from 5 to 30 years, and for breast cancer, it increased likewise from 7.2% to 18.9% after diagnosis from 5 to 40 years. **Conclusions:** Except for lung and ovarian cancers, patients diagnosed with major cancers were more likely to die from causes other than cancer. Colorectal, bladder, melanoma or uterine corpus cancer patients surviving more than 10 years after diagnosis are unlikely to ever die from that disease. Research Sponsor: U.S. National Institutes of Health.

All-cause* and cancer-specific† mortality rates of men (1986-2018) and women (1976-2018) diagnosed with major cancers.

	Men				Women		
		30-year				40-year	
Cancer Types	N	AC	CS	Cancer Types	N	AC	CS
Prostate	6,993	86.5	15.1	Breast	19,904	70.9	18.9
Lung and bronchus	1,309	98.1	83.1	Lung and bronchus	4,251	98.1	80.8
Colon and rectum	1,424	89.5	36.7	Colon and rectum	3,736	88.4	37.7
Urinary bladder	1,570	85.4	21.7	Uterine corpus	1,645	81.7	16.3
Melanoma	3,212	76.1	7.4	Thyroid	1,119	50.8	3.2
				Ovary	1,734	88.6	58.8

Abbreviations: AC, All-cause; CS, Cancer-specific.

12076 Poster Session (Board #364), Fri, 8:00 AM-11:00 AM

Risk of secondary hematologic malignancies in patients with ovarian cancer treated with PARP inhibitors: A combined meta-analysis of seven phase III randomized controlled trials. *First Author: Thura Htut, Department of Haematology, Aberdeen Royal Infirmary, Foresterhill Health Campus, Aberdeen, United Kingdom*

Background: Ovarian cancer (OC) is a leading cause of death from gynecologic cancers in women worldwide. Poly adenosine diphosphate ribose polymerase (PARP) inhibitors prevent the repair of single-strand breaks and generate double-strand breaks in tumor cells and have recently shown survival benefits in OC. Yet, the impact on the risk of secondary hematologic malignancies (SHM) remains uncertain. We performed a combined meta-analysis of randomized controlled trials (RCT) to determine the risk of SHM in patients with advanced OC treated with PARP inhibitors. **Methods:** MEDLINE, EMBASE databases and meeting abstracts from inception through January 2020 were queried. Phase III RCTs utilizing PARP inhibitors maintenance in advanced OC were eligible. Mantel-Haenszel (MH) method was used to calculate the estimated pooled risk ratio (RR) with 95% confidence interval (CI). Heterogeneity was assessed with I^2 and Cochran's Q- statistic. Fixed effects model was applied. **Results:** A total of 4,445 patients with advanced OC from seven phase III RCTs were included. The study arm used olaparib or niraparib or rucaparib or veliparib or olaparib +bevacizumab while the control arm utilized placebo or bevacizumab. Randomization ratio was 2:1 in all studies. The I^2 statistic for heterogeneity was 0, suggesting some heterogeneity among RCTs. The overall SHM incidence was 0.80% in PARP inhibitors group vs 0.47% in control group (RR 1.45; 95% CI: 0.68 – 3.07, P = 0.34). In patients with newly diagnosed OC (n = 3,044), the incidence was 0.59% vs 0.09% in control group (RR 2.7; 95% CI: 0.7—10.37, P = 0.15). In recurrent OC subset (n = 1,401), 1.28% were reported in both study and control arms (RR 0.96; 95% CI: 0.38-2.46, P = 0.94). SHM was noted in 1.3% in the olaparib subgroup compared to 1% in the control with RR of 1.24 (95% CI: 0.46 –3.31, P = 0.67). SHM occurred in 0.7% in the niraparib subgroup compared to 0.47% in the control with RR of 1.28 (95% CI: 0.30-5.45, P = 0.74). **Conclusions:** Our study demonstrated that the risk of SHM was not significantly increased in patients who received PARP inhibitors compared to control arm, despite attaining survival benefits. Further studies and long term follow up are necessary to define the actual relation and definitive incidence. Research Sponsor: None.

12077 Poster Session (Board #365), Fri, 8:00 AM-11:00 AM

High flow oxygen for dyspnea in hospitalized patients with cancer: A 4x4 crossover randomized clinical trial. *First Author: David Hui, University of Texas MD Anderson Cancer Center, Houston, TX*

Background: Dyspnea is common in hospitalized cancer patients and highly distressing. High flow oxygen (HFOx) is administered for oxygenation in this setting; however, its effect on dyspnea has not been well examined, particularly among non-hypoxemic patients. In this phase II trial, we assessed the effect of HFOx, high flow air (HFAir), low flow oxygen (LFOx) and low flow air (LFAir) on dyspnea. We hypothesized that HFO and HFA can alleviate dyspnea. **Methods:** This double-blind, 4x4 crossover clinical trial enrolled hospitalized patients with cancer who were dyspneic (NRS $\geq$3 at rest) and non-hypoxemic (SpO2>90% on room air). Patients were randomized to 10 minutes of HFOx, HFAir, LFOx and LFAir in different orders. The flow rate was titrated between 20-60 L/min in the high flow groups and 2 L/min in the low flow groups. The primary outcome was dyspnea 0-10 numeric rating scale (NRS) "now", where 0=none and 10=worst. Secondary outcomes included modified Borg scale dyspnea intensity and unpleasantness, adverse effects, and overall preference. We compared among the interventions with a linear mixed model adjusting for time, treatment effect, period effect and carryover effect. **Results:** 17 patients completed 55 interventions in a random order. Mean age 51, 58% female, mean baseline dyspnea NRS 6.3 (SD 1.7). The absolute change of dyspnea NRS between 0 and 10 minutes was -1.8 (SD 1.7) for HFOx, -1.8 (2.0) for HFAir, -0.5 (0.8) for LFOx and -0.6 (1.2) for LFAir. In mixed model analysis, HFOx group provided greater dyspnea relief than LFOx (mean difference [95% CI] -0.80 [-1.45, -0.15], P=0.02) and LFAir (-1.24 [-1.90, -0.57], P<0.001). HFAir also provided a significantly greater dyspnea relief than LFOx (-0.95 [-1.61, -0.30], P=0.005) and LFAir (-1.39 [-2.05, -0.73], P<0.001). No difference was found between HFOx and HFAir nor between LFOx and LFAir. There was no significant carryover effect. Dyspnea Borg scale intensity and unpleasantness showed similar changes. Oxygen saturation increased in the HFOx group (97.2% to 99.7%) and LFOx group (95.5% to 98.2%) but not HFAir nor LFAir groups. HFOx was well tolerated. At the end of the study, 7 (54%), 4 (31%), 1 (8%) and 1 (8%) patients blindly preferred HFOx, HFAir, LFOx and LFAir, respectively. **Conclusions:** For the first time, we found that HFOx and HFAir provided a rapid and clinically significant reduction of dyspnea at rest in hospitalized cancer patients even when they were non-hypoxemic, supporting a role for high flow devices to provide palliation beyond oxygenation. Larger studies are needed to confirm these findings. Clinical trial information: NCT02932332. Research Sponsor: Sabin Family Foundation Fellowship Award.

12078 Poster Session (Board #366), Fri, 8:00 AM-11:00 AM

Patient controlled analgesia (PCA) vs non-PCA intravenous hydromorphone titration for severe cancer pain: A multi-center, phase III trial, HMORCT09-1. *First Author: Rongbo Lin, Gastrointestinal Medical Oncology, Fujian Cancer Hospital, Fuzhou, China*

Background: The titration of opioid dosage is necessary for adequate pain relief with acceptable side effects among individuals with cancer pain. The titration process can be achieved by non-patient administration or PCA pump. The aim of this study was to evaluate the efficacy of PCA versus non-PAC titration for severe cancer pain. **Methods:** Patients with severe cancer pain (NRS $\geq$ 7/10 at rest) were randomized into PCA or non-PCA titration and stratified by opioid tolerance or intolerance. For PCA, the pump was set as no continuous dose, hydromorphone bolus dose was 10%-20% of the total equianalgesic of past 24h for opioid tolerance, or 0.5 mg for opioid intolerance. The lockout time was 15 min. For non-PCA, initial hydromorphone bolus was the same with PCA. Reassess pain at 15 min. The dose of hydromorphone was increased by 50%-100% if pain unchanged or increased, or repeated if NRS was 4-6, or continue at current dose as needed if NRS$\leq$3. The primary endpoint was the time to successful titration (TST) - time from start to the time of pain controlled at NRS $\leq$ 3 in two consecutive evaluation with 15-min intervals, which was tested by K-M curve. **Results:** A total of 214 patients were randomized (106 in PCA, 108 in non-PCA) in 17 study sites. The most common sites of primary cancer were lung (21.03%), stomach (15.89%), colorectal (14.49%) etc. Median TSTs were 0.50h in PCA, 0.79h in non-PCA, HR 1.64 (95% CI 1.23, 2.17, P = 0.00127). In opioid tolerance, 0.50h in PCA, 1.00h in non-PCA (HR 1.92, 95% CI 1.32, 2.78, P = 0.0025). while in opioid intolerance, 0.50h in PCA and 0.50 in non-PCA (HR 1.35, 95% CI 0.88, 2.04, P = 0.162). The median dosage of hydromorphone for TST was 1.00mg (P_{25}, P_{75} 0.50, 2.00) in PCA, 1.50mg (P_{25}, P_{75} 1.00, 2.50) in non-PCA (P = 0.086). In opioid tolerance, 1.00mg (P_{25}, P_{75} 1.00, 2.00) in PCA, 2.00mg (P_{25}, P_{75} 1.00, 4.00) in non-PCA (P = 0.009). In opioid intolerance, 1.00mg (P_{25}, P_{75} 0.50, 2.00) in PCA and 1.00 mg (P_{25}, P_{75} 0.50, 2.00) non-PCA (P = 0.793). Mean patient satisfaction assessed by ESAS score was significantly superior in PCA to non-PCA (0.62$\pm$0.67 vs 1.27$\pm$0.98 for ITT, 0.66$\pm$0.66 vs 1.39$\pm$1.00 for opioid tolerance, and 0.56$\pm$0.69 vs 1.13$\pm$0.95 for opioid intolerance). Adverse events were similar in both PCA/non-PCA groups. **Conclusions:** PCA IV hydromorphone titration provided quicker analgesic effect, higher patients satisfaction, and a similar tolerability as compared to non-PCA administration in patients with severe cancer pain. Clinical trial information: NCT03375515. Research Sponsor: None.

12079 Poster Session (Board #367), Fri, 8:00 AM-11:00 AM

Using digital engagement to proactively manage symptoms in patients on capecitabine. *First Author: Mandeep Sohal, CVS Health, Woonsocket, RI*

Background: Adherence to oral chemotherapy is a challenge due to the toxic adverse events (AEs) patients' experience. Capecitabine (CAP) may cause patients to experience AEs such as diarrhea and hand and foot syndrome (HFS), leading to therapy non-adherence. Digital patient engagement has successfully improved patient adherence and has been used to monitor AEs in a variety of cancer types. We used proprietary secure messaging to engage specialty patients receiving CAP and to message them at the expected onset of diarrhea and HFS; nurse care management was deployed for patients reporting an AE. The objective of this study was to determine whether nurse engagement using digital tools to manage oncology AEs resulted in improved medication adherence. **Methods:** CAP patients were sent outgoing SMS branching logic messages during November 2019, and respondents reporting AEs were engaged by nurses using a proprietary secure messaging platform. Nurses made clinical interventions in these patients by either making a pharmacologic or non-pharmacologic recommendation or referring the patient to an oncologist. The number of patients responding to outgoing SMS and secure messaging, nurse interventions, and medication fill history were measured. We compared 30-day post-intervention proportion of days covered (PDC) in the intervention group (those that engaged with nurses and received digital adherence and clinical messages) to standard of care (those who received digital adherence and clinical messages but did not engage) using the Student's t-test. **Results:** 1,421 outgoing messages were sent to utilizers of CAP; 95 patients replied indicating the occurrence of either diarrhea or HFS. Nurse care managers reached 49 (52%) unique patients resulting in 54 interventions where care coordination was provided. The majority of engaged patients reached (74%) had symptom resolution as a result of nurse intervention. PDC was 79.3% in the intervention group and 68.8% (p = 0.038) in the standard of care group. **Conclusions:** SMS and secure messaging patients with AEs on CAP resulted in clinical interventions by nurse care managers. Nurse intervention resulted in the majority of patients having symptomatic resolution and therapy continuation. PDC indicated greater medication adherence in the engaged group. These results for one drug suggest that nurse digital engagement can be effective in increasing adherence for patients treated with oral oncolytics suffering from AEs. Proactive symptom tracking supports the early identification of potential AEs and effective nurse care coordination. Research Sponsor: CVS Health.

12080 Poster Session (Board #368), Fri, 8:00 AM-11:00 AM

Relationships between worry about dying in patients with advanced cancer and their illness understanding, treatment preferences, and advance care planning. *First Author: Rachel Rodenbach, University of Pittsburgh Medical Center, Pittsburgh, PA*

Background: Patients with advanced cancer often worry about dying, yet little is known about the role their fears play regarding future care. We aimed to explore relationships between patients' worry about dying and their illness understanding, treatment preference, and advance care planning. **Methods:** This cross-sectional study uses baseline data from a community-based, primary palliative care intervention trial. Patients had metastatic solid tumors, an Eastern Cooperative Oncology Group performance status of 0-2, and their oncologist "would not be surprised" if they died in the next year. Using patients' response to "I worry about dying" (not at all, a little bit, somewhat, quite a bit, or very much) from the Functional Assessment of Chronic Illness - Palliative Care survey instrument, univariate and multivariate analyses assessed associations with illness understanding (report of being terminally ill or not), treatment preference (life-extending vs. symptom-focused), and advance care planning (completion of an advance directive or not). We also performed sensitivity analyses substituting "I feel scared about my future" (strongly disagree, disagree, agree, or strongly agree) from the Herth Hope Index for "I worry about dying." **Results:** Of 672 patients, 54% were female, 94% white, and 69% currently receiving chemotherapy. 47% reported worrying about dying "not at all," while 9.7% worried "quite a bit" or "very much." In regression analysis, those who worried "quite a bit" or "very much" were more likely to describe themselves as terminally ill (adjusted odds ratio (AOR)=1.98, 95% CI=1.10-3.54, p=0.021) and more likely to prefer life-extending treatment over symptom-focused care (AOR=2.61, 95% CI=1.30-5.22, p=0.007) compared with patients who reported not worrying about dying. They also were less likely to have completed an advance directive (AOR=0.49, 95% CI=0.25-0.94, p=0.032). The same relationships were observed using patients' response to "I feel scared about my future." **Conclusions:** Patients with advanced cancer who worry more about dying can affirm they are terminally ill and are more likely to want life-extending treatment over symptom care while less likely to engage in advance care planning. Understanding these patients' decision making is critical to ensuring that their values are known and understood near the end of life. Research Sponsor: U.S. National Institutes of Health.

12081 Poster Session (Board #369), Fri, 8:00 AM-11:00 AM

Results of a randomized, open-label, multicenter trial to assess the safety, dose, and schedule ofRRx-001(001) in reducing incidence, severity and duration of severe oral mucositis (SOM) inpatients receiving concomitant chemoradiation (CRT) for advanced head and neck cancer (HNC). *First Author: Marcelo Raul Bonomi, James Cancer Hospital Solove Research Institute, The Ohio State University, Columbus, OH*

Background: SOM occurs in 70% of patients receiving CRT for HNC with consequent pain, treatment interruptions and increased costs of care. Supraphysiologic levels of oxidative stress are key SOM initiators. 001 activates nuclear factor erythroid related factor 2 (Nrf2) increasing expression of multiple antioxidant genes including superoxide dismutase glutathione peroxidase and glutathione S-transferase. This trial examined the effect of dose and schedule on safety and efficacy of 001. Primary efficacy endpoint was duration of SOM (WHO criteria assessed); secondary endpoints included time to onset, incidence grade 4 through 60Gy and 70Gy. **Methods:** Locally advanced HNC treated with definitive or postoperative CRT (cisplatin + RT) received one of 3 001 schedules: (ARM1) 2 doses/wk for 2 weeks (prior to) CRT. ARMS 2, 3: prior to + 2 doses or 6 doses with CRT respectively or standard of care (SOC). **Results:** 53 patients randomized, 45 evaluable. Benefit trends for endpoints were consistent across all 3 001 arms with greatest effect size in pre-treatment only, ARM1. Compared to SOC, 001 reduced duration of SOM by 45% (40 vs 22 days). Through 60Gy and 70Gy a reduction of 95% and 79% in duration SOM was also observed (17 vs 1 day, and 23 vs 5 days) respectively. No patients in ARM1 developed grade 4, (0% vs SOC 30%). Side effects were comparable to SOC. **Conclusions:** In this small, open label trial, 001 demonstrated a favorable risk-benefit profile supported by reductions in overall SOM duration including through 60Gy and 70Gy with no grade ARM1 was most effective suggesting short periods of Nrf2 activation before CRT oxidative stress generation may increase the threshold and buffering capacity of upregulated antioxidants. Larger, blinded trials, confirming the observed dose, schedule and treatment effects are warranted. Clinical trial information: NCT03515538. Research Sponsor: Prothex Pharma, Inc.

12082 Poster Session (Board #370), Fri, 8:00 AM-11:00 AM

Value of oncologist generated "surprise question" in predicting survival in metastatic cancer. *First Author: Stephen B. Edge, Roswell Park Comprehensive Cancer Center, Buffalo, NY*

Background: Treating patients with metastatic cancer (MCA) requires timely integration of palliative and hospice care (PHC). The Surprise Question (SQ-"Would you be surprised if your patient died in the next year?") may help predict short-term mortality in patients with chronic disease and prompt initiation of PHC. There limited data on the utility of the SQ in oncology and none controlling for age and cancer site (CS). This study evaluates the SQ in MCA. **Methods:** SQ data were collected using a clinical oncology pathway program (COP) in which the treating oncologist is required to answer the SQ for all patients with MCA. The cohort includes MCA patients with SQ entries from 5-1-2018 to 4-30-2019 providing cohorts with 6- and 12-months follow-up (f/u) from the date of the SQ. Vital status was determined as of 1-15-20. Over 90% of deaths are reported with 3 months of death. Models using SQ response (yes/no), cancer site and age were tested with logistic regression (LR) with Akaike Information Criterion (AIC) for model selection (lower number best model) and ANOVA to assess the value of the SQ in predicting mortality. **Results:** There were 655 and 1276 patients with MCA in COP with 1 year and 6 months f/u from the SQ, respectively. The proportion with the SQ response "No" (shorter expected survival) varied by cancer site (range 19% – 82% - e.g. breast 42%; pancreas 81%). The SQ was the best predictor compared to cancer site and age for 6 and 12-month mortality (LR Model A – lowest AIC). The odds ratio of death at one year from SQ-No vs. SQ-Yes was 3.8 (95% CI 2.7, 5.4) with a strong association between SQ response and 1-year and 6-month mortality ($p < 0.001$). See Table. **Conclusions:** Oncologist assessment of survival expectancy by the SQ in MCA is a strong predictor of mortality beyond cancer site and age. The treating oncologist's response to SQ can serve as a simple and reliable predictive tool to identify those with MCA likely to die sooner who may benefit from timely referral to PHC. Research Sponsor: None.

Follow-up Time	6-month	6-month SQ-No	6-month SQ-Yes	1-year	1-year SQ-No	1-year SQ-Yes
Total at Risk	1276	972	604	655	328	327
Mortality	324 (25%)	230 (34%)	94 (16%)	278 (42%)	191 (58%	87 (26%)
Pearson's c^2 test			$p_{val}<$ 0.001			$p_{val}<$ 0.001
Model Description	AIC	Comparison	p_{val}	AIC	Comparison	p_{val}
A: Mortality = SQ	1389.8	D vs A	0.014	828.6	D vs A	0.098
B: Mortality = CS	1426.5	C vs B	< 0.0001	881.6	C vs B	< 0.0001
C: Mortality = SQ + CS	1393.8	C vs A	0.026	836.2	C vs. A	0.096
D: Mortality = SQ + CS + Age	1392.1	D vs C	0.057	837.0	D vs. C	0.281

12083 Poster Session (Board #371), Fri, 8:00 AM-11:00 AM

Assessing the impact of antiemetic guideline compliance on prevention of chemotherapy-induced nausea and vomiting (CINV): Results of the Nausea/Emesis Registry in Oncology (NERO). *First Author: Matti S. Aapro, Clinique de Genolier, Genolier, Switzerland*

Background: Evidence-based antiemetic guidelines offer predominantly consistent recommendations for CINV prophylaxis. However, studies and surveys suggest that adherence to these recommendations is suboptimal. We explored potential inconsistencies between clinical practice and guideline-recommended treatment with a registry evaluating the effect of guideline-consistent CINV prophylaxis (GCCP) on patient outcomes. **Methods:** This was a prospective, non-interventional, observational, multicenter study designed to assess overall (0-120 h) complete response (CR: no emesis/no rescue use) rates in patients who received GCCP or guideline inconsistent CINV prophylaxis (GICP) using diaries for 5 days following chemotherapy. Cycle 1 results are presented in patients who received either 1) anthracycline/cyclosphosphamide (AC) highly emetogenic chemotherapy (HEC), non-AC HEC or carboplatin, with GCCP for all these groups consisting of prophylaxis with an NK_1 receptor antagonist (RA), 5-HT_3RA, and dexamethasone (DEX) prior to chemotherapy or 2) moderately emetogenic chemotherapy (MEC), with GCCP consisting of a 5-HT_3RA and DEX prior to chemotherapy as per MASCC 2016 guidelines. CR rates for cohorts deemed to be GCCP and GICP were compared using a chi-square test. **Results:** A total of 1,089 patients were part of the cycle 1 efficacy evaluation. Overall GCCP was 23% for all patients. CR rates were significantly higher in patients receiving GCCP versus GICP (Table). **Conclusions:** Consistent with prior studies, GCCP was very low. The primary endpoint of the study was achieved as there was a significant benefit of almost 10% improved prevention of CINV when administering GCCP. As per MASCC/ESMO guidelines such an absolute difference should be practice changing. Comprehensive multifaceted strategies are needed to achieve better adherence to antiemetic guidelines. Research Sponsor: Angelini Pharma Oestereich GmbH.

All Patients (N = 1089)	GCCP	GICP
Proportions of Patients who Received GCCP vs. GICP	251/1089 **(23.0%)**	838/1089 **(77.0%)**
Overall CR Rates	156/251 **(62.2%)***	441/838 **(52.6%)**

*Statistically significant difference ($P < 0.05$, chi-square test) between GCCP vs. GICP group

12084 Poster Session (Board #372), Fri, 8:00 AM-11:00 AM

Symptom burden as a predictor of emergency room use and unplanned hospitalization in patients with head and neck cancer: A population-based study. *First Author: Christopher Noel, Department of Otolaryngology Head and Neck Surgery, Faculty of Medicine, University of Toronto, Toronto, ON, Canada*

Background: Symptoms are common in oncology patients, though they remain undetected and untreated by clinicians in up to 50% of cases. Integrating patient reported outcomes (PRO) within routine clinical practice has been suggested as a way to improve detection. In order to inform an effective and efficient PRO symptom screening program, we sought to determine whether outpatient symptom scores could predict emergency room use and unplanned hospitalization (ER/Hosp) in a cancer patient population. **Methods:** This was a population-based study of patients diagnosed with head and neck cancer who had completed at least one outpatient Edmonton Symptom Assessment System (ESAS) assessment between January 2007 and March 2018 in Ontario. Logistic regression models were used to determine the relationship between reported outpatient ESAS scores and ER/Hosp use in the 14-day period following ESAS completion. A generalized estimating equations approach was incorporated to account for possible patient-level clustering. **Results:** There were 11,761 unique patients identified with a total of 73,282 ESAS assessments. There were 5,203 ER/Hosp outcome events. In adjusted analysis, the odds of ER/Hosp use increased log linearly with ESAS score (1.23 per 1 unit increase in index ESAS score, [95% confidence interval (CI) 1.22 – 1.25]). This corresponds to a 9.23 (95%CI 7.22-11.33) higher odds of ER/Hosp use for the maximum index ESAS score of 10. Seven of the nine ESAS symptom scores were significantly associated with ER/Hosp use with pain, appetite and shortness of breath demonstrating the strongest association. **Conclusions:** ESAS scores are independently associated with 14-day ER/Hosp in head and neck cancer patients. Appropriate and timely management of symptom burden may reduce rates of ER/Hosp. Research Sponsor: Canadian Institute of Health Research Terry Fox New Investigator Award, Other Foundation, Other Government Agency.

Logistic regression models for odds of 14-day ER use or unplanned hospitalization (ER/Hosp) by Index ESAS score.

ESAS Score (0-10)	Univariable		Multivariable*		14-day ER/Hosp use (%)
	OR	(95% CI)	OR	(95% CI)	
0	1	REF	1	REF	1.5
1	1.55	(1.21-1.99)	1.51	(1.17-1.95)	2.3
2	1.68	(1.34-2.10)	1.57	(1.24-1.97)	2.4
3	2.60	(2.09-3.23)	2.33	(1.87-2.90)	3.8
4	3.14	(2.52-3.92)	2.68	(2.14-3.35)	4.6
5	3.65	(2.97-4.49)	3.05	(2.48-3.77)	5.3
6	5.05	(4.10-6.23)	4.16	(3.36-5.15)	7.2
7	5.55	(4.52-6.81)	4.52	(3.67-5.56)	7.7
8	7.20	(5.90-8.80)	5.81	(4.74-7.12)	9.9
9	9.63	(7.83-11.84)	7.67	(6.21-9.47)	12.9
10	11.75	(9.61-14.36)	9.23	(7.52-11.33)	15.1

*adjusted for age, sex, rurality, comorbidity, treatment modality, subsite, diagnosis year and treatment centre

12085 Poster Session (Board #373), Fri, 8:00 AM-11:00 AM

Optimizing management of the oncological patient with pulmonary embolism: Validation of the epiphany index—PERSEO study. *First Author: Manuel Sánchez Cánovas, Department of Hematology and Medical Oncology, Hospital G. Universitario Morales Meseguer, IMIB-Arrixaca, Murcia, Spain*

Background: EPIPHANY is the first algorithm to predict serious complications in both suspected and unsuspected cancer-associated pulmonary embolism (PE), overcoming limitations of previous models. **Methods:** PERSEO is a prospective multicenter study. We recruited cancer patients with both incidental and symptomatic PE treated between Oct. 2017 and Dec. 2019. The primary aim was to determine the percentage of serious complications in patients at low predicted risk, with at least 3% accuracy. We also compared the predictive parameters of EPIPHANY with other available scores for prediction 15-day serious complications and 30-day mortality. **Results:** Cohort includes 831 patients (men, 58.6%; median age, 66 years). Most frequent tumors were lung (27.1%), colorectal (19%) and breast (7.8%). 78.6% had stage IV disease, and 77.6% were receiving antineoplastic treatment. EPIPHANY classified 27%, 24% and 49% of patients as low, medium and high risk, respectively. The rate of 15-day serious complications increased significantly across these prognostic categories: 2.67 (95% CI 0.6 - 4.8), 8.9% (95% CI 0.5 - 12.8), and 25.9% (95% CI 21.7 - 30.2), for low, intermediate, and high risk patients, respectively ($p<0.001$, linear-by-linear test). In comparison with other validated scores, EPIPHANY has a higher negative predictive value, lower negative likelihood-ratio, and comparable sensitivity (Table). **Conclusions:** The EPIPHANY index is able to identify a subgroup of patients with cancer-associated pulmonary embolism at very low risk of serious complications or short-term mortality, with potential implications for decision making. Research Sponsor: Leo Pharma.

		EPIPHANY (all patients)	EPIPHANY (patients with non-incidental EP)	RIETE*	PESI*	s-PESI*
15-day serious complications	S	95,3% (CI 95% 91,7 - 99)	97,4% (CI 95% 90,07 - 99,55)	81,67% (CI 95% 69,15 - 90,07)	96,9% (CI 95% 92,7 - 100)	100 %
	E	31,1% (CI 95% 27,6 - 34,5)	5,58% (CI 95% 3,05 - 9,78)	24,46% (CI 95% 18,57 - 31,44)	5,1% (CI 95% 1,9 - 8,4)	0 %
	PPN	97,3% (CI 95% 95,2 - 99,4)	85,71% (CI 95% 56,15 - 97,48)	80,36% (CI 95% 67,17 - 89,34)	81,8% (CI 95% 59 - 100)	0 %
	LR -	0,15	0,44	0,749	0,61	0
30-day mortality	S	99% (CI 95% 94,3 -100)	100 %	97,5% (CI 95% 85,27 - 99,87)	97,9% (CI 95% 93,7-100)	100 %
	E	30,3% (CI 95% 27-33,7)	5,86% (CI 95% 3,36 - 9,85)	26,96% (CI 95% 21,1-33,69)	5,2% (CI 95% 2,1 - 8,3)	0 %
	PPN	99,6% (CI 95% 98,7 - 100)	100 %	98,21% (CI 95% 89,18 - 99,91)	90,9% (CI 95% 73,9 - 100)	0 %
	LR -	0,03	0	0,09	0,41	0

*For the calculation of the SCORE in these models, incidental EPs have not been taken into account since they are scales developed for symptomatic EP.

12086 Poster Session (Board #374), Fri, 8:00 AM-11:00 AM

Frequency and prediction of non-medical opioid use behaviors (NMOU) among advanced cancer patients referred to a supportive care center (SCC). *First Author: Sriram Yennu, The University of Texas MD Anderson Cancer Center, Houston, TX*

Background: One of the methodological barriers to conducting research on interventions for NOMU (Aberrant Opioid Use Behaviors) among cancer patients is the lack of data on the frequency of this problem. Although the frequency of risk factors has been established by our group and others, not all the patients with risk factors will be diagnosed with having NMOU behaviors, and some patients with no previous risk factors will engage in NMOU. AIM: To characterize the overall frequency of NMOU for a duration of 3 months, as well independent predictors for NMOU. **Methods:** In this retrospective study, 1558 consecutive patients referred to supportive care clinic (SCC) from 3/18/2016 to 6/6/2018 were reviewed for development of NMOU using established diagnostic criteria. Patients were eligible if they were $\geq$18 years, had a diagnosis of cancer, and were on opioids for pain for at least a week. All patients were assessed with the Edmonton Symptom Assessment Scale (ESAS), SOAPP-14, and CAGE-AID. Descriptive statistics, spearman correlation coefficient, multivariate analysis were performed. **Results:** 299 patients (19%) had $\geq$1 NMOU behavior. The median (IQR) NMOU behavior was 1 (1-2); range 1-10. Most NMOU occurred at 1st and 2nd follow up visits. The most frequent NMOU behavior was unscheduled clinic visit for inappropriate refills. 29/299 (10%) NMOU patients received specialized care for high-risk for aberrant opioid misuse by interdisciplinary team. Results of multivariate logistic regression model showed Marital status (Divorced vs. Married, OR=1.47, 95% CI: 0.98, 2.22, p=0.654 (marginally significant); Single vs. Married, OR=1.68, 95% CI: 1.15, 2.46, p=0.0079), SOAPP (Positive vs. Negative, OR=1.42, 95% CI: 1.05, 1.93, p=0.0238), morphine equivalent daily dose (MEDD) (OR=1.004, 95% CI: (1.003, 1.006), $p<0.0001$) and ESAS pain (OR=1.11, 95% CI: 1.06, 1.17, $p<0.0001$) were independently associated with the presence of NMOU during follow-up visits. **Conclusions:** 19% cancer patients followed at SCC had detectable NMOU behaviors. Being single, SOAPP+, pain severity and high MEDD were independent predictors for NMOU. This information will assist clinicians and investigators designing clinical and research programs in this important field. Research Sponsor: Institutional funds.

12087 Poster Session (Board #375), Fri, 8:00 AM-11:00 AM

Feasibility of olanzapine at reduced dose in highly emetogenic chemotherapy: A randomised controlled trial against aprepitant in triple therapy (FORESIGHT). *First Author: Michelle Chen, CISSS Monteregie-Centre-Hopital Charles LeMoyne, Greenfield Park, QC, Canada*

Background: Olanzapine is used as an adjunct antiemetic in oncology as salvage therapy and in four-drug prophylaxis. Growing literature supports its effectiveness in initial three-drug prophylaxis in highly emetogenic chemotherapy (HEC). **Methods:** This prospective, multi-centre, open-label study evaluated the feasibility of a large-scale randomized controlled trial comparing the effectiveness and tolerability of 5 mg olanzapine once daily for four days (starting the night before chemotherapy) versus standard dose aprepitant (in tritherapy with standard ondansetron and dexamethasone) in treatment-naive patients receiving the first cycle of a HEC. Secondary outcomes included: complete response (no nausea, no emesis, no use of rescue medication), complete remission (no emesis, no rescue medication), intensity of patient-reported nausea and emesis on a visual analog scale, quality of life (scored with the Functional Living Index Emesis [FLIE]), and incidence of adverse events. **Results:** We randomized 30 patients in an intent-to-treat analysis. The large-scale trial was deemed not feasible without support from a research centre. Complete response rates were significantly higher in the olanzapine group in the delayed phase (24-120h post-chemotherapy) (86,7% v 21,4%, $p < 0,001$) and overall phase (0-120h post-chemotherapy) (60,0% v 21,4%, $p = 0,04$). Similar results were observed for complete remission. Intensity of patient-reported nausea was significantly lower in the olanzapine group in the delayed phase ($p = 0,001$). FLIE scores were significantly lower for the nausea domain (mean 62,3 v 60,9, $p = 0,004$) and overall score (124,3 v 108,8, $p = 0,006$). Depression on the ESAS-R was more common in the aprepitant group (0% v 38%, $p = 0,01$). Other adverse events were not significantly different. **Conclusions:** Support from a research centre must be ensured for study feasibility. Tritherapy olanzapine significantly improved complete response and remission in the delayed and overall phases post-chemotherapy among patients receiving HEC. It was also associated with higher quality of life and a reassuring safety profile. This feasibility trial, despite its small sample size, is one of the first prospective randomised trials to suggest similar efficacy of 5 mg olanzapine to aprepitant and to measure a difference in patient quality of life with this regimen. Clinical trial information: NCT04075955. Research Sponsor: Funding was provided by the Pharmacy department of the CISSS Monteregie-Centre.

12088 Poster Session (Board #376), Fri, 8:00 AM-11:00 AM

Efficacy and safety of direct oral anticoagulants (DOACs) and low molecular weight heparin (LMWH) for primary prevention of venous thromboembolism (VTE) in ambulatory cancer patients. *First Author: Mina Shenouda, Tampa General Hospital, Tampa, FL*

Background: Active malignancy is a well described risk factor for thrombosis. Randomized clinical trials (RCT) have evaluated anticoagulation (AC) with DOACs or LMWH for prevention of VTE in ambulatory cancer patients. This objective of this meta-analysis is to evaluate the efficacy and safety of DOACs and LMWH thromboprophylaxis in adult patients with active solid organ malignancy or lymphoma. **Methods:** We conducted a search of MEDLINE, EMBASE, and CENTRAL from 10/31/2009-11/31/2019. Data for meta-analysis was extracted from studies that met inclusion criteria (RCT, ambulatory patients age >18 years with active solid organ malignancy or lymphoma, prophylactic AC with DOAC or LMWH). Risk ratio (RR) were calculated for primary (efficacy) end point of VTE occurrence and secondary (safety) end points of major bleeding (MB) and clinically relevant non-major (CRNMB). Subgroup analyses of efficacy and safety endpoints were conducted based on AC and cancer types. **Results:** Eleven trials met inclusion criteria with total of 7741 participants. Two trials evaluated DOACs and nine trials evaluated LWMH for thromboprophylaxis. Efficacy results are noted in Table. Safety outcomes for MB and CRNMB for AC were RR 1.83 (95% CI 1.26, 2.65), p=0.001 and RR 1.36 (95% CI 1.05, 1.76), p=0.02. Safety outcomes for MB and CRNMB for DOAC were RR 1.95 (95% CI 0.88, 4.30), p=0.10 and RR 1.35 (95% CI 0.80, 2.27), p=0.26. Safety outcomes for MB and CRNMB for LMWH were RR 2.05 (95% CI 1.19, 3.51), p=0.009 and RR 1.44 (95% CI 1.01, 2.05), p=0.04. **Conclusions:** Both DOACs and LMWH decrease risk for VTE development in ambulatory adult cancer patients. MB and CRNMB were significantly increased in patients taking LMWH but not in patients taking DOACs. A large clinical trial using DOACs for thromboprophylaxis would help elucidate the thrombosis and bleeding event rate in ambulatory cancer patients. Research Sponsor: None.

Efficacy outcomes.

Intervention	Outcome/ Subgroup	# Studies	Participants	Risk Ratio (95% CI)	p-value
AC	VTE	11	7741	0.74 (0.36, 061)	<0.00001
DOACs	VTE	2	1404	0.55 (0.34, 0.90)	0.02
LMWH	VTE	9	6337	0.44 (0.32, 0.61)	<0.00001
AC	VTE/ Pancreas	5	1011	0.33 (0.13, 0.81)	0.02
AC	VTE/ Lung	5	2502	0.42 (0.28, 0/62)	<0.0001
AC	VTE/ Stomach	2	587	0.34 (0.09, 1.23)	0.10

12089 Poster Session (Board #377), Fri, 8:00 AM-11:00 AM

Improving cancer pain control: Potential impact of *CYP2D6* pharmacogenomic (PGx) testing in oncology (Onc) patients. *First Author: Natalie Reizine, University of Chicago Medical Center, Chicago, IL*

Background: Several opioid analgesics have well-known germline PGx associations which may predict either inefficacy or exaggerated (toxic) responses, depending on the patient's genotype. Despite this, germline PGx testing has not been routinely incorporated into oncology care. We hypothesized that *CYP2D6* germline PGx profiling offers the potential to improve oncology patients' pain control by identifying individuals at increased risk for inadequate analgesia with standard opioid dosing. **Methods:** We retrospectively analyzed the medication histories of over 81,000 adult oncology patients treated at the University of Chicago from 2012-2018 for exposure to opioids. *CYP2D6* genotype (permitting assignment of metabolizer phenotype: normal metabolizer [NM], intermediate metabolizer [IM], or poor metabolizer [PM]) was determined post-hoc for 127 patients who were genotyped for other reasons unrelated to pain prescribing. The primary endpoint was the number of opioids required for pain control over the course of longitudinal care, comparing PM/IMs with NMs. The secondary endpoint was the number of hospitalizations for pain control. **Results:** Over 47,000 oncology patients were exposed to opioids, with an average of 2.67±1.6 different opioid medication exposures per patient. Thirteen percent of genotyped patients were IM/PM, who were at risk for inadequate analgesia. IM/PM patients demonstrated an increased number of different opioid exposures (4.5±2.1) compared to NM (2.7±2.1, P value = 0.002). IM/PM patients were also more likely to have a pain related hospitalization (OR 4.17, CI 1.3-13.2, P = 0.016). **Conclusions:** Based on population prevalence, we estimate that > 6000 oncology patients (1000 patients/year) who received opioids at our center were IM/PM and thus at risk for inadequate analgesia due to genetic predisposition. CYP2D6 germline PGx profiling offers the potential to improve oncology patients' pain management. Research Sponsor: Benjamin McAllister Fellowship, Clinical Therapeutics Training Grant â€“ T32GM007019.

12090 Poster Session (Board #378), Fri, 8:00 AM-11:00 AM

Phase II randomized controlled trial (RCT) of medical intensive nutrition therapy (MINT) to improve chemotherapy (CT) tolerability in malnourished patients with solid tumor malignancies. *First Author: Michael Shusterman, Weill Cornell Medicine, New York-Presbyterian Hospital, New York, NY*

Background: Malnutrition is an underrecognized predictor of inferior cancer related outcomes. Subjective global assessment (SGA), a brief validated survey for malnutrition, may predict increased CT toxicity. This phase II RCT was performed to validate SGA as a predictive tool for malnutrition and to evaluate the impact of MINT on CT associated toxicity. **Methods:** CT naive pts screened by SGA were assigned to well-nourished (SGA A) or malnourished (SGA B/C) cohorts. Both cohorts were followed for CT delivery, toxicity, quality of life (QOL) by FACT-G, biomarkers, radiology, and survival. SGA B/C pts, stratified by regimen/disease, were randomized 1:1 to MINT vs. usual care. The MINT cohort received weekly registered dietician counseling and symptom assessment over the 8-week study period. Percent standard and planned CT doses were calculated. Wilcoxon rank sum tests were used for differences between groups, log-rank tests for survival, and multivariable linear regression for adjusted comparisons. **Results:** 186 eligible pts were enrolled (94 SGA A, 92 SGA B/C). SGA A were younger (median age [range]; 63 [22, 89] vs. 70 [22, 91], p = 0.011) and more fit (ECOG 0-1; 96.8% vs. 72.8%, p < 0.001). Baseline QOL was higher for SGA A (median [range], 87 [34, 115]) vs SGA B/C (70 [31, 101], p < 0.001). SGA A was associated with higher CT delivery: median proportion of planned CT (1 [Q1 0.87, Q3 1] vs 0.94 [0.70, 1], p = 0.022) and standard CT (0.91 [0.72, 1] vs. 0.74 [0.57, 0.95] p < 0.001). Adjusted for age/ECOG, SGA A remained associated with > 80% of planned (OR 2.32, p = 0.05) and standard (OR 2.33, p = 0.04) CT. SGA B/C pts (n = 92) were randomized to MINT vs usual care: median nutrition encounters MINT 5.5 vs. usual care 0.5; we observed no differences in CT delivery: median proportion of planned CT (0.91 [0.69, 1] vs. 0.94 [0.74, 1], p = 0.84) and standard CT (0.75 [0.58, 0.96] vs 0.71 [0.52, 0.99], p = 0.59). SGA A was associated with a longer 12-month survival (77.8% [95% CI 69.6%, 86.9%]) vs. B/C (53.3% [42.8%, 66.4%], p < 0.0001; 12-month survival was similar for MINT (52.3% [38.1%, 71.9%]) vs usual care (54.4% [40.2%, 73.6%], p = 0.58). **Conclusions:** SGA is a validated tool to characterize malnutrition in pts receiving CT. Malnourished pts received significantly less CT, experienced worse baseline QOL, and had worse 12-month survival. Intensive medical nutrition therapy was not associated with differences in CT associated toxicity. Novel nutritional interventions are still needed to improve pt outcomes. Research Sponsor: Sandra and Edward Meyer Cancer Center Internal Grant.

12091 Poster Session (Board #379), Fri, 8:00 AM-11:00 AM

A systematic review of evidence for cannabis and cannabinoids as adjuvant therapy in palliative and supportive oncology care. *First Author: Sebastian Jugl, Department of Pharmaceutical Outcomes & Policy, College of Pharmacy, University of Florida; Center for Drug Evaluation and Safety (CoDES), Gainesville, FL*

Background: Medical cannabis use is increasing significantly in the United States as states reduce restrictions. However, ambiguity concerning the evidence for medical cannabis efficacy and safety, especially in the field of oncology, is persistent. Clinicians therefore face challenges in examining benefits and risks of medical cannabis as adjuvant treatment for cancer patients. This study identifies and evaluates the most recent available evidence for the efficacy of cannabis and cannabinoids as adjuvant in supportive and/or palliative use in patients with cancer. **Methods:** Electronic databases searched included PubMed, Embase, Web of Science, and Cochrane Library to identify studies published following the latest available systematic review, between July 2016 through October 2019. Studies conducted outside the United States, studies not evaluating cannabis or cannabinoids in Oncology care, and preclinical studies were excluded. Findings were organized in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) framework. Lastly, qualitative synthesis was used to generate summary statements about the role of cannabis and cannabinoids as adjuvant in supportive and/or palliative cancer care. **Results:** We screened 2,267 articles and included 96 studies in our qualitative synthesis. Among those were 2 RCT's (1 completed), 6 Systematic reviews with Meta-analysis, 4 Systematic reviews without Meta-analysis, 71 other types of reviews and 13 observational studies. The most frequently reported outcomes assessed were efficacy of cannabis and cannabinoids for: pain (40 of 96; 17 indicating improvement), nausea and vomiting (26 of 96; 20 indicating improvement), cachexia (22 of 96; 2 indicating improvement), and utilization patterns of cannabis and/or cannabinoids among cancer patients (8 of 96). **Conclusions:** Latest available prevalence estimates indicate that a significant proportion of patients in the United States with cancer use cannabis and/or cannabinoids (18.3-40.0%). There is substantial evidence for the effectiveness of cannabis and cannabinoids in treating cancer-related pain; specifically, oromucosal THC/CBD spray. There is conclusive evidence for the effectiveness of cannabis and cannabinoids in relieving chemotherapy-induced nausea and vomiting; specifically, oral THC. There is inconclusive evidence regarding the effectiveness of cannabis and cannabinoids in treating cancer-related cachexia. Research Sponsor: Consortium for Medical Marijuana Clinical Outcomes Research.

12092 Poster Session (Board #380), Fri, 8:00 AM-11:00 AM

Quality of life in patients with locally advanced head and neck cancer undergoing chemoradiation with once-a-week versus once-every-three-weeks cisplatin. *First Author: Nandini Sharrel Menon, Tata Memorial Hospital, Mumbai, India*

Background: This trial was conducted to compare the efficacy of low dose once-a-week cisplatin with once-every-3-weeks cisplatin with radiation in locally advanced head and neck squamous cell carcinoma (LAHNSCC). The current analysis focuses on the quality of life (QoL) of patients in this trial. **Methods:** In this phase III randomized trial, patients with stage III or IV non-metastatic LAHNSCC were randomized to receive cisplatin 30 mg/m^2 once a week or cisplatin 100 mg/m^2 once every 3 weeks concurrently with curative intent radiotherapy. The primary endpoint was locoregional control. QoL was a key secondary endpoint. QoL was assessed using the EORTC QLQ-C30 (v.3) and EORTC QLQ-H&N35 (v.1). QoL data were assessed at baseline and days 22 and 43 during treatment; at the end of chemoradiation and at each follow-up. The linear mixed effects model was used for longitudinal analysis of QoL domains to determine the impact of treatment (arm) and time on QoL scores. **Results:** Three hundred patients were enrolled, 150 in each arm. QoL data from 283 patients with at least one assessable questionnaire were analyzed. The pretreatment QoL scores were similar in both the arms in all domains. There was no significant difference in the global health status/QoL with respect to the treatment arm (P=0.608) or time (P=0.0544). There was no significant difference in the longitudinal QoL scores between the two treatment arms in all domains except the physical function (P= .0074), constipation (P= .0326), trouble with social contact (P= .0321) and sexuality (P= .0004). There was a decline in the QoL scores in all domains in both arms during treatment. After completion of treatment, the QoL scores started improving steadily up to 1 year and plateaued thereafter in both arms. **Conclusions:** The use of once-every-three weeks cisplatin significantly improved the locoregional control without adversely impacting the quality of life as compared to once-a-week cisplatin in combination with radical radiotherapy in locally advanced HNSCC. Clinical trial information: CTRI/2012/10/ 003062.. Research Sponsor: Tata Memorial Centre Research Administration Council.

12093 Poster Session (Board #381), Fri, 8:00 AM-11:00 AM

Patient-reported distress and healthcare utilization in patients with advanced cancer. *First Author: Jordan Danielle Hildenbrand, Duke University School of Medicine, Durham, NC*

Background: The National Comprehensive Cancer Network (NCCN) defines distress as an unpleasant, multidimensional experience that may interfere with patient behavior, emotions, and ability to cope with illness. Distress screening is a critical aspect of comprehensive cancer treatment, but the relationship between patient-reported distress and healthcare utilization remains unclear. We assessed this relationship in patients with advanced cancers historically associated with high utilization, specifically non-small cell lung cancer (NSCLC) and non-colorectal gastrointestinal (NCRGI) cancer. **Methods:** We extracted data from the electronic medical record of adult patients with metastatic NSCLC and NCRGI cancers who were receiving active treatment, visited outpatient Duke Cancer Institute clinics between July 2013 and January 2017, and completed at least two self-report NCCN Distress Thermometer (DT) and Problem List (PL) surveys as part of routine clinical care between July 2013 and March 2019. Mixed effects logistic regression was used to estimate the odds of hospitalization or emergency room (ER) visit within either 3 or 6 months after each self-reported DT, with adjustment for age at first distress score, sex, primary tumor site, race (white vs. non-white) and duration of participation (i.e., time from first distress score to 3 months after the last distress score) information from the EMR. **Results:** A total of 11,027 DT scores were collected from 848 patients, with 508 (60%) having NSCLC, 340 (40%) having NCRGI cancer, and 192 (23%) reporting actionable distress (i.e., DT score $\geq$4). Actionable distress was associated with higher odds of hospitalization or visiting the ER within 3 months (OR = 1.37; 95% CI = 1.19, 1.58; $p < 0.001$) and 6 months (OR = 1.19; 95% CI = 1.03, 1.37; p = 0.019) after DT self-report. Patients who had an average DT score of $\geq$4 were more likely to report the following problems at least once: worry (89% of patients), nervousness (79%), fatigue (95%), pain (92%), sleep problems (79%), and eating problems (79%). **Conclusions:** Patient-reported distress is associated with greater healthcare utilization in patients with advanced NSCLC and NCRGI cancers who are receiving active treatment. These patients report high burden of physical and emotional problems. Actionable distress may be a useful indicator of patients in need of specialist palliative care interventions. Research Sponsor: None.

12094 Poster Session (Board #382), Fri, 8:00 AM-11:00 AM

A community oncology palliative care program: Pain-related inpatient utilization in oncology care model (OCM) patients. *First Author: Adil Jamal Akhtar, Michigan Health Professionals, Sterling Heights, MI*

Background: Oncology Division of Michigan Health Professionals (MHP) participates in OCM. A comprehensive community oncology program for early and timely involvement of palliative care (PC) was launched in September 2017 to help achieve the OCM program goals of high-quality, cost-effective, coordinated care. PC provides a single point of care for all-cause pain management. PC program included pre-program training and continuous education for early and timely involvement of PC. This study aims to assess the educative effect of PC to reduce pain-related inpatient admissions (Pain IP) in all MHP OCM patients, irrespective of PC-referral. **Methods:** This initiative was led by palliative care physicians and included continuous education and reinforcement of the benefits, every 2-4 weeks, by sharing PC outcomes data with MHP physicians. Physician feedback was part of the program enhancements that were regularly reviewed during monthly MHP physician meetings. Retrospective claims review was performed with OCM episodes from Oct 2016 – Mar 2019. Monthly Pain IP utilization (based on diagnosis code) per 1000 OCM patients (UPK) was analyzed within pre- and post- PC Program start (Sep 2017). Cost per Pain IP included mean of 30-day follow-up skilled nursing facility (SNF) stay and 30-day outpatient facility expenses. Monthly historical Pain IP (pre-PC UPK) was compared to post-PC Pain IP UPK to calculate OCM savings from PC education at MHP. **Results:** Pain IP peaked at 7.12 UPK in September 2017 when PC program training and education started, then fell as low as 0.87 UPK in January 2019. Unit cost per Pain IP was $12,473. Post-PC (Sep 2017 – Mar 2019), there were 40 fewer Pain IP admissions compared to Pre-PC Pain IP for a total cost savings of $498,920. **Conclusions:** After PC Program, Pain IP decreased in MHP OCM population (PC-referred and PC not referred). This trend suggests PC training and continuous education for OCM providers is reducing IP utilization. This also translated to a significant cost saving for OCM/Medicare of $498,920. Study was limited by OCM claims available as of December 2019. Results may be refreshed as more data becomes available. Research Sponsor: None.

12095 Poster Session (Board #383), Fri, 8:00 AM-11:00 AM

Antiemetic prophylaxis with NEPA: Final results of the German AKYPRO study. *First Author: Joerg Peter Schilling, Onkologische Schwerpunktpraxis, Berlin, Germany*

Background: NEPA is a fixed combination antiemetic of the NK_1-receptor-antagonist (RA) netupitant and the 5-HT_3-RA palonosetron. Primary objective of this prospective non-interventional study in Germany was to assess quality of life of cancer patients (pts) undergoing moderately (MEC) or highly (HEC) emetogenic chemotherapy (CT) who received NEPA for prophylaxis of nausea and vomiting (CINV). Secondary objectives were patient reported outcomes as well as effectiveness and safety of NEPA. Here we report final data of the quality of life analysis. **Methods:** The study included 2.405 pts in 162 centers receiving 3 consecutive cycles of CT as one or two day MEC or HEC. Primary endpoint was impact of quality of life (QoL) due to vomiting or nausea, documented by Functional Living Index–Emesis (FLIE) questionnaires. Effectiveness was reported in patient diaries. Complete response (CR) was defined as no emesis and no rescue medication (RM). Non-significant nausea (NSN) was no or mild nausea. Adverse events (AEs) were reported on d1–21 of each cycle. **Results:** 2.173 patients were included in the final analysis (full analysis set; FAS). The majority of patients (n = 1976; 91%) received 1-day chemotherapy, 64% HEC, 36% MEC. Median age was 58 years and the majority (85%) was female. Cancer diagnoses: breast 66%, gastrointestinal 10%, ovarian 7% or lung 5%, other 12%. Chemotherapy: AC 57%, carboplatin 19%, cisplatin 8%, oxaliplatin 8% and other 8%. 84% of pts with HEC and 82% with MEC felt no impact on daily life due to vomiting in cycle 1 remaining constant in C2 and C3. 54% HEC patients and 59% MEC patients reported no impact on daily life due to nausea in cycle 1. CR rates ranged between 81-84% and were comparable between different HEC or MEC. NSN rates in MEC ranged from 75% (MEC) to 62% (HEC). Drug-related AEs were rare with constipation, fatigue, insomnia, and nausea as the most common (in $>$ 1% pts). **Conclusions:** NEPA was highly effective in the prevention of CINV and maintenance of QoL in this real world study. Over 80% of pts reported that their daily live was not influenced by emesis while nausea was more difficult to control. Effectiveness was high and patients and physicians estimate was comparable**.** Research Sponsor: Riemser Pharma.

12096 Poster Session (Board #384), Fri, 8:00 AM-11:00 AM

Myelopreservation and reduced use of supportive care with trilaciclib in patients with small cell lung cancer. *First Author: Jared Weiss, Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, NC*

Background: Chemotherapy (CT) is a mainstay of cancer treatment; however, its side effects, notably myelosuppression, cause significant suffering. Trilaciclib (T) is an IV CDK4/6 inhibitor that protects hematopoietic stem and progenitor cells by preventing proliferation during CT administration. Results from three randomized, double-blind, placebo (P)-controlled phase II trials in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC) have previously been reported. Data from these studies were pooled to understand the effects of T on specific myelosuppression endpoints with greater statistical precision. **Methods:** All pts received standard CT (etoposide/carboplatin [E/C], E/C/atezolizumab, or topotecan) plus T or P. Analyses were conducted on pooled intent-to-treat datasets from three ES-SCLC studies (NCT02499770; NCT03041311; NCT02514447). **Results:** 123 pts were treated with T and 119 with P. Median age in both groups was 64 years. Addition of T decreased measures of myelosuppression and the need for supportive care interventions (Table). From the pooled dataset, median OS and PFS (months [95% CI]) were comparable between pts treated with T vs P (OS: 10.6 [9.1, 11.7] vs 10.6 [7.9, 12.8]; PFS: 5.3 [4.6, 6.1] vs 5.0 [4.4, 5.5], respectively). Fewer pts on T had grade 3/4 hematologic events (54 [44.3%]) vs P (91 [77.1%]). Among pts who continued after cycle 1, 11 pts (9.2%) treated with T had $\geq$1 CT dose reduction vs 36 (30.8%) with P. **Conclusions:** T significantly and meaningfully reduced both CT-induced myelosuppression and its consequences, with no detrimental effect on PFS or OS, thus improving the patient experience with CT in ES-SCLC. T has potential to become a new standard of care for preventing myelosuppression in SCLC. Research Sponsor: G1 Therapeutics, Inc.

	T + CT (n=123)	P + CT (n=119)	P value
Mean duration of severe neutropenia in cycle 1, days (SD)	0 (1.8)	4 (5.1)	<0.0001*
Severe neutropenia, n (%)	14 (11.4)	63 (52.9)	<0.0001
Febrile neutropenia, n (%)	4 (3.3)	11 (9.2)	0.089
G-CSF administration, n (%)	35 (28.5)	67 (56.3)	<0.0001
Grade 3/4 anemia, n (%)	25 (20.3)	38 (31.9)	0.028
RBC transfusion on/after Week 5, n (%)	18 (14.6)	31 (26.1)	0.025
ESA administration, n (%)	4 (3.3)	14 (11.8)	0.025
Grade 3/4 thrombocytopenia, n (%)	24 (19.5)	43 (36.1)	0.0067
Platelet transfusion, n (%)	10 (8.1)	11 (9.2)	0.96

*Two-sided p value calculated using nonparametric ANCOVA; other p values calculated using modified Poisson method.

12097 Poster Session (Board #385), Fri, 8:00 AM-11:00 AM

Development and validation of a risk prediction model for poor performance status and severe symptoms among cancer patients. *First Author: Hsien Seow, McMaster University, Hamilton, ON, Canada*

Background: Existing cancer predictive tools focus on survival, but few incorporate patient-reported outcomes to predict quality-of-life domains, such as symptoms and performance status. The objective was to develop and validate a predictive cancer model (called PROVIEW) for poor performance status and severe symptoms over time. **Methods:** We used a retrospective, population-based, cohort study of patients, with a cancer diagnosis, in Ontario, Canada between 2008-2015. We randomly selected 60% of patients for model derivation and 40% for validation. Using the derivation cohort, we developed multivariable logistic regression models with baseline characteristics, using a backward stepwise variable selection process. The primary outcome was odds of having poor performance status six months from index date, as measured by a score $<=30$ out of 100 on the Palliative Performance Scale. The index date for each model was diagnosis (Year 0), which was then re-calculated at each of 4 annual survivor marks after diagnosis (up to Year 4). Secondary outcomes included having severe pain, dyspnea, well-being, or depression, as measured by a score of $>=7$ out of 10 on the Edmonton Symptom Assessment System. Covariates included demographics, clinical information, current symptoms and performance status, and healthcare utilization. Model performance was assessed by AUC statistics and calibration plots. **Results:** Our population-based cohort identified 125,479 cancer patients for the performance status model in Year 0. The median diagnosis age was 64 years, 57% were female, and the most common cancers were breast (24%), lung (13%), and prostate (9%). 32% had Stage 3 or 4 disease. In Year 0 after backwards selection, the odds of having a poor performance status in 6 months was increased by more than 10% when the patient had: COPD, dementia, diabetes; radiation treatment; a hospital admission in the prior 3 months; high pain or depression; a current performance status $<=30$; any issues with appetite; or received end-of-life homecare. Generally, these variables were also associated with a $>10\%$ increased odds in other years and for the secondary outcomes. The average AUC across all 25 models is 0.7676 which indicates high model discrimination. **Conclusions:** The PROVIEW model accurately predicts risk of having a poor performance status or severe symptoms over time among cancer patients. It has the potential to be a useful online tool for patients to integrate earlier supportive and palliative care. Research Sponsor: Canadian Institutes of Health Research.

12098 Poster Session (Board #386), Fri, 8:00 AM-11:00 AM

The impact of the use of opioids among older breast cancer survivors and adverse events. *First Author: Aaron N Winn, Medical College of Wisconsin, Milwaukee, WI*

Background: Older adults and cancer survivors are underrepresented in the literature underpinning recent opioid prescribing guidelines. As prevention of unnecessary persistent opioid use and inadvertent opioid-related harms gains importance in clinical practice, it is necessary to fully capture the risks of opioid related adverse events among patients with cancer pain. The objective of this study was to determine the association between opioid use after cancer diagnosis and comprehensive opioid-related adverse events among older adult breast cancer survivors. **Methods:** We conducted a retrospective cohort study using Surveillance, Epidemiology, and End Results tumor registry data linked with Medicare administrative claims data from 2007-2016 of women with newly diagnosed non-metastatic breast cancer. The study observation period was the year following a patient's end of active cancer treatment. The primary exposure was a daily measure of opioid exposure based on Part D prescription claims. The primary outcomes were daily indicators of all-cause hospitalization, substance use event and a composite of other opioid-related adverse events (infections, gastrointestinal events, falls/fractures, cardiovascular events) and each component of the composite adverse event. We estimated the association of current opioid use and the immediate risk of an outcome event the following day using modified Poisson generalized estimating equation models. We adjusted for patient demographics, cancer characteristics and cancer treatments received. **Results:** We found that opioid exposure more than doubled the immediate risk of all-cause hospitalization (aRR = 2.77; 95%CI = 2.57, 2.99; $p < 0.001$) and having a composite adverse event (aRR = 2.50; 95%CI = 2.18, 2.87; $p < 0.001$) and dramatically increases the immediate risk of a substance use event (aRR = 14.26; 95%CI = 7.11, 28.59; $p < 0.001$). We find consistent results when looking at individual components of the composite adverse event measure. **Conclusions:** Older adult breast cancer survivors with continued prescription opioid use in the year after completing active cancer treatment experienced an immediate increased risk of all-cause hospitalization, substance use events, and myriad opioid-related adverse effects. Research Sponsor: None.

12099 Poster Session (Board #387), Fri, 8:00 AM-11:00 AM

Inflammatory and clinical risk factors for chemotherapy-induced peripheral neuropathy (CIPN): A nationwide longitudinal study in 143 cancer patients during chemotherapy. *First Author: Ian Kleckner, University of Rochester Medical Center, Rochester, NY*

Background: CIPN is a common dose-limiting side effect of taxane and platinum chemotherapy. It is difficult for clinicians to predict who will experience CIPN before initiating chemotherapy, partly because the etiology of CIPN is poorly understood. Specifically, although inflammation putatively plays a role in CIPN, there is limited evidence of the role of inflammation in CIPN in humans. Here, we identified the strongest predictors of CIPN using variables measured before taxane or platinum chemotherapy, including serum inflammation. **Methods:** 143 sedentary patients with cancer (81% breast, 7% colon, 5% lung; 7% other; mean age 56 years) receiving taxane or platinum chemotherapy rated the severity of (a) numbness and tingling, and (b) hot/coldness in hands/feet on 0-10 point scales before and after their first 6 weeks of chemotherapy. Linear regression models were fit to predict CIPN symptom severity at 6 weeks using variables related to inflammation (serum IL-1β, IL-6, IL-8, IL-10, IFN-γ, sTNFR1; 69 patients who gave blood), clinical factors (cancer stage, baseline neuropathy, fatigue, anxiety, depression, using diabetes medications), behavior (daily pedometer steps), and demographics (age, race) measured before chemotherapy. The final model was identified by the smallest AIC goodness of fit. **Results:** The strongest pre-chemotherapy predictors of numbness and tingling after 6 weeks of taxane and/or platinum chemotherapy were worse patient-reported fatigue/anxiety/depression (explaining 25% of variance), platinum chemotherapy (7%), and older age (5%). The strongest predictors of hot/coldness in hands/feet included worse baseline neuropathy (13%), platinum chemotherapy (8%), and fatigue/anxiety/depression (6%). In the 69 patients with serum data, a more pro-inflammatory state was a risk factor for CIPN as higher levels of pro-inflammatory IL-1β (7%) predicted numbness/tingling, and lower levels of anti-inflammatory IL-10 (7%) predicted hot/coldness in hands/feet. **Conclusions:** The strongest pre-chemotherapy predictors of CIPN included worse fatigue/anxiety/depression and platinum chemotherapy in this sedentary population of cancer patients (mostly breast). A pro-inflammatory state before chemotherapy may also increase risk for CIPN, suggesting that inflammation may underlie the etiology of CIPN in humans. Clinicians should consider assessing these factors to inform the patient's risk for CIPN. Funding: NCI UG1CA189961, NCI K07 K07CA221931, T32CA102618. Clinical trial information: NCT00924651. Research Sponsor: U.S. National Institutes of Health.

12100 Poster Session (Board #388), Fri, 8:00 AM-11:00 AM

Depression, anxiety, and patterns of mental health care among men with prostate cancer on androgen deprivation therapy (ADT). *First Author: Phoebe A. Tsao, Department of Hematology/Oncology, University of Michigan Medical School, Ann Arbor, MI*

Background: ADT is associated with an increased risk of depression and anxiety, raising the concern that a substantial portion of men with prostate cancer need mental health care. We sought to investigate the development of depression or anxiety and subsequent patterns of mental health care in men with prostate cancer on ADT. **Methods:** Clinformatics DataMart, a claims database of commercially insured patients, was used to identify men with prostate cancer who received ADT between 2001-2015 and had continuous enrollment for 1 year before and 2 years after starting ADT. We determined the rate of incident diagnoses of depression or anxiety and the incident use of mental health treatments - psychotherapy and psychiatric medications ($\geq$ 5 day supply) - after the start of ADT. **Results:** Among 37,388 men in the final analytic cohort, 11.3% (n=4239, 95% confidence interval (CI) 11.0-11.6%) received new diagnoses of depression or anxiety: 5.8% depression (95% CI, 5.5-6.0%), 3.7% anxiety (95% CI 3.5-3.9%), and 1.8% both (95% CI, 1.7-1.9%). Those who received a diagnosis of depression or anxiety were more likely to be white (68% v. 64%, $p<0.01$); no differences were noted in age, education, or household income. Among those with a new diagnosis of depression or anxiety, 0.07% received psychotherapy (95% CI, 0.02-0.23%), 34.9% a selective serotonin reuptake inhibitor (95% CI, 33.5-36.4%), 11.6% a serotonin norepinephrine reuptake inhibitor (95% CI, 10.7-12.6%), and 19.9% a benzodiazepine (95% CI, 18.7-21.1%). **Conclusions:** Among men with prostate cancer receiving ADT, more than 1 in 10 received a new diagnosis of depression or anxiety. Of those, 1 in 5 were introduced to a benzodiazepine, a drug class with risks of dependence, cognitive impairment, falls, and fractures, whereas receipt of psychotherapy was rare. Further investigation into how to improve the mental health care of men on ADT is needed. Research Sponsor: None.

Depression and anxiety among men with prostate cancer on ADT.

	No depression or anxiety N = 33,149 n (%)		Depression or anxiety N = 4239 n (%)		p-value*
Age (mean, standard deviation)	73	(8.1)	73	(8.7)	0.39
Race					
White	21,204	(64)	2869	(68)	<0.01
Black	4278	(13)	343	(8)	
Hispanic	2442	(7)	306	(7)	
Other/Unknown	5225	(16)	721	(17)	
Education					
< 12th grade	306	(1)	38	(1)	0.11
High school diploma	9731	(29)	1226	(29)	
< Bachelor degree	17,021	(51)	2191	(52)	
Bachelor degree plus	4574	(14)	554	(13)	
Unknown	1517	(5)	230	(5)	
Household income					
< $50,000	10,043	(30)	1286	(30)	<0.01
$50,000-99,000	9658	(29)	1178	(28)	
> $99,000	5369	(16)	623	(15)	
Unknown	8079	(24)	1152	(27)	

*Two sample t-test or chi-square test

12101 Poster Session (Board #389), Fri, 8:00 AM-11:00 AM

Scalp cooling to prevent chemotherapy induced alopecia (CIA) in black patients: Differences in efficacy? *First Author: Asma Ali Dilawari, MedStar Washington Cancer Institute, Lombardi Comprehensive Cancer Center, Washington, DC*

Background: The Paxman scalp cooling device has been used for over 20 years to prevent CIA, obtaining FDA clearance in the U.S. in 2017. Prior studies reported 50-80% success and high patient satisfaction yet included few or no black patients. In the U.S. this may reflect disparities in access due to cost, awareness, or availability. We opened a prospective observational study combining patient-reported outcomes with clinical assessments of alopecia and planned to deliver scalp cooling to 30 black patients receiving chemotherapy for breast cancer. **Methods:** Patients who self-identified racially as black, had a new diagnosis of stage I-III breast cancer, and planned to receive chemotherapy with taxane-containing regimens were eligible. Anthracycline (AC) and non-anthracycline (NAC) chemotherapy agents were included; costs for the intervention were covered by Paxman and internal philanthropic funding. Patients who declined scalp cooling were approached for enrollment as controls. Primary endpoints were grade of alopecia as measured by providers and patient self-report using Modified Dean Scale and Visual Analog Scale (VAS) respectively. Hair preservation was defined as <50% hair loss (<grade 2) by Dean and score < 50 on VAS. Secondary endpoints were alopecia by NCI grading scale and psychosocial from CADS and EORTC QLQ BR45 questionnaires. **Results:** 15 out of 30 planned participants enrolled by February 2020 with interim analysis and hold in accrual due to lack of efficacy. Four patients remain on treatment. Of 11 scalp cooling patients who completed chemotherapy, 0 prevented significant alopecia. Nine discontinued use of scalp cooling before completion (1 due to scheduling, 8 due to >grade 3 alopecia). The 2 patients who used scalp cooling for the duration had >grade 3 alopecia before the last cycle of treatment. **Conclusions:** Scalp cooling is an important supportive therapy that can reduce chance of alopecia, a bothersome side effect for patients. Our experience indicates decreased efficacy in black patients with both AC and NAC regimens. This is an important negative result to explore. Discussions with the Paxman team and providers with expertise in alopecia are underway to explore contributing factors such as hair thickness, prior hair treatments, and cap design. Research Sponsor: Paxman Scalp Cooling Company and Four Seasons Washington Cancer Institute Philanthropic Fund.

Alopecia in scalp cooling patients by chemotherapy.

	AC	NAC*	Total
Completed Chemotherapy	4	7	11
# with Grade> 3 alopecia prior to completion	4	7	11 (100%)
Mean # sessions before Grade >3 alopecia	2.2	2.5	2.5

*Taxotere, Cytoxan = 5, Taxotere/Carboplatin/Trastuzumab/Pertuzumab = 2

12102 Poster Session (Board #390), Fri, 8:00 AM-11:00 AM

Palliative referrals in advanced cancer patients: Utilizing the Supportive and Palliative Care Indicators Tool and Rothman Index. *First Author: Abigail Sy Chan, Sinai Hospital of Baltimore, Baltimore, MD*

Backgroun1d: Timely identification of palliative care needs have the ability to reduce hospitalizations and improve QOL. The Supportive & Palliative Care Indicators Tool (SPICT) is used to identify patients with advanced stage medical conditions who may need special care planning. The Rothman Index (RI) detects patients at high risk of acutely decompensating in the inpatient setting and has been validated to assess 24-hour mortality risk. We used SPICT and RI in cancer patients admitted to the hospital and evaluated their roles in recognizing early palliative care needs and 6-month mortality. **Methods:** Advanced/metastatic cancer patients admitted to our institution from Jan 1, 2019 to June 30, 2019 were retrospectively reviewed. Patient demographics, length of hospital stay (LOS), comorbidities, palliative/hospice care referrals, vital status, initial RI score, and computed SPICT scores were obtained. Worse clinical indicators were defined as SPICT positive if it met > 2 clinical indicators or RI < 60. Univariate and bivariate analyses were performed. **Results:** A total of 227 patients were included, mean age 68, 34% Caucasians, 63% Blacks, 59% female, median comorbidities of 3, with majority having lung and GI malignancies. A total of 137 (60%) were SPICT +, 47 (21%) had RI < 60, and 38 (17%) concurrent SPICT + and RI < 60. SPICT + patients were more likely to have longer hospital stay, change in code status, more palliative/hospice referrals, and increased mortality. Those with RI < 60 had similar results (Table). SPICT + patients are more likely to have RI < 60 (p = 0.0013). **Conclusions:** SPICT and RI are valuable tools in predicting 6-month mortality and palliative/hospice care referrals. These can also be utilized to initiate early palliative and goals of care discussions in patients with advanced cancer. Research Sponsor: None.

Comparison of SPICT and RI in clinical outcomes.

	SPICT +	SPICT -	P-value	RI < 60	RI > 60	P-value
LOS, mean in days	9.6	5.7	P < 0.001	11	7	P = 0.0187
Code status change, %	33	7	P < 0.001	47	16	P < 0.001
Palliative referrals, %	45	3	P < 0.001	55	21	P < 0.001
Hospice referrals, %	31	1	P < 0.001	47	12	P < 0.001
6-month mortality, %	66	20	P < 0.001	70	42	P = 0.0006

12103 Poster Session (Board #391), Fri, 8:00 AM-11:00 AM

Impact of embedded palliative care providers compared to externally available palliative care services on the number of patients receiving palliative care referrals in a large community oncology practice. *First Author: Garrett Young, OneOncology, Nashville, TN*

Background: Palliative care improves quality of life and may increase overall survival in patients with solid tumor malignancies. Despite having the ability to refer patients to in-home and external palliative care services, we observed low palliative care referral rates in our practice of 90 oncologists across 30 clinics. We tested whether embedding palliative care providers directly in clinic would improve palliative care referral rates for solid tumor patients. **Methods:** Between 2017 and 2020, we embedded an independent palliative care provider into five clinics across middle Tennessee. Access to external palliative care services was present both before and after the intervention. Using data from our EHR and billing systems, we performed a pre-post analysis measuring palliative care referrals in the six-month periods immediately before (pre-intervention period) and after (post-intervention period) a palliative care provider was embedded in each clinic. Statistical significance was assessed using Welch's two sample t-test. **Results:** 8,636 unique solid tumor patients were seen in the five clinics during the study periods (Table). Despite having the ability to refer patients to external palliative care services in the pre-intervention period, the placement of a palliative care provider into clinic increased the number of solid tumor patients that received a palliative care referral per month at all clinics (min.: 200%; max.: 990%; median: 600%). Four of the five increases were statistically significant (p-values < 0.05). **Conclusions:** Even when external palliative care services are available, embedding palliative care providers into community oncology clinics significantly increases the rate of palliative care referrals for solid tumor patients. Research Sponsor: None.

Change in palliative care order rates after placing a palliative care provider in clinic.

Clinic	Solid tumor patients seen during study period	Patients referred to palliative care per month: pre-intervention	Patients referred to palliative care per month: post-intervention	Percent change	p-value
1	753	1	5	600%	< 0.01
2*	752	4	13	200%	0.16
3*	1,502	4	37	796%	0.03
4	2,939	2	18	990%	0.01
5**	2,690	3	15	444%	0.01

*Only three months of post-intervention data available; **Only three months of pre-intervention data available

12104 Poster Session (Board #392), Fri, 8:00 AM-11:00 AM

A highly effective and practical desensitization regimen: Results in comparable clinical outcomes for multiple myeloma patients with skin rash after immunomodulatory drugs. *First Author: Amin Firoozmand, University Hospitals Seidman Comprehensive Cancer Center, Cleveland, OH*

Background: Immunomodulatory drugs (IMiDs) are backbone of myeloma therapy for patients with Multiple Myeloma (MM). The incidence of IMiD-associated rash is up to 27% in some reports impeding maximal benefit of this agent. The optimal management of IMiDs-associated skin is unclear. The concurrent weekly Dexamethasone (Dex) does not diminish the incidence of skin eruptions with IMiDs (Sviggum, et al. 2006), therefore we designed a low dose daily and tapering corticosteroid regimen to tame this immune response upon restarting IMiDs and allow desensitization and reinstitution of the same IMiD. Furthermore, we assessed the impact of this desensitization regimen on clinical outcome. **Methods:** A total of 160 patients were evaluated. The incidence of rash was found to be 13% (n = 21). A cohort of age- and gender-matched without rash (n = 39) was randomly selected. The effects of rash on overall and progression free survival (OS and PFS) were further estimated using Cox regression controlling the effects of age and gender. **Results:** Median time to development of rash after IMiD initiation was 28 days (range, 2-232). Rashes were graded as low (I-II) in 89% (n = 17) and high (III-IV) in 19% of pts. All pts were managed by temporary treatment interruption and upon clearance of rash, re-institution of the same IMiD concomitantly with a standardized 3-week steroid rash prophylaxis protocol (prednisone at 10 mg daily for 10 days, followed by 5 mg daily for 10 days, followed by 5 mg on alternate days for 10 days). As a result, all patients were able to restart the same IMiD with none re-experiencing any dermatologic adverse effect afterward. Comparing to no-rash controls, there was no significant difference in PFS (0.13) or OS (p = 0.12) in multivariate regression model. **Conclusions:** Proposed 3-week corticosteroid regimen showed 100% success rate in reinstituting IMiDs in our cohort. It may provide a highly effective and practical short term immunosuppression required to enable patients to restart IMiDs and enjoy comparable outcome to pts without skin rash. Research Sponsor: None.

12105 Poster Session (Board #393), Fri, 8:00 AM-11:00 AM

High-dose vitamin D supplementation for cancer-treatment-induced bone loss in 164 breast and prostate cancer patients: A pooled analysis of two randomized controlled trials (RCTs). *First Author: Luke Joseph Peppone, University of Rochester Medical Center, Rochester, NY*

Background: Aromatase Inhibitor (AI) therapy and androgen deprivation therapy (ADT) significantly accelerate bone loss and increase fracture risk. Vitamin D (VITD) protects against bone loss, but it is unclear whether the recommended daily allowance (RDA; 600 IU/day for ages 51-70) of VITD is sufficient for cancer patients. Data from two RCTs were pooled to examine the safety and efficacy of high-dose VITD versus the RDA of VITD on bone mineral density (BMD). **Methods:** 164 breast and prostate cancer patients on AIs and ADT, respectively, with low VITD (<32 ng/ml) were randomized to either high-dose VITD (50,000 IU/week; n=99) or placebo (n=65) for 24 weeks. All subjects received 600 IU/day of VITD. Of the 99 subjects assigned to high-dose VITD, 38 breast subjects also received the Exercise for Cancer Patients (EXCAP) program combining walking and resistance training. Serum VITD and calcium were assessed at weeks 0, 6, 12, 18, and 24. BMD was assessed at the hip and spine via DXA at weeks 0 and 24. The effect of high-dose VITD was tested via ANCOVA model adjusted for cancer type, baseline BMD and VITD. **Results:** High-dose VITD significantly reduced the amount of hip BMD loss versus the RDA of VITD (high-dose VITD: −0.8% vs placebo: −2.6%; p<0.01) over 24 weeks. Hip BMD loss was greater for subjects on ADT (high-dose VITD: −1.5% vs placebo: −4.1%; p=0.03) than subjects on AI therapy (high-dose VITD: −0.2% vs placebo: −1.7%; p=0.02). Among the high-dose VITD group, there was no BMD difference at the total hip between those who received EXCAP exercise vs no EXCAP (p=0.96). The largest differences in BMD were for those with lower baseline VITD levels (<27 ng/ml) for both total hip (high-dose VITD: −0.6% vs placebo: −3.2%; p<0.001) and femoral neck (high-dose VITD: +0.2% vs placebo: −2.4%; p=0.03). No between-group pooled differences were noted for total spine BMD (high-dose VITD: −0.2% vs placebo: −0.1%; p=0.82). High-dose VITD increased serum VITD without negatively affecting serum calcium (Table). **Conclusions:** High-dose VITD was safe and effective in significantly reducing hip BMD loss, with the largest benefit in those with lower baseline VITD levels. A phase III RCT is needed to confirm these findings. NCI Funding: K07 CA168911/R21 CA175793/UG1 CA189961/T32 CA102618 Clinical trial information: NCT02064946, NCT01419730. Research Sponsor: U.S. National Institutes of Health.

	Week				
	0	6	12	18	24
Mean serum VITD					
High-dose VITD	26.8	52.5	57.8	59.3	61.0
Placebo	27.9	30.6*	33.5*	30.2*	32.2*
Mean Serum Calcium					
High-dose VITD	9.22	9.36	9.42	9.39	9.37
Placebo	9.22	9.31	9.35	9.31	9.41

*p<0.05, high-dose VITD vs. placebo

12106 Poster Session (Board #394), Fri, 8:00 AM-11:00 AM

Safety and effectiveness of medical cannabis as a complementary option for supportive cancer care: Results from the Cannabis Pilot Project. *First Author: Antonio Vigano, McGill University Health Centre, Montréal, QC, Canada*

Background: Access to medical cannabis (MC) is a common request by patients and caregivers in supportive cancer care (SCC). However, health-care professionals require more evidence on MC safety and effectiveness. **Methods:** The Cannabis Pilot Project (CPP) was implemented at the Cedars Cancer Centre of the McGill University Health Centre to evaluate MC as a complementary option for symptom control in SCC. Referral to the CPP was reserved for patients who were receiving SCC but had not obtained adequate symptom relief. An interdisciplinary team (physician, nurse and research coordinator) was established to systematically assess patients, prescribe and monitor MC treatments and record data on their safety and effectiveness. Patients were enrolled in the CPP between February 2018 and December 2019 and reassessed at intervals of one to six months. **Results:** Ninety-six cancer patients (mean age 60.0y (±13.9); 41 (42.7%) males) had at least one follow-up (FUP) and were included in the study. The main cancer types were breast (19.8%), lung (9.4%) and colorectal (9.4%). Adverse events (top three: drowsiness, low energy and nausea) were reported in 28% of patients, with 9% having to stop MC. Mean Brief Pain Inventory scores significantly improved between baseline, FUP-2 and FUP-3 for worst pain (5.4± SEM 0.3 vs 4.3±0.3 and 3.7±0.4) and average pain severity (4.2±0.2 vs 3.2±0.3 and 3.2±0.4). Anorexia improved (3.4±0.3 vs 2.2±0.4 and 1.7±0.4), as measured via the revised Edmonton Symptom Assessment System (ESAS-r). ESAS-r wellbeing improved significantly between baseline and FUP-1 (4.4±0.2 vs 3.7±0.2). Between baseline and each FUP, approximately a third of patients dropped their use of concurrent medications (including analgesics, antidepressants and anxiolytics), as measured by the Medication Quantification Scale. **Conclusions:** The CPP data support the safety and effectiveness of MC as a complementary option for improving pain control, appetite and quality of life in SCC. Research Sponsor: Cedars Cancer Foundation - Rossy Cancer Network.

12107 Poster Session (Board #395), Fri, 8:00 AM-11:00 AM

Validity of patient-reported outcomes to describe the symptom experience of patients enrolled on phase I clinical trials. *First Author: Ramy Sedhom, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD*

Background: Symptoms are common among patients enrolled in phase I trials. To integrate the patient perspective, the National Cancer Institute developed a patient-reported outcomes version of the CTCAE (PRO-CTCAE) to capture symptomatic adverse events (AEs) directly from patients; however, the tool has not been used often in early phase trials or in palliative care studies. Our overall objective was to assess the validity of PRO-CTCAE items to previously validated assessments of quality of life (FACT-G) and psychological distress (Distress Thermometer). We utilized data from a randomized trial testing a palliative care intervention for patients with cancer enrolled on phase I trials. **Methods:** Patients (n = 481) were accrued to the parent study prior to initiating a Phase I clinical trial with data collected at baseline, 4, and 12 weeks. We determined the correlation of PRO-CTCAE with Distress Level, FACT-G total and subscale domain scores. Aggregate scores using PRO-CTCAE were calculated to explore the effect of overall symptom frequency, severity, and interference by calculating the total of all scored items classified within each of those domains. We used these metrics to identify associations between this and other validated tools. **Results:** Patients were predominantly female (56.8%), over age 60, and 30.7% were minority populations. Correlations between PRO-CTCAE items and corresponding FACT-G (total and subscales) and Distress levels reached statistical significance for all items ($p < 0.001$). Importantly, many of symptoms captured would have been missed using HRQOL assessment tools. Some of these symptoms affected nearly 50% of patients and were frequently rated as severe or very severe. The correlation coefficient for Distress Level for all PRO-CTCAE items was small to moderate (Pearson $r = 0.33$ to 0.46). Pearson's correlation coefficient for FACT-G total was moderate ($r = -0.45$ to -0.69). Mood items of the PRO-CTCAE had stronger associations (Pearson $r > 0.5$). PRO-CTCAE symptom interference scores had the strongest correlation with Distress (Pearson $r = 0.46$) and FACT-G Total (Pearson $r = -0.69$). **Conclusions:** Patients entering Phase I trials are willing to report on symptoms they experience as a result of advancing disease and adverse effects from experimental treatment. Evidence demonstrates favorable validity of PRO-CTCAE in a heterogeneous US sample of patients undergoing cancer treatment on phase I trials. The granular assessment of symptomatic AEs may be on increasing importance as we enter a new therapeutic era in oncology. Clinical trial information: NCT01828775. Research Sponsor: U.S. National Institutes of Health.

12108 Poster Session (Board #396), Fri, 8:00 AM-11:00 AM

A survey of cannabis use for symptom palliation in breast cancer patients by age and stage. *First Author: Marisa C. Weiss, Breastcancer.org, Ardmore, PA*

Background: Most US states have legalized medical cannabis for the treatment of serious conditions, including cancer. It is not well known which symptoms breast cancer patients seek to control with cannabis. **Methods:** Members of the Breastcancer.org and Healthline communities were invited to participate in this survey between 12/16/2019 and 1/19/2020. Eligibility criteria included age ≥18 years, resident of the US and a breast cancer diagnosis within the past 5 years. Eligible respondent data were analyzed for the symptomatic profile of cannabis users. Symptoms were compared between two groups using a Chi-square test of independence. The survey was led by Socanna, conducted by Outcomes Insights, and supported by a grant from Ananda Health/Ecofibre. **Results:** Among the 832 respondents who completed screening, 725 met the eligibility criteria, and 612 (84%) completed the survey. The median age of respondents was 57 years, and 85% had non-metastatic disease An estimated 42% of respondents have used medical cannabis to treat symptoms or side effects of breast cancer. Medical cannabis users reported using cannabis to treat insomnia (70%), joint and muscle aches, discomfort, stiffness, or pain (59%), anxiety (57%), and stress (51%). The medical cannabis users less than 50-year-old were more likely to use cannabis to treat these symptoms than their over 50-year-old counterparts, however, the differences were not statistically significant. Medical cannabis users under age 50 used cannabis significantly more than over 50 to treat nausea/vomiting (58% vs 40%; p = 0.010) and inflammation (34% vs 20%; p = 0.021). Medical cannabis users with metastatic disease were more likely to use medical cannabis to treat chronic pain 60% vs 41%; p = 0.017) than non-metastatic users. Post-surgery patients were most likely to use cannabis for nerve pain; and those who were beyond treatment, for stress. Patients suffered an average of 5 symptoms. **Conclusions:** A significant proportion of breast cancer patients reported using cannabis to treat a combination of symptoms from their cancer and its treatment. Although younger patients are somewhat more likely to use this form of palliative management, older patients are suffering from the same symptoms and their use is nearly as high. More research is needed on the personalization of safe and effective symptomatic management with medical cannabis, for people of all ages, stages, and forms of treatment. Research Sponsor: Ananda Hemp/Ecofibre.

12109 Poster Session (Board #397), Fri, 8:00 AM-11:00 AM

The Quebec Cannabis Registry: a pharmacovigilance and effectiveness study on the use of medical cannabis in cancer patients. *First Author: Antonio Vigano, McGill University Health Centre, Montréal, QC, Canada*

Background: The Quebec Cannabis Registry (QCR) was launched in 2015 to allow physicians to prescribe medical cannabis (MC) in the province of Quebec, Canada. This study aimed to investigate the safety and effectiveness of MC in cancer patients using pharmacovigilance data prospectively collected for up to 24 months. **Methods:** Patients were enrolled in the QCR between May 2015 and October 2018 and followed every 3 months. Study outcomes included adverse events (AE), pain severity and interference (Brief-Pain Inventory), wellbeing (Revised-Edmonton Symptom Assessment Scale) and overall health scale (EQ5D5L) at baseline and at each follow-up (F-UP). Significance of changes over time were assessed using repeated-measures ANOVA. **Results:** Out of the 2991 patients enrolled in the QCR, 358 (12.8%) were cancer patients (mean age 57.7 ($\pm$ 14.6); 171 (47.8%) males). The main cancer types were breast (16.2%), lung (11.7%), leukemia (11.5%) and colorectal (11.2%). MC was prescribed primarily for pain (72.1%), anxiety (4.7%), nausea (4.5%), anorexia (3.9%), and insomnia (3.1%). A total of 13 patients (3.6%) reported AE with only three being serious (one unrelated to MC: stroke; and two possibly related: diarrhea, from CBD oil overdose and pneumonia from smoking MC). Mean scores significantly ($p < 0.05$) improved between baseline and 3 months F-UP for pain severity (4.8 ± 1.5 vs 4.1 ± 1.8), pain interference (4.6 ± 1.8 vs 3.8 ± 1.7), and the overall health scale (60 ± 21 vs 71 ± 18). Well-being scores also significantly improved between baseline and 6 months F-UP (4.4 ± 2.1 vs 3.5 ± 2.8). **Conclusions:** Population-based data shows that cancer patients can benefit safely and effectively from MC as a complementary treatment, when prescribed and monitored under medical-nursing supervision. Research Sponsor: College des Medecins de Quebec - Canadian Consortium for the Investigation of Cannabis - Canopy Growth.

12110 Poster Session (Board #398), Fri, 8:00 AM-11:00 AM

Questions prompt lists used by palliative care teams help trigger discussions on prognosis and end-of-life issues with advanced cancer patients. *First Author: Carole Bouleuc, Supportive Care Department, Institut Curie, Paris, France*

Background: Accuracy of prognosis perception is a key element to allow advanced cancer patients to make informed decisions and to reflect on their end-of-life priorities. This study aims to explore whether a question prompt list can promote discussions on prognosis and end-of-life issues during palliative care consultations for advanced cancer patients. **Methods:** In this multicentric randomised study, patients assigned in the interventional arm receive a question prompt list during the first palliative care consultation (T1) after referral by oncologists. The primary endpoint is the number of questions asked by patients during the second palliative care consultation (T2) one month later. Secondary objectives are anxiety and depression, quality-of-life, satisfaction with care, coping assessed at baseline (T1) and at two months (T3). Palliative care teams from 3 french comprehensive cancer centers participate in the study. Main inclusion criteria were adult patients with metastatic non-haematological cancer referred to the palliative care team and with an estimated life expectancy less than one year. **Results:** Patients (n = 71) in the QPL arm asked more questions (mean 21.8 versus 18.2, p-value = 0.03) during the palliative care consultations compared to patients in the control arm (n = 71). These questions addressed palliative care (mean 5.6 versus 3.7, p-value = 0.012) and end-of-life issues (mean 2.2 versus 1, p = 0.018) more frequently than in the control arm. At two months, compared to baseline, there was no change in anxio-depressive symptoms or quality of life. **Conclusions:** QPL favours discussion on prognosis and end-of-life care during the palliative care consultations for advanced cancer patients. Clinical trial information: NCT02854293. Research Sponsor: INCA.

12111 Poster Session (Board #399), Fri, 8:00 AM-11:00 AM

A prospective analysis of chemotherapy-induced nausea and vomiting in gastrointestinal cancers: Results from a tertiary cancer center. *First Author: Akhil Kapoor, Tata Memorial Hospital, Mumbai, India*

Background: Chemotherapy-induced nausea and vomiting (CINV) is a bothersome side-effect associated with cancer chemotherapy which adversely impacts both quality of life and the ability to carry out the activities of daily living. This study was conducted to assess the proportion of patients developing CINV after receiving chemotherapy for gastrointestinal (GI) cancers, in spite of receiving antiemetic prophylaxis as per the standard guidelines. **Methods:** Consecutive patients with GI malignancy who had not received previous chemotherapy were eligible for enrollment in the study if they were scheduled to receive at least one cycle of chemotherapy. SPSS version 20 was used for all statistical calculations. **Results:** 701 patients fulfilling the eligibility criteria were included in this study, out of which 55.4% were males, median age was 51 years (range 22-77). Biliary tract cancer (34%) was the most common diagnosis followed by colorectal (30.2%) and gastric cancer (19.6%). As per MASCC guidelines, 22.1% patients received highly emetogenic chemotherapy, 56.0% moderately emetogenic chemotherapy (MEC) while 19.9% received regimen with low emetogenicity. Failure to achieve complete response (CR, absence of acute and delayed CINV) was found in 27.4% patients. On separately analysing MEC group, overall CR was not achieved in 33.8% with failure in acute settings in 17.8% and delayed in 16.0% patients. Only significant factor for not achieving CR was use of oxaliplatin based chemotherapy (p = 0.018 for acute and p = 0.014 for delayed CINV). **Conclusions:** More than one fourth patients failed to achieve complete response for CINV in gastrointestinal cancers despite using prophylaxis as per standard guidelines. Use of oxaliplatin based therapy is an important factor for MEC causing CINV. There is urgent need to update the guidelines for prophylaxis in this setting. Research Sponsor: None.

	Acute	Delayed
Nausea		
Across All Chemo Groups	98 (14.0%)	89 (12.7%)
Minimal	1 (7.7%)	1 (7.7%)
Low	11 (7.8%)	10 (7.1%)
Moderate	68 (17.3%)	62 (15.8%)
High	18 (11.6%)	16 (10.3%)
Vomiting		
Across All Chemo Groups	49 (7.0%)	41 (5.8%)
Minimal	0 (0%)	0 (0%)
Low	3 (2.1%)	3 (2.1%)
Moderate	41 (10.4%)	33 (8.4%)
High	5 (3.2%)	5 (3.2%)
Complete Response Not Achieved		
Across All Chemo Groups	101 (14.4%)	91 (13.0%)
Minimal	1 (7.7%)	1 (7.7%)
Low	12 (8.6%)	11 (7.8%)
Moderate	70 (17.8%)	63 (16.0%)
High	18 (11.6%)	16 (10.3%)

Complete Response Not Achieved	Overall
Across All Chemo Groups	192 (27.4)
Minimal	2/13 (15.4%)
Low	23/140 (16.4%)
Moderate	133/393 (33.8%)
High	34/155 (21.9%)

12112 Poster Session (Board #400), Fri, 8:00 AM-11:00 AM

Overall survival (OS) and healthcare utilization results of a randomized controlled trial (RCT) assessing a patient navigation (PN) intervention to increase early access to supportive care (SC) for patients with metastatic cancer in a resource-limited setting. *First Author: Miguel Araujo, Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, Delegacion Tlalpan, Mexico*

Background: We previously reported improvements in access to SC, advance directive completion, and pain control in a RCT comparing a patient navigator-led early SC intervention vs. usual care among patients with newly-diagnosed metastatic cancer in Mexico (NCT03293849). We now present results on healthcare utilization and OS. **Methods:** Patients were randomized to PN or usual oncology care. Patients in the PN arm received SC interventions by a navigator-led multidisciplinary team (palliative care, physical therapy, geriatrics, psychology) in the first 12 weeks after diagnosis. At 12-weeks, patients allocated to usual care were able to cross-over to PN and receive multidisciplinary SC. We analyzed the number (no.) of emergency room (ER) visits, their cause, and whether they were potentially avoidable (as determined by expert consensus), using descriptive statistics and X2 tests. OS was estimated using the Kaplan-Meier method and the log-rank test. **Results:** 133 patients (median age 60, range 23-93; 52% male) were randomized (66 PN, 67 control) from 08/17 to 04/18. Median follow-up was 22.8 months. 61% had gastrointestinal tumors, and 45% had a calculated life expectancy $\leq$6 months. 69% of patients randomized to usual care crossed-over to PN and received SC interventions. 80% of patients attended the ER $\geq$once (median no. of visits = 2). No difference was found between patients randomized to early SC or usual care in ER visits (2.4 vs. 2.3, p = 0.58). Out of a total 316 ER visits, the most common reason was infections (n = 69, 22%), followed by pain (n = 40, 13%), and indwelling catheter-related complications (n = 23, 7%). 41% of ER visits were considered as potentially avoidable, with no difference in avoidable visits found between arms (1.7 vs. 1.7, p = 0.49). No differences between arms were found in no. of hospitalizations (0.8 vs. 0.6 p = 0.82). Survival results were assessed after 64% of patients had died (n = 85), finding no statistically significant OS difference between the early SC intervention and the usual care arms (11.0 vs 13.0 months, p = 0.77) **Conclusions:** In the context of a limited-resource healthcare system, the early delivery of SC did not improve healthcare utilization, reduce avoidable ER visits, or prolong OS compared to the implementation of SC at a later time, which might be partially explained by the unavailability of hospice or home care, and by high rates of cross-over between arms. Clinical trial information: NCT03293849. Research Sponsor: Global Cancer Institute.

12113 Poster Session (Board #401), Fri, 8:00 AM-11:00 AM

Evaluation of the incidence of acute nausea and vomiting after administration of an amino acid solution containing only arginine and lysine with lutetium Lu-177 dotatate. *First Author: Nicholas Alonzo, Stanford Health Care, Stanford, CA*

Background: Lutetium Lu-177 dotatate is used to treat patients with gastroenteropancreatic neuroendocrine tumors, and an amino acid (AA) solution must be administered concurrently to mitigate nephrotoxicity. AA solutions may lead to increased rates of nausea and vomiting (NV) due to the inclusion of unnecessary non-essential and essential AA. **Methods:** This study is a single academic center retrospective chart review from October 6th, 2015 to December 17th, 2019 evaluating the incidence of acute NV in adult patients after administration of an AA solution containing only arginine 25 grams and lysine 25 grams in 1 liter of normal saline (Arginine-Lysine amino acid [AL AA]) with lutetium Lu-177 dotatate. The incidence of acute NV will be compared to the historical incidence in patients administered Parenteral amino acids 10%, Aminosyn II 10% or Clinisol 15% (commercial AA). Secondary endpoints include the incidence of rescue anti-emetic usage and the percentage of patients that require interruption of the AA infusion. Acute NV are defined as any occurrence of NV within twenty-four hours of the AA infusion. **Results:** 53 patients received a total of 164 treatments with the AL AA, while 18 patients received a total of 48 treatments with the commercial AA. The AL AA significantly decreased the incidence of acute NV, the mean AA infusion time, the interruption of the AA infusion, and the utilization of rescue anti-emetics compared to the commercial AA (Table) in patients on lutetium Lu-177 dotatate. **Conclusions:** The study findings support the use of an AL AA to be administered concurrently with lutetium Lu-177 dotatate to minimize commercial AA related acute NV. Research Sponsor: None.

Infusion specific outcomes.

	AL AA, (n = 164)	Commercial AA, (n = 48)	P-Value
Incidence of acute nausea, n (%)	33 (20.1)	31 (64.6)	< 0.0001
Incidence of acute vomiting, n (%)	2 (1.2)	5 (10.4)	0.0072
Amino acid infusion time, mean minutes	252.8	403.6	< 0.0001
Interruption or prolonged amino acid infusion, n (%)	2 (1.2)	15 (31.3)	< 0.0001
Rescue anti-emetic use within 24 hours of treatment, n (%)	33 (20.1)	31 (64.6)	< 0.0001

n = number of AA infusions

12114 Poster Session (Board #402), Fri, 8:00 AM-11:00 AM

Associations of functional, psychosocial, and medical factors with cognitive impairment in older, chemotherapy-naïve patients with early breast cancer. *First Author: Zev Nakamura, University of North Carolina at Chapel Hill, Chapel Hill, NC*

Background: Cognitive decline related to cancer and its treatments is a common concern among patients receiving treatment for cancer. Routine cognitive screening in oncology practice has been limited by the absence of a reliable, cancer-specific cognitive test. The Blessed Orientation Memory Concentration Test (BOMC) [1], has been incorporated in cancer-specific geriatric assessments, but there is no established cutpoint for cancer-related cognitive impairment. Recent research suggests that BOMC scores ≥ 5 may represent cognitive impairment in older patients with cancer. The purpose of this study was to identify cognitive impairment and associated characteristics in chemotherapy-naïve patients with breast cancer. **Methods:** Women with stage I-III breast cancer were recruited between 2009 and 2018. The BOMC (range 0-28, higher is worse function) was administered prior to chemotherapy. Associations between cognitive dysfunction (BOMC ≥ 5) and functional, psychosocial, medical variable were assessed using log binomial regression analysis. **Results:** In a sample of 331 women with breast cancer, the mean age was 65.2 years and 68.6% were 65 and older. Twenty-seven percent demonstrated cognitive impairment prior to treatment. Patients with Time Up and Go Test (TUG) ≥ 14 had increased risk of cognitive impairment compared to those with TUG < 14 (44% vs. 23%, p = 0.0002). After controlling for demographic factors, the estimated increase in risk was 66% (RR: 1.66, 95% CI (1.20, 2.31), p = 0.002). For Medical Outcomes Survey (MOS) Physical Function, after controlling for demographic factors, each 1 point increase in physical function (range 0-20, higher is better function) was associated with a 5% decrease in risk of cognitive impairment (p = 0.0004). **Conclusions:** Using a newly proposed BOMC cutpoint of ≥ 5, our study identified cognitive impairment in over 25% of older, chemotherapy naïve women with breast cancer. This is similar to what has been reported using rigorous neuropsychological testing in comparable populations. Additionally, we found that this degree of cognitive dysfunction was associated with both patient-reported and clinician-assessed impairment in physical function, further supporting the clinical relevance of this new cutpoint. Reference: [1] Katzman et al. Am. J. Psychiatry. 140 (1983) 734–739. Research Sponsor: Kay Yow Foundation, Other Foundation, U.S. National Institutes of Health.

12115 Poster Session (Board #403), Fri, 8:00 AM-11:00 AM

CIFeR: A novel Clinician-lead Intervention to address Fear of cancer Recurrence (FCR) in breast cancer survivors. *First Author: Jia Liu, Psycho-Oncology Co-operative Research Group, Camperdown, Australia*

Background: FCR affects 50-70% of cancer survivors. There are no validated oncologist-delivered FCR interventions. This multicentre, single-arm study sought to determine the helpfulness, feasibility and efficacy of an oncologist-delivered FCR intervention. **Methods:** Women were invited to participate if they had completed local treatment, chemotherapy and/or HER2 targeted therapy for early stage breast cancer and had a FCR score >0 on the 42-item FCR Inventory. The brief intervention, delivered by their medical oncologist at routine follow-up, entailed 1) FCR normalisation; 2) provision of personalised prognostic information; 3) take-home education sheet on recurrence symptoms; and 4) advice on managing worry. Consultations were audio-recorded. FCR, need for help, depression and anxiety were assessed before the intervention (T0), and at one week (T1) and three months (T2) after the intervention. Satisfaction with the intervention was assessed at T1. The primary outcome was participant-rated helpfulness. Secondary outcomes included feasibility (response rate, time taken for intervention) and efficacy. **Results:** Five oncologists delivered the intervention to 61 women (255 women invited; response rate 24%). The mean age was 57 $\pm$ 13 years. The mean time since breast cancer diagnosis was 2.5 $\pm$ 1.3 years. Forty-three (72%) were on adjuvant hormonal therapy. Overall, 58 women (95%) found the intervention helpful and 59 (98%) would recommend it to others. FCR severity, and the proportion of women with clinically significant FCR decreased significantly over time. There were no significant changes in unmet need, depression, or anxiety. Forty (66%) of consultations were recorded. Mean consultation length was 22 minutes (range 12-37 minutes) and mean intervention length was 9 minutes (3-20 minutes). The intervention was perceived as useful and feasible by oncologists, all of whom have used components of the intervention to help manage FCR in other breast cancer patients. **Conclusions:** A brief oncologist-delivered intervention to address FCR is helpful and feasible, and has shown preliminary efficacy in reducing FCR. Plans for an implementation study amongst oncologists in Australia are underway. Clinical trial information: ACTRN12618001615279. Research Sponsor: Sydney Breast Cancer Foundation, AVANT Foundation.

	T0 (n=61)	T1 (n=52)	T2 (n=33)	P-value
FCR Severity (mean $\pm$ SD)[1]	15.5 $\pm$ 6.3	13.3 $\pm$ 5.8	10.9 $\pm$ 4.6	$p<0.0001$[2] $p<0.0001$[2]
Proportion with clinically significant FCR (≥13)[1]	39 (64%)	27 (52%)	12 (36%)	$p=0.016$[3] $p=0.006$[3]

[1]Measured using the severity subscale of 42-item validated FCR Inventory [2]Repeated measures ANOVA [3]McNemar's test (exact significance)

12116 Poster Session (Board #404), Fri, 8:00 AM-11:00 AM

Nonconscious nonverbal synchrony and patient and physician affect and rapport in cancer treatment discussions with black and white patients. *First Author: Lauren M. Hamel, Karmanos Cancer Center, Wayne State University, Detroit, MI*

Background: Clinical communication is poorer with Black patients than with White patients, but most studies are limited to verbal communication. Nonverbal synchrony, the subtle, nonconscious coordination of movement between individuals, has been shown to reflect relationship quality. We investigated nonverbal synchrony's association with patient and physician affect and rapport in cancer treatment discussions, and if those associations differed by patient race. **Methods:** We used motion detection software to measure overall synchrony and synchrony based on who is leading in the interaction (similar to leading in dancing) in video recordings of 68 Black patients and 163 White patients discussing treatment with their non-Black physicians. Additionally, naïve observers rated the interaction for six constructs: patient and physician positive and negative affect and patient-physician positive and negative rapport. We examined associations between nonverbal synchrony and the six constructs. **Results:** In interactions with Black patients, overall synchrony was positively associated with patients' positive affect and positive patient-physician rapport and negatively associated with patients' negative affect and negative patient-physician rapport. When the physician was leading, synchrony was positively associated with patients' positive affect and positive patient-physician rapport and negatively associated with patients' negative affect and negative patient-physician rapport. When the patient was leading, synchrony was positively associated with patients' and physicians' positive affect and positive patient-physician rapport, and negatively associated with patients' negative affect and negative patient-physician rapport. In interactions with White patients, overall synchrony was positively associated with patient positive affect; when the physician was leading, synchrony was negatively associated with patient negative affect. **Conclusions:** This is the first study to use an innovative measure of dynamic communication in patient-physician cancer treatment discussions. Nonverbal synchrony was related to patient and physician affect and rapport in interactions with Black patients, but only patient affect in interactions with White patients, suggesting *nonverbal synchrony is particularly important in interactions with Black patients.* Next steps include investigating associations with patient outcomes (e.g., satisfaction). Findings could contribute to physician training. Research Sponsor: U.S. National Institutes of Health.

12117 Poster Session (Board #405), Fri, 8:00 AM-11:00 AM

Health and cancer concerns among siblings of childhood cancer survivors: A report from the Childhood Cancer Survivor Study (CCSS). *First Author: Sonia Morales, Children's Hospital of Orange County, Orange, CA*

Background: Siblings of long-term survivors of childhood cancer can be at risk for persistent concerns regarding their future health and risk for cancer. We examined self-perceived future health and cancer risk concerns among such siblings. **Methods:** 3,969 siblings (median age 29 [range 18–56] years) of 5+ year matched pair cancer survivors (n= 3,969; age 25 [6–48] years; time since diagnosis 19.6 [9.6-33.8] years) in the CCSS self-reported physical/psychosocial problems, including concerns regarding future health and cancer risk (dichotomized as concerned vs not concerned). Chronic health conditions (CHC) were graded using the Common Terminology Criteria for Adverse Events system: mild (grade 1), moderate (grade 2), severe/disabling (grade 3),or life-threatening (grade 4). Sibling demographics, their matched survivor's diagnosis, era and treatment components, complications (death, relapse, disfigurement) as well as self-reported health status and CHCs for siblings and survivors were examined as potential risk factors for concern using multivariable logistic regression. Adjusted odds ratios (OR) and 95% confidence intervals (CI) are reported. **Results:** The prevalence of siblings reporting concerns regarding health and cancer risk decreased based on decades of matched survivor diagnosis: 1970-79 (73.3%; 63.9%), 1980-89 (67.2%; 62.6%), 1990-99 (45.7%; 52.3%). Risk factors for concerns included sibling poor/fair current health (future health OR 3.65, 95% CI 2.37-5.62; cancer risk OR 1.54, 1.12-2.13) compared to good/very good/excellent health. Sibling grade 2 (future health OR 1.46, 1.23-1.74; cancer risk OR 1.20, 1.01-1.42) or grade 3-4 CHCs (future health OR 1.37, 1.09-1.71; cancer risk OR 1.28, 1.03-1.58) were associated with greater concerns compared to those with less than grade 2 CHCs. Survivor treatment with chemotherapy/radiation was associated with elevated cancer risk concerns (OR 1.51, 1.13-2.02) compared to surgery/no therapy. Siblings of survivors with grade 3-4 CHCs (OR 1.35, 1.12-1.63) had greater future health concerns compared to those with less than grade 2 CHCs. Sibling bereavement was a risk factor for future health (OR 1.45, 1.04-2.03) and cancer risk (OR 1.44, 1.05-1.99) concerns. **Conclusions:** The prevalence of sibling concerns regarding future health and cancer have diminished in more recent decades. Subgroups of siblings are at-risk for concerns over future health and cancer risk, partially determined by medical characteristics of their survivor and their own health status. Research Sponsor: None.

12118 Poster Session (Board #406), Fri, 8:00 AM-11:00 AM

Defining patient-elicited concepts unique to adolescents and young adults with cancer. *First Author: Viswatej Avutu, Memorial Sloan Kettering Cancer Center, New York, NY*

Background: Adolescents and young adults (AYAs) require a multidisciplinary approach to cancer care due to complex biopsychosocial variables and varied developmental maturity. Currently, age and diagnosis determine referral to pediatric or adult oncology with differing care paradigms and service utilization. These issues, in conjunction with differences in tumor biology and lower accrual to clinical trials, have contributed to marginal improvements in outcomes for AYAs. Compounding this dilemma is a lack of validated patient-reported outcome measures (PROs) for AYAs. Tracking standardized PROs longitudinally is a crucial step in understanding psychosocial variables, identifying tailored needs, improving outcomes and standardizing care. However, developing a PRO tool for AYAs first requires identifying AYA-unique domains. **Methods:** Three, 90-minute focus groups were conducted with AYAs treated at Memorial Sloan Kettering in the context of 1) pediatric oncology, 2) medical oncology, and 3) either service. Topics explored included: experiences of cancer care as an AYA; physical, social and emotional concerns; and information needs, including appropriateness, timing, and depth of information. Thematic content analysis of transcripts was performed by four interdisciplinary coders in weekly iterative consensus rounds. Phase one consisted of identification of key domains to guide line-by-line coding with NVivo software. Phase two consisted of independent review and categorization of codes, followed by three successive consensus meetings to identify distinct themes. **Results:** A mean of 6 patients (range 5-7) participated in each of the 3 groups; the total sample (n = 17) included 9 males and 8 females, ages 19-35 years (median 26). Four AYA-unique themes were identified: 1. AYAs have an uncertain sense of the future and desire more engagement in conversations pertaining to survivorship, long-term effects and transition to outpatient life. 2. Cancer as an AYA is a socially-isolating experience, prompting a strong desire to connect with peers during and post-treatment. 3. AYAs want control over who can be present during discussions with their care team as the presence of loved ones can impede or facilitate communication. 4. AYAs may be living far away from loved ones during treatment and lack supports needed to help them navigate treatment and daily life. **Conclusions:** Concept elicitation via focus groups identified novel themes related to survivorship, isolation, communication and social support, which can inform development of AYA-specific PROs. Research Sponsor: Memorial Sloan Kettering Cancer Center Patient and Family Advisory Council for Quality Grant.

12119 Poster Session (Board #407), Fri, 8:00 AM-11:00 AM

An intervention RCT-study aimed at improving mental health and increasing understanding of fertility preservation with Oncofertility! Psycho-Education And Couple Enrichment (O!PEACE) therapy. *First Author: Nao Suzuki, Department of Obstetrics and Gynecology, St. Marianna University School of Medicine, Kawasaki, Japan*

Background: Although ASCO revised Guidelines (2013) recommends referring to psychological professionals if cancer patients show concerns or anxiety about fertility, there is no evidence regarding the efficacy of psychotherapy. The aim of this study is to examine whether the Psycho-Education And Couple Enrichment (O!PEACE) therapy can reduce psychiatric symptoms and improve stress coping and marital relationship in breast cancer patients. **Methods:** Trial design: multicenter randomized controlled trial, pre-post design. Subjects were women aged 20–39 years with breast cancer before cancer treatment and their husbands. Couples were randomly assigned to receive O!PEACE therapy (n = 37) or not (usual care: n = 37). Assessments of PTSD symptoms, depression and anxiety were made as the primary end points at baseline and at the end of therapy before cancer treatment. Stress coping strategies, resilience, marital relationships, and marital communication were examined as secondary end points. **Results:** Four participants in O!PEACE therapy and one participant in the usual care withdrew from the trial. Intention-to-treat analyses were conducted using analysis of covariance after multiple imputation by R and SPSS. Series of ANCOVAs were integrated according to Rubin's rule. A significant decrease was observed in the primary outcome of PTSD symptoms, from baseline to post-intervention, in women who participated in O!PEACE therapy ($p = .011$, $\eta_p^2 = .089$). According to post-hoc analyses, for patients with a higher baseline IES-R-J score, O!PEACE therapy resulted in a significantly higher reduction in follow-up assessment IES-R-J score when compared with usual care ($U = 172.80$, $p = .027$, $r = .258$): 59.3% of the women in O!PEACE therapy showed a 5-point or greater reduction, whereas in usual care, 30.0% showed a 5-point or greater reduction. For husbands, the O!PEACE therapy also showed a significant improvement of giving up and blaming others as the stress coping strategy and escape-avoidance coping strategy in their marital communication. For breast cancer patients, the O!PEACE therapy significantly improved support from husbands and the patients' knowledge level of oncofertility compared with those receiving usual care. **Conclusions:** Only two counseling sessions of O!PEACE therapy can reduce patients' distress, improve their husbands' coping style, and may build a better cooperative relationship for couples in terms of fertility preservation and cancer treatment. Clinical trial information: UMIN000017754. Research Sponsor: Health Labour Sciences Research Grant #H26-Cancer-017, The Ministry of Health Labour and Welfare in Japan.

12120 Poster Session (Board #408), Fri, 8:00 AM-11:00 AM

Relationship between caregiver burden and psychological distress among stem cell transplant (SCT) recipients prior to transplant. *First Author: Carlisle Topping, Massachusetts General Hospital, Boston, MA*

Background: SCT is a potentially curative therapy for patients with hematologic malignancies that involves prolonged hospitalization, intensive follow-up, and a considerable risk of morbidity and mortality. Family and friends caring for SCT recipients experience substantial caregiving burden as they prepare for SCT. Previous research demonstrates caregiver distress is highest pre-transplant and is comparable to or higher than patient-reported distress. However, the extent of this distress and its relationship to certain domains of quality of life (QOL) and caregiving burden is currently unknown. **Methods:** We conducted a secondary analysis of cross-sectional data from two supportive care studies focused on caregivers of SCT recipients. Caregivers completed the Hospital Anxiety and Depression Scale (HADS) and the CareGiver Oncology QOL questionnaire to assess their psychological distress and QOL prior to SCT. Scores >8 on the HADS anxiety and depression subscales indicated clinically significant symptoms. We selected eight domains from the CareGiver Oncology QOL questionnaire including social support, physical wellbeing, self-efficacy, coping, leisure time, financial stability, private life concerns, and caregiving burden. Multivariate regression models adjusted for age, sex, caregiver relationship, and SCT type were used to examine associations between these domains and caregivers' anxiety and depression symptoms. **Results:** A total of 193 caregivers (age *M*= 57 years, 70% female, 52% allogeneic transplant) were enrolled with a majority caring for their spouse (80%), parent (8%) or child (5%). Overall 47% and 16% of caregivers reported clinically significant anxiety and depression symptoms, respectively. Low social support, physical well-being, coping and leisure time as well as high caregiver burden, private life concerns and financial distress were associated with both caregiver anxiety and depression symptoms ($p < .05$). Low self-efficacy was associated with higher anxiety symptoms ($p < .05$). **Conclusions:** Caregivers of SCT recipients experience substantial anxiety and depression symptoms prior to SCT. Impairments across multiple QOL domains are associated with caregiver's psychological distress. Psychosocial interventions designed to improve coping, reduce caregiving burden, and enhance QOL are needed for caregivers prior to transplant. Research Sponsor: Lymphoma and Leukemia Society.

12121 Poster Session (Board #409), Fri, 8:00 AM-11:00 AM

Effect of linguistic acculturation on self-efficacy and anxiety in caregivers of Latina breast cancer survivors. *First Author: Ilana Schlam, Medstar Washington Cancer Institute, Washington, DC*

Background: Latina breast cancer survivors and their caregivers face unique challenges. Acculturation is the acquisition of the cultural elements of a dominant society. Higher acculturation in Latino survivors is positively correlated with self-efficacy in patient-provider communication and improved patient-reported outcomes. There is a paucity of research on how language acculturation affects caregiver and patient outcomes. We examined associations over time between linguistic acculturation among caregivers of Latina survivors and outcomes of caregiver self-efficacy and anxiety. **Methods:** We partnered with four community-based organizations that serve Latino families facing cancer. We enrolled 136 Latina breast cancer survivors and their caregivers for a randomized trial comparing a dyadic coping intervention to usual care (e.g., support groups). Participants completed surveys including demographic and clinical information, the short acculturation scale for Hispanics, caregiver inventory to assess self-efficacy and PROMIS domains of anxiety at baseline and 6-months after the intervention. **Results:** In multivariate linear regressions models, we examined the effect of acculturation on caregiver self-efficacy and anxiety, controlling for demographics (patient and caregiver age, caregiver education, employment), patient treatment history (chemotherapy and surgery) patient and caregiver language preference (Spanish or English) and intervention arm (intervention vs. usual care). Greater caregiver self-efficacy at 6-months was associated with younger patient age (t=-2.93, p=.004), older caregiver age (t=2.63, p = .01), female caregiver gender (t=2.79, p = .006) and higher acculturation (t=2.01, p=.04), controlling for baseline self-efficacy, patient language and randomization group. Caregiver anxiety was not related to caregiver acculturation or patient language preferences. **Conclusions:** Caregivers' language acculturation was significantly associated with their self-efficacy over time, suggesting that caregivers with lower acculturation experience lower confidence in their provision of care for Latina survivors. These findings are particularly salient because participants for this study were enrolled from organizations with bilingual services. Caregivers of Latina survivors without access to these community resources may face even more striking challenges. Future work can explore how caregivers' confidence relates to survivors' adherence to care and patient outcomes over time. Research Sponsor: None.

12122 Poster Session (Board #410), Fri, 8:00 AM-11:00 AM

Enhanced coping and self-efficacy in caregivers of hematopoietic stem cell transplant (HCT) recipients: Identifying mechanisms of a multimodal psychosocial intervention. *First Author: Madeleine Elyze, Massachusetts General Hospital, Boston, MA*

Background: A brief multimodal psychosocial intervention (BMT-CARE) for caregivers of HCT recipients demonstrated promising efficacy for improving caregiver quality of life (QOL), mood, coping skills, and self-efficacy. We examined whether improvements in coping and self-efficacy mediated the intervention effects on QOL and mood. **Methods:** We conducted a randomized clinical trial of BMT-CARE for caregivers of patients undergoing autologous or allogeneic HCT at a single institution. Caregivers were randomly assigned to BMT-CARE or usual care. BMT-CARE was tailored to the HCT trajectory and integrated treatment-related education and self-care with cognitive-behavioral skills and caregiving-specific strategies to promote coping. Caregivers completed self-report measures of QOL (CareGiver Oncology QOL), depression and anxiety symptoms (Hospital Anxiety and Depression Scale), coping skills (Measure of Current Status), and self-efficacy (Cancer Self-Efficacy Scale-Transplant) at enrollment and 60 days post-HCT. We used causal mediation regression models to examine whether changes in coping and self-efficacy mediated intervention effects on QOL, depression and anxiety symptoms. **Results:** Caregivers randomized to BMT-CARE reported improved self-efficacy (adjusted means: 156.20 vs. 147.06, P=0.023) and coping skills (adjusted means: 36.54 vs. 25.41, P<0.001). Improved coping and self-efficacy partially mediated the intervention effects on 60-day QOL (indirect effect=6.93, SE=1.85, 95% CI [3.71, 11.05]). Similarly, improved coping and self-efficacy partially mediated reductions in 60-day depression and anxiety symptoms (indirect effect depression=-1.19, SE=0.42, 95% CI [-2.23, -0.53]; indirect effect anxiety=-1.46, SE=0.55, 95% CI [-2.52, -0.43]). Combined improvements in coping and self-efficacy accounted for 67%, 80%, and 39% of the total intervention effect on QOL and depression and anxiety symptoms, respectively. **Conclusions:** A brief multimodal intervention for caregivers of HCT recipients may improve QOL and mood by enhancing coping skills and self-efficacy. These findings offer important insights into the mechanisms by which caregiver-directed interventions may enhance caregiver QOL and reduce their psychological distress. Research Sponsor: Lymphoma and Leukemia Society.

12123 Poster Session (Board #411), Fri, 8:00 AM-11:00 AM

Video conference intervention for distance caregivers (DCGs) of patients with cancer: Improving psychological outcomes. *First Author: Sara L Douglas, Case Western Reserve University and Case Comprehensive Cancer Center, Cleveland, OH*

Background: Family caregivers are increasingly involved in providing care and support for patients with cancer. Approximately 20% of caregivers live > 1 hour away from the patient and are considered DCGs. DCGs report higher distress and anxiety than local caregivers—often due to lack of first hand information and a high degree of uncertainty regarding the patient's condition. **Methods:** This RCT was conducted at a large, urban comprehensive cancer center. Patients of all cancer types were eligible if they had monthly oncologist appointments and were receiving treatment. DCGs were randomized to one of three arms. Arm 1 received 4 monthly videoconference coaching sessions with a nurse practitioner or social worker focused upon information and support, participated in patient's appointments with the oncologist via videoconference over the 4 month study period, and had access to a website designed for DCGs. Arm 2 did not receive the coaching sessions but received the other 2 components of Arm 1. Arm 3 received access to the DCG website only. Primary variables of interest were DCG distress and anxiety. DCGs completed online surveys prior to randomization and at the completion of the intervention period. PROMIS Anxiety and the NCCN distress thermometer were used. **Results:** Between November, 2016 and October, 2019, 441 patient-dyads were enrolled. Mean DCG age was 47 years; 71% were female, 65% Caucasian, 63% were the child of the patient and 81% were employed. Mean patient age was 65 years, 60% were female, 30% had GI cancer and 18% had hematologic cancer. For patients with solid tumor cancers, 59% were Stage IV. RMANOVA was used to examine the change in anxiety t-scores over time by arms of the intervention, controlling for DCG age, race, and gender. There was a significant anxiety by group interaction (p = .03) with Arm 1 being the only group that showed a significant reduction in anxiety over time (21.2% improved, ES = .57). Distress followed a similar pattern with a significant distress by group interaction (p = .02) with Arm 1 demonstrating the greatest improvement in distress over time (54.3%). **Conclusions:** These data suggest that the use of a coaching videoconference intervention made significant and clinically meaningful differences in anxiety and distress for these important members of the family caregiving team. Clinical trial information: NCT02666183. Research Sponsor: U.S. National Institutes of Health.

TPS12124 Poster Session (Board #412), Fri, 8:00 AM-11:00 AM

The effect of longitudinal exercise programming in breast cancer patients. *First Author: Jami Aya Fukui, University of Hawaii Cancer Center, Honolulu, HI*

Background: Obesity and weight gain are significant concerns for breast cancer survivors. Obesity at diagnosis is an established negative prognostic factor and studies suggest that post-diagnosis weight gain may increase risk for recurrence and decrease disease free survival. Various interventions such as dietary modification, physical activity, individualized counseling, cognitive behavioral therapy, and combinations of these interventions have been studied in order to identify strategies for weight loss in breast cancer survivors. However, one of the main challenges have been to show sustainability in these interventions. Given the adverse consequences of weight gain after diagnosis, continued efforts to identify appropriate weight management interventions aimed at promoting overall health and long term survivorship are needed. **Methods:** We have opened an investigator initiated Breast Cancer Exercise Study that provides a tailored exercise program and body health assessments for breast cancer patients along their treatment journey. We are enrolling women diagnosed with breast cancer up to 2 years after their diagnosis into a two 12-week exercise program. Participants' biometrics and physical assessments will be assessed at baseline to determine the appropriate exercise intensity to implement. Women will attend private 1:1, 90min sessions, 3 days/week. At the end of the initial 12-week program, biometric assessments are again performed and participants are then randomized to either: a) continue with individual exercise classes, 2 days/week or b) continue with group exercise classes, 2 days/week. The study follows their long term outcomes including cancer recurrence, exercise adherence as well as quality of life symptoms. The functional health assessment and subsequent personalized exercise program utilizes kinesiology students from University of Hawaii-Manoa during their clinical practicum and is based at our community partner facility the Rehabilitation Hospital of the Pacific. Body assessments and other biomarkers are evaluated through expertise at University of Hawaii Cancer Center. Collectively, our study exemplifies our partnership with community facilities, utilizes cutting edge research and incorporates local students, to provide an important health program for cancer patients all the while enriching our understanding of the unique patient population. The results of this project may help to develop standardized exercise protocols for breast cancer survivors and provide insights to other important health concerns. Clinical trial information: NCT04013568. Research Sponsor: None.

TPS12125 Poster Session (Board #413), Fri, 8:00 AM-11:00 AM

A phase Ib adaptive study of dasatinib for the prevention of oxaliplatin-induced neuropathy in patients with metastatic colorectal cancer receiving FOLFOX chemotherapy and bevacizumab. *First Author: Anne M. Noonan, The Ohio State University Comprehensive Cancer Center, Arthur G. James Cancer Hospital, Columbus, OH*

Background: Neurotoxicity is one of the most significant and disabling side effects of oxaliplatin and frequently limits the cumulative amount that can be used. The mechanism of oxaliplatin-induced neurotoxicity remains uncertain, although our preliminary studies suggest that oxaliplatin uptake by organic cation transporter 2 (OCT2) into mouse and rat dorsal root ganglion is a prerequisite for oxaliplatin-induced peripheral neuropathy. The activity of OCT2 is dependent on tyrosine phosphorylation by the SRC-kinase family member Yes1, which is highly sensitive to inhibition by several FDA-approved, small molecule kinase inhibitors such as dasatinib. We have previously shown that pre-treatment with oral dasatinib prevented acute and chronic oxaliplatin-induced peripheral neuropathy in mouse and rat models. **Methods:** This is a phase Ib dose-finding study of dasatinib given in combination with mFOLFOX6 with or without bevacizumab. The study explores the hypothesis that the addition of dasatinib prior to oxaliplatin will inhibit OCT2 activity and reduce oxaliplatin-induced neuropathy. This hypothesis will be tested in a Bayesian Phase 1b trial with adaptive dose selection using efficacy-toxicity trade-offs (modified toxicity-efficacy probability interval dose-finding design) in patients with confirmed stage IV colorectal cancer who are candidates for mFOLFOX6 with bevacizumab therapy. Patients who have documented peripheral neuropathy or prior exposure to oxaliplatin will be excluded. The primary objective is to determine the recommended Phase 2 dose which is defined as the lowest intermittent dose of dasatinib that affects serum biomarkers of OCT2, including methylnicotinamide and creatinine, by $\geq$2-fold without influencing the clearance of oxaliplatin by $>$ 20%. The following doses will be used: oxaliplatin 85mg/m^2 IV, 5FU bolus 400mg/m^2 IV bolus with Leucovorin 400mg/m^2, bevacizumab 5mg/kg, followed by infusional 5FU 2400mg/m^2 IV over 46 hours given on a day 1 and 15 schedule every 28 days. Dasatinib will be administered at one of 2 dose levels – 100mg or 140mg po. Dasatinib will be given 24 hours and 30 mins prior to oxaliplatin on C1D14, C1D15 respectively and repeated on C1D28 and C2D1. Secondary objectives include evaluation of the influence of dasatinib on the pharmacokinetics of oxaliplatin and vice versa. Quality of life will be explored using the CIPN20 questionnaire. The trial opened to enrollment in Dec 2019 (NCT04164069) and is accepting patients. Clinical trial information: NCT04164069. Research Sponsor: Pelotonia IDEA grant.

TPS12126 Poster Session (Board #414), Fri, 8:00 AM-11:00 AM

Feasibility of a digital medicine program in optimizing opioid pain control in cancer patients (SWOG S1916). *First Author: Sherry Shen, Columbia University Medical Center, New York, NY*

Background: The undertreatment of pain in patients with advanced or metastatic cancer is well described in cancer research. Overcoming barriers that prevent successful use of opioid analgesics for cancer pain requires a clear understanding of how individuals use oral medications at home. The Proteus Discover is a digital medicine program (DMP) consisting of an FDA-approved ingestible sensor made of dietary minerals co-encapsulated with patients' medications, a wearable sensor patch, and a mobile device app that enables patients to electronically transmit their medication adherence patterns. Use of the DMP has demonstrated improved clinical outcomes vs. usual care in patients with diabetes and hypertension, shown superiority over directly-observed therapy in tuberculosis and has been studied in the treatment of patients with hepatitis C, HIV, cancer and severe mental illness, but it has not been previously studied with opioids or in monitoring cancer-related pain. **Methods:** We are conducting a multicenter pilot study at SWOG NCORP sites to test the feasibility of using the DMP to monitor opioid use in the treatment of metastatic cancer pain. Eligible patients must have a diagnosis of metastatic cancer, have a baseline Brief Pain Inventory worst pain score of $\geq$3, be deemed by their physician to need initiation or up-titration of oxycodone-acetaminophen for pain control, and be able to read English. Primary outcomes include: (1) study accrual of 60 patients within six months of study activation at all participating sites; (2) patient retention defined as $\geq$50 patients completing the study, and; (3) adherence to the DMP defined as $\geq$66% of patients wearing the sensor patch for $\geq$28 days of the 42-day observation period. Secondary outcomes include change in Brief Pain Inventory pain scores, opioid medication consumption, number of safety alert triggers for high consumption, hospital or emergency room visits for pain, activity levels, and frequency of changes to the pain control regimen. The study will enroll patients at six sites; the first patient was enrolled on 1/20/2020. If successful, this study will inform design of a randomized controlled trial of the DMP vs. usual care in optimizing medication utilization and controlling cancer-related pain. Clinical trial information: NCT04194528. Research Sponsor: U.S. National Institutes of Health, Proteus Digital Health.

TPS12127 Poster Session (Board #415), Fri, 8:00 AM-11:00 AM

An oro-buccal nanoparticle delivered cannabis medicine for pain management in cancer: A clinical trial in progress. *First Author: Stephen John Clarke, Northern Cancer Institute, Sydney, Australia*

Background: Cannabinoid molecules derived from Cannabis sativa L. have been posited to ameliorate conditions, including pain, chemotherapy induced nausea and multiple sclerosis associated spasticity. The clinical use of cannabinoids refers to a wide variety of formulations and extracts that may contain different active ingredients and adulterants as well as inter batch variability. Novel matrix formulations (e.g., water-soluble nanoparticles) for cannabis delivery may add further efficacy and tolerability to standard routes of administration (e.g., oral / gastrointestinal, inhaled, sublingual). This is further emphasized by the dysbiotic effects on the intestinal microbiome reported for oral formulations of medicinal cannabis, and which resulted in reduced efficacy. Similar results have been reported for other psychotropic compounds, such as alcohol and nicotine. Therapeutic use of cannabinoid formulations may be mode of delivery dependent in order to achieve safe, tolerable and effective doses. **Methods:** A water soluble oro-buccal nanoparticle spray with a racemic 1:1 mixture of Delta9Tetrahydrocannabinol (D9THC) and Cannabidiol (CBD), which bypasses the gastrointestinal system and first pass metabolism by accessing the systemic circulation via the facial lymphatics system, was investigated in patients with advanced cancer and unrelieved pain in a single ascending dose and multiple ascending dose in a first-in-human study. **Results:** The THC / CBD combination delivered as a submicron particle demonstrated safety, tolerability and a pharmacokinetic profile suitable for maintenance analgesic therapy. Preliminary analysis found an overall (n = 25) improvement in pain scores, especially in the subgroup of patients with bone metastases (n = 8), who obtained a greater than 30% average reduction in pain severity. 1 Clinical trial information: ACTRN12617001480370. Research Sponsor: Medlab Clinical.

TPS12128 Poster Session (Board #416), Fri, 8:00 AM-11:00 AM

A phase Ib study of the safety and pharmacology of nilotinib to prevent paclitaxel-induced peripheral neuropathy in patients with breast cancer. *First Author: Elizabeth J. Adams, Ohio State University Wexner Medical Center, Columbus, OH*

Background: Chemotherapy-induced peripheral neuropathy (CIPN) is a debilitating adverse effect of paclitaxel, but convincing evidence for a preventative technique founded on mechanistic rationale is lacking. We previously report that paclitaxel accumulation is mediated by the murine organic anion transporting polypeptide, OATP1B2 in mice (OATP1B1 and OATP1B3 in humans) (Leblanc, J Clin Invest, 2018). We found that paclitaxel induces acute and chronic neurotoxicity in mice in an OATP1B2-dependent manner, which is reversed by pre-treatment with FDA-approved tyrosine kinase inhibitor, nilotinib. **Methods:** This phase Ib dose finding study of nilotinib in combination with weekly paclitaxel is investigating the hypothesis that intermittent dosing of nilotinib 24 hours before paclitaxel infusion (excluding C1D1) and again 30 minutes before paclitaxel infusion will inhibit OATP1B1 and prevent CIPN. This hypothesis will be assessed using an adaptive Bayesian method for dose finding based on efficacy-toxicity trade-offs in patients with breast cancer stages I-III who qualify for paclitaxel therapy. Patients with previous $\geq$ grade 2 neuropathy on breast cancer therapies will be excluded. The primary objectives are to find the recommended phase II dose of nilotinib in combination with paclitaxel for early stage breast cancer, defined as the lowest intermittent dose of nilotinib that temporarily inhibits OATP1B1 function without affecting paclitaxel plasma pharmacokinetics (PK), and to determine the toxicity profile of nilotinib in combination with paclitaxel. OATP1B1 inhibition by nilotinib will be assessed via validated surrogate endogenous substrates, glycochenodeoxycholate sulfate (GCDGA-S) and chenodeoxycholate-24-glucuronide (CDCA-24G). Effective OATP1B1 inhibition will be $\geq$5-fold increase in AUC of GCDCA-S from pre- to post- treatment or detectable CDCA-24G levels post-treatment. The 4 nilotinib dose levels are 50 mg (dose level -1), 100 mg (dose level 1), 200 mg (dose level 2), 300 mg (dose level 3). IV paclitaxel dose of 80 mg/m^2 on D1,8,15 for 12 total weekly doses will be used. Oral nilotinib will be administered 24 hours before paclitaxel infusion on C1D7,D14 and again 30 minutes before infusion on C1D8,D15. Secondary objectives are to determine paclitaxel's effect on PK of nilotinib and vice versa. Quality of life via CIPN-20 survey, disease free survival, event free survival, overall survival are exploratory objectives. NCT04205903 enrollment opened February 2020 and is accepting patients. Clinical trial information: NCT04205903. Research Sponsor: U.S. National Institutes of Health.

TPS12129 Poster Session (Board #417), Fri, 8:00 AM-11:00 AM

Use of simulation for training family caregivers of patients receiving radiation therapy. *First Author: Susan R Mazanec, Case Western Reserve Univ, Cleveland, OH*

Background: Positive treatment outcomes and avoidance of complications are dependent to a large extent on the care provided by family members. However, family caregivers report feeling unprepared to assume the multiple, complex tasks of caregiving, including tracheostomy care, tube feedings, wound and colostomy care, pain management, and emotional support. Despite being a critical extension of the oncology healthcare team, training of caregivers to manage symptoms, deal with communication issues with the care recipients, and take care of their own physical and emotional health as caregivers, is not integrated into clinical practice. The purpose of this clinical trial is to measure the effect of a psychoeducational caregiver intervention that incorporates simulation techniques focused on skill development to improve caregiver and patient outcomes. Simulation, commonly used in training healthcare professionals, is a form of experiential learning that creates events or situations to mimic clinical situations. Use of simulation for skills training in family caregivers of patients with cancer is rarely studied. **Methods:** This two-group, randomized clinical trial, which opened to accrual in December 2019, will recruit 180 caregivers from University Hospitals Seidman Cancer Center. Patients must be receiving radiation therapy for a diagnosis of stage I - III cancers of the rectum, anus, and esophagus; stage III NSCLC; or stage I – IV A/B head/neck cancer. Adult caregivers must be identified by the patient as their primary caregiver, who is providing daily assistance and/or emotional support. The intervention involves three in-person, one-on-one sessions during radiation treatments. The control group is usual care. Data will be collected at baseline, at the end of radiation treatment, and 4 and 20 weeks post-radiation treatment. The primary outcome is caregiver anxiety at 20 weeks postradiation treatment. Other caregiver outcomes include depression, health-related quality of life [HRQOL], and fatigue. Patient outcomes (HRQOL and interrupted treatment course) and healthcare utilization outcomes (unplanned hospital admission, emergency room visits, and use of intravenous fluids) will be measured. The analysis will consist of linear mixed model repeated measures, mediation and moderation tests, and Poisson regression methods. Clinical trial information: NCT04055948. Research Sponsor: U.S. National Institutes of Health.

TPS12130 Poster Session (Board #418), Fri, 8:00 AM-11:00 AM

Effects of an e-home based symptom management and mindfulness training program on quality of life in breast cancer survivors. *First Author: Karis Kin-Fong Cheng, National University of Singapore, Singapre, Singapore*

Background: The first five years post-treatment for breast cancer are a critical phase, when the survivors may face a multitude of problems, including persistent and/or late-emerging symptoms following the cancer and its treatment, psychosocial distress associated with the risk of cancer recurrence, chronic uncertainty and social disruption. Thus, this trial will answer the research questions of 'Will the combined symptom management and mindfulness-based training programme be a promising approach to assist women with breast cancer in transition from treatment to survivorship?', and 'Since breast cancer survivors have infrequent clinical follow-up, will e-Home based system provide a feasible option for post-treatment care?' **Methods:** We aim to develop an e-Home based symptom management and mindfulness training programme for breast cancer survivors and to determine its effects on the endpoints including quality of life, symptom distress, psychosocial adjustment, psychological morbidity, and unplanned outpatient attendance or hospitalisation in breast cancer survivors. (ClinicalTrials.gov Identifier: NCT02931864) We employ a randomised clinical trial with four study arms (with 47 subjects, who have completed cancer treatment for stage 0 to 3 breast cancer between 6 months to 5 years previously, in each arm) together with a process evaluation; group 1 (usual care), group 2 (experimental group: five weekly sessions of online symptom management + mindfulness training programme and usual care), group 3 (comparison group 1: online symptom management programme and usual care), and group 4 (comparison group 2: online mindfulness training programme and usual care). Subjects will complete questionnaires measures of 6-item Social Support Questionnaire, Breast Cancer Survivor Self- Efficacy Scale, the Quality of Life-Cancer Survivor Scale, Memorial Symptom Assessment Scale, Psychosocial Adjustment to Illness Scale, short version of the Fear of Recurrence Scale, Hospital and anxiety Depression Scale, and Five Facet Mindfulness Questionnaire at baseline, at 8 weeks from time 1 (time 2), at 12 weeks from time 1 (time 3) and at 24 weeks from time 1 (time 4). Intention-to-treat approach will be used. Repeated measures analysis of variance will be used to examine the differences on outcome measures among the experimental, comparison, and control groups across study time points. Currently, 162 of 188 planned subjects have been enrolled and the trial continues as planned. Clinical trial information: NCT02931864. Research Sponsor: Singapore Cancer Society Research Fund.