RESEARCH POSTER PRESENTATIONS - SESSION IV

DISEASE- SPECIFIC STUDIES
CANCER – Clinical Outcomes Studies

PCN1
BONE SAFETY PROFILE OF DENOSUMAB THERAPY: A PHARMACOVIGILANCE CHARACTERIZATION ANALYSIS

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OBJECTIVES: Denosumab is a biologic approved in June 2010 to treat bone tumors and hypercalcemia of malignancy. This study characterizes bone-related safety signals of subtrochanteric atypical femoral fractures (SAF) and osteonecrosis of the jaw (ONJ) in relation to denosumab therapy. **METHODS:** The FDA Adverse Event Reporting System was used to detect signals of SAF and ONJ in relation to denosumab therapy. Adverse event reports submitted between July 2010 and December 2013 were retrieved and disproportional reporting of SAF and ONJ was calculated by Empirical Bayes Geometric Mean (EBGM). Denosumab-event pairs with EBGM 95% confidence interval lower limit ≥2.0 are considered signals of SAF and ONJ excess reporting compared to other drugs in the database. Events were defined by the Preferred Terms of the Medical Dictionary for Regulatory Activities, and denosumab was defined by the Anatomical Chemical Therapeutic Classification. **RESULTS:** A total of 26,216 adverse event reports submitted for denosumab during the analysis period, corresponding to 30 for SAF and 721 for ONJ. Denosumab was significantly associated with more than expected reporting of SAF (EBGM=17.5, 95%CI=9.67-30.0) and ONJ (EBGM=26.9, 95%CI=20.1-35.9) compared to other drugs. The majority of denosumab users who experienced both events were females, and average age was 69 years (SAF SD=9.5; ONJ SD=11.3). 12 SAF and 65 ONJ events lead to hospitalization; 25 and 14 ONJ events contributed to patient disability and death, respectively. Other factors could have lead to these serious outcomes, including comedications and comorbidities. **CONCLUSIONS:** SAF and ONJ are potential risks of denosumab therapy. Patients with thigh or hip pain should seek immediate medical help, and periodic dental and maxillofacial evaluations should be performed before and during denosumab therapy. Pharmacoepidemiologic studies are recommended to further characterize these risks, as some patients were treated with other medications, including systemic corticosteroids at the time of event occurrence.

PCN2
META-ANALYSIS OF THE SAFETY OF SIPULEUCEL-T IMMUNOTHERAPY IN PROSTATE CANCER

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OBJECTIVES: Sipuleucel-T is an autologous active cellular immunotherapy designed to reduce the risk of death in patients with prostate cancer. The aim of this study was to evaluate the safety of Sipuleucel-T for patients with prostate cancer. **METHODS:** PubMed, EMBASE and the Cochrane Central Register of Controlled Trials were searched through January 10, 2015. Criteria for inclusion were randomized, placebo-controlled clinical trials on Sipuleucel-T, patients receiving three infusions, 36 months follow-up and the availability of outcomes data for adverse events. The primary outcome was the total number of adverse events. Secondary outcomes examined eighteen specified adverse events. Two investigators selected studies independently and assessed the quality of studies using the Jadad scale. Point estimates with a 95% confidence interval were generated. Fixed-effects or random random-effects models were based on the evaluation of heterogeneity. **RESULTS:** Five clinical trials encompassing 1031 patients were included. The overall adverse events relative risk (RR) was 1.02 (95% CI 1.00 to 1.05, p=0.091). For the secondary outcomes, differences were detected between Sipuleucel-T and placebo on chills (RR 4.87; 95% CI 2.50 to 6.78, p=0.000; 904 patients), fatigue (RR 1.20; 95% CI 1.01 to 1.43, p=0.035; 1031 patients), pyrexia (RR 5.40; 95% CI 1.90 to 15.35, p=0.002; 1031 patients), headache (RR 2.68; 95% CI 1.75 to 4.10, p=0.000; 1031 patients), influenza like illness (RR 3.07; 95% CI 1.48 to 6.36, p=0.003; 681 patients), myalgia (RR 2.24; 95% CI 1.26 to 4.00, p=0.006; 681 patients), nausea (RR 1.40; 95% CI 1.05 to 1.88, p=0.023; 1031 patients), vomiting (RR 1.86; 95% CI 1.21 to 2.88, p=0.005; 856 patients) and dyspnea (RR 3.72; 95% CI 1.34 to 10.36, p=0.012; 350 patients). **CONCLUSIONS:** Sipuleucel-T significantly increased the risk of selected adverse events in patients with prostate cancer. Although many adverse events were transient, patients and providers should consider the potential risk of treatment with Sipuleucel-T.

PCN3
TREATMENT FOR CHEMOTHERAPY-RELATED COGNITIVE DYSFUNCTION: REVIEW OF THE LITERATURE

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OBJECTIVES: Chemotherapy-related cognitive dysfunction (CRCD), colloquially known as 'chemo fog' or 'chemo brain,' describes the impact of chemotherapy on cognitive functioning in domains ranging from memory to expressive language. CRCD is generally attributed to the direct or indirect effects of chemotherapy on the central nervous system, may occur at some level of intensity in as many as 75% of patients who have undergone chemotherapy, and impacts patient quality of life, educational/occupational achievement, and social functioning. Management of CRCD includes both pharmacological and non-pharmacological therapies. **METHODS:** To better understand the range of treatments that have been studied for CRCD, and their relative efficacy, a comprehensive review of the published literature was undertaken. A MEDLINE search was conducted for relevant sources published in English between January 2005 and December 2014. The search was limited to studies describing trials of interventions to manage or treat CRCD using non-pharmacological interventions. **RESULTS:** Of 161 records retrieved, 11 described interventions targeting CRCD. Pharmacological therapies used included erythropoietin, dexmethylphenidate, ginkgo biloba, and pycnogenol. Half of the studies focused on breast cancer. Most resulted in statistically non-significant findings, but two studies of erythpoietin and the pycnogenol trial had significant results. All 3 of the non-pharmacological studies focused on patients with breast cancer, two using a form of cognitive-behavior therapy (CBT) and the third studying a yoga program. **CONCLUSIONS:** The review found a large number of studies documenting the problem of CRCD, discussing innovative ways of measuring the extent of the cognitive impairment, and describing etiological theories, such as the relationship of CRCD to fatigue and anemia. However, there was a paucity of well-designed, sufficiently powered studies of potential treatments, given the extent of the problem and its impact on patient functioning. This is an area of clear patient need which warrants further scientific study.

PCN4
HYPOFRACTIONED RADIOTHERAPY IN THE TREATMENT OF EARLY BREAST CANCER: SYSTEMATIC REVIEW AND META-ANALYSIS

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OBJECTIVES: To evaluate short and long term effects of hypofractioned radiation therapy in women with early stage breast cancer, after undergoing breast conservative surgery. **METHODS:** We searched for randomized controlled trials in Embase, Medline, Cochrane Library and Lilacs comparing unconventional versus conventional fractioning. The authors performed data extraction independently. Disagreements were resolved by consensus. Random-effects risk ratios (RR) were calculated comparing patients randomized to unconventional with those to conventional fractioning. Periods before and after five years of treatment were considered. **RESULTS:** Five trials reported on 7.802 women. The studies were of medium to high quality. Unconventional fractionation did not affect, until five years and after five years, respectively: (1) local recurrence RR 0.90 (95% CI 0.68 to 1.18, P = 0.44) and RR 0.98 (95% CI 0.83 to 1.17, P = 0.86); (2) distant recurrence (RR) 1.04 (95% CI 0.73 to 1.46, P = 0.84) and RR 1.02 (95% CI 0.79 to 1.32, P = 0.88); (3) mortality RR 0.89 (95% CI 0.77 to 1.05, P = 0.16) and RR 0.96 (95% CI 0.89 to 1.08, P = 0.48); (4) disease-free survival RR 0.96 (95% CI 0.78 to 1.18, P = 0.69) and RR 0.96 (95% CI 0.84 to 1.09, P = 0.49); (5) cardiac ischemia RR 0.73 (95% CI 0.34 to 1.57, P = 0.42) and RR 0.61 (95% CI 0.33 to 1.15, P = 0.13); (6) rib fracture RR 1.02 (95% CI 0.25 to 4.20, P = 0.98) and RR 1.08 (95% CI 0.26 to 4.53, P = 0.91); (7) pulmonary fibrosis RR 2.42 (95% CI 0.50 to 11.71, P = 0.27) and RR 0.97 (95% CI 0.89 to 11.21, P = 0.07). **CONCLUSIONS:** Using hypofractioned radiotherapy regimens does not affect any of the outcomes analyzed in women with early stage breast cancer, after undergoing breast conservative surgery.

PCN5
RISK OF CARDIOTOXICITY AND ALL-CAUSE MORTALITY IN BREAST CANCER PATIENTS AFTER ADJUVANT CHEMOTHERAPY OR HORMONAL THERAPY

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OBJECTIVES: The purpose of this study was to estimate incidence of and identify factors associated with cardiotoxicity, defined as heart failure and/or cardiomyopathy, and all-cause mortality in breast cancer patients undergoing adjuvant chemotherapy or hormones. **METHODS:** A retrospective, population-based cohort study of 108,672 women (≥66 years of age) newly diagnosed with breast cancer from 2001-2009 was conducted using the Surveillance, Epidemiology, and End Results (SEER)-Medicare-linked database. Adjuvant chemotherapy were classified as mutually exclusive groups: trastuzumab-based, anthracycline-based, anthracycline and trastuzumab-based, taxane-based, and other chemotherapy. Propensity score matching adjusted for differences in patient characteristics across treatments. The final sample included a total of 11,250 women. Multivariable Cox proportional hazards regression models estimated hazard ratios (HRs) of cardiotoxicity and all-cause mortality with adjustment for inverse probability weights, sociodemographics, cancer characteristics, comorbidities, surgery and radiation, region, and year at diagnosis. **RESULTS:** Compared with hormones, risk of cardiotoxicity was higher in patients treated with anthracycline and trastuzumab-based (adjusted HR=1.87; 95% confidence intervals [CI]=1.51-2.33), trastuzumab-based (HR=1.32; 95%CI=1.14-1.52), and anthracycline-based (HR=1.14; 95%CI=1.03-1.27) regimens, respectively. Certain baseline characteristics were significant predictors of cardiotoxicity, including demographics (older age (vs. ≤70), non-Hispanic black), cancer characteristics (advanced stage), comorbidities (cardiovascular conditions or renal failure), year at diagnosis, and West region (vs. Northeast). Additionally, risk of all-cause mortality was higher in patients treated with taxane-based (HR=1.54; 95%CI=1.43-1.67) regimens compared to hormones. Baseline characteristics including sociodemographics, cancer characteristics, cardiovascular or renal failure comorbid conditions, year at diagnosis, and South region were significant predictors of all-cause mortality (all P<0.05). **CONCLUSIONS:** Women with breast cancer treated with trastuzumab-based and/or anthracycline-based regimens had increased cardiotoxicity risk compared with hormones, while those treated with taxane-based regimens had higher rates of all-cause mortality. Types of chemotherapy are associated with increased risk of cardiotoxicity and all-cause mortality. Practitioners should further evaluate treatment and patient characteristics for risk mitigation strategies.

PCN6
RACIAL/ETHNICITY DISPARITIES IN THE ASSOCIATION BETWEEN DIABETES AND PANCREATIC CANCER IN THE ELDERLY MEDICARE POPULATION

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OBJECTIVES: Although the relationship between diabetes and risk of pancreatic cancer are well-documented, limited research has examined whether racial/ethnicity differences accounted for the association between diabetes and pancreatic cancer. The aims of this study were to 1) assess whether diabetes is associated with pancreatic cancer in the elderly Medicare population, and 2) identify if any racial/

ethnicity disparities exist in the association between diabetes and pancreatic cancer. **METHODS:** In a retrospective cross-sectional study, community-dwelling and institutionalized Medicare beneficiaries aged 65 or over without health maintenance organization enrollment from the Medicare Current Beneficiary Survey (MCBS) from 2001 to 2010 were included. The outcome of the study was pancreatic cancer; and the key explanatory variables were diabetes and race/ethnicity. Potential confounders considered included age, gender, education, marital status, income, residence area, body mass index (BMI), smoking status, Charlson comorbidity index (CCI), and use of preventive services. The International Classification of Diseases-9 codes were used to identify the outcome and explanatory variables from the Medicare Part A and B claims. Logistic regressions were performed to estimate the association between diabetes and pancreatic cancer. **RESULTS:** A total of 98,966 person-years of elderly Medicare beneficiaries were included in the analysis. After controlling for potential confounders, the association between diabetes and pancreatic cancer was statistically significant (odds ratio [OR], 3.15; 95% confidence interval [CI], 2.07-4.77). Compared to non-Hispanic whites, non-Hispanic blacks (OR, 0.43; 95% CI, 0.15-1.20) and Hispanics (OR, 0.78; 95% CI, 0.33-1.85) had similar risks of pancreatic cancer. **CONCLUSIONS:** This study found that diabetes is associated with pancreatic cancer in the elderly Medicare population. However, racial/ethnicity differences do not explain the association between diabetes and pancreatic cancer.

PCN7

COMORBIDITY AND POSTOPERATIVE OUTCOMES AMONG LUNG CANCER PATIENTS IN THE UNITED STATES

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OBJECTIVES: The burden of comorbid illness is known to be higher among lung cancer patients and it's also shown to impact survival outcomes. However, the influence of comorbidity on in-hospital surgical outcomes among lung cancer patients remains unknown. Therefore, this study examined the effect of comorbidity on risk of post-operative complications, prolonged hospitalization, and in-patient death among lung cancer patients following surgery. **METHODS:** A retrospective analysis of hospital discharge data from the 2011 Health Care Utilization Project - Nationwide Inpatient Sample (HCUP-NIS) database was performed. Discharges of patients who underwent surgery for lung cancer during 2011 were identified. Information about patients and hospitals characteristics were obtained. Comorbidities were identified and used to calculate Charlson comorbidity index score. Patients were then divided based on these scores into four groups: 0, 1, 2, and ≥3. Multivariate logistic regression analyses was used to examine risk adjusted association between comorbidity score and the study outcomes. **RESULTS:** We identified 19,564 patients' discharges that meet our inclusion criteria. Compared to patients with no comorbid conditions, patients with one or more comorbid conditions saw a two-fold increase in the risk of post-operative complications ($p<0.001$). The risk of prolonged hospitalization was also higher among patients with a comorbidity score of 1, 2, or ≥3, compared to patients with a comorbidity score of zero ($p<0.001$). Higher comorbidity burden also increased the risk of in-patient death by three folds ($p<0.001$). **CONCLUSIONS:** In-hospital outcomes among lung cancer patients following surgery are negatively impacted by presence of comorbid illness. Post-operative morbidity and mortality among these patients may be reduced if their comorbid conditions are managed effectively.

PCN8

INCREASED PREVALENCE OF LIPID DISORDERS IN CANCER PATIENTS ADMITTED TO U.S. HOSPITALS

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OBJECTIVES: Some new cancer therapies are associated with prolonged patient survival; therefore, management of chronic comorbidities in cancer patients has become more important. We sought to measure the prevalence of lipid disorders, and other chronic comorbidities, among cancer patients admitted to U.S. hospitals over a 14-year period. **METHODS:** We utilized data from the U.S. National Hospital Discharge Surveys from 1996 to 2009. We limited the study to patients ≥18 years of age with a primary discharge diagnosis of lung, breast, prostate, or colorectal cancer (ICD-9-CM codes 162, 174, 185, and 153, respectively). Data weights were used to derive national estimates. The prevalence of diabetes (250), ischemic heart disease (410-414), heart failure (428), cerebrovascular disease (430-438), and lipid disorders (272) was calculated for each year and cancer type. **RESULTS:** Roughly 6 million visits were represented over the 14-year study period (lung 2.1, breast 1.3, prostate 1.3, and colorectal cancer 1.6 million). One-third of patients admitted with cancer had at least one comorbidity, and 8% had at least two comorbidities over the entire 14-year study interval; however, the rates of comorbidity changed drastically over time—particularly for lipid disorders. Of the patients admitted with lung cancer in 1996, only 2% had lipid disorders, compared to 13% in 2009. Similar patterns were observed for those patients admitted with breast cancer (2% to 17%), prostate cancer (3% to 30%), and colorectal cancer (2% to 12%). Prevalence of diabetes and ischemic heart disease also increased, but to a lesser extent. **CONCLUSIONS:** Management of lipid disorders in patients with cancer has become increasingly important. U.S. studies focused on improving cancer mortality, as well as the rising costs of care, should increasingly take chronic conditions—particularly lipid disorders—into account.

PCN9

PRE-EXISTING TYPE 2 DIABETES MELLITUS AND EMERGENCY COLORECTAL SURGERY AMONG ELDERLY MEDICARE BENEFICIARIES WITH COLORECTAL CANCER

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OBJECTIVES: To examine the association between pre-existing Type 2 Diabetes Mellitus (T2DM) and risk of emergency colorectal surgery among elderly patients with colorectal cancer (CRC) after controlling for other risk factors. **METHODS:** We identified a cohort of 37,044 elderly Medicare beneficiaries with incident CRC between 2003 and 2009 who had colorectal surgery using the SEER-linked Medicare database. T2DM was identified using the ICD-9-CM (International Classification of Diseases, 9th Revision, and Clinical Modification) codes during the 12-months prior to incident diagnosis of CRC. CRC surgery was identified with procedure codes for colon resection, rectal resection, and other operations on the intestine including colostomy and ileostomy. If individuals with CRC had ICD-9-CM codes indicative of bowel perforation, peritonitis, or obstruction, they were considered to have emergency surgery. Chi-square tests and logistic regression were used to analyze the association between pre-existing T2DMand emergency surgery after adjustments for sex, race/ethnicity, age, cancer site, stage, region, and office visits in the 12 months prior to incident cancer. **RESULTS:** Unadjusted rates of emergency surgery were significantly lower among CRC patients with pre-existing T2DM compared to CRC patients without diabetes (9.8% vs.11.4%). This association, however, was not significant in adjusted analyses. CRC patients with highest number of annual office visits were significantly less likely than CRC patients with lowest number of annual office visits to receive emergency surgery (AOR=0.69; 95%CI=0.61, 0.78). Other risk factors for emergency surgery in CRC patients were old age (80-84 years: AOR=1.15, 95%CI=1.03, 1.29; 85 years and above: AOR=1.41, 95%CI=1.26, 1.58), and late stage at diagnosis (regional stage: AOR=2.14, 95%CI=1.99, 2.31; distant stage: AOR=2.78, 95%CI=2.54, 3.05). CRC patients with atherosclerosis were less likely to have emergency surgery compared to those without atherosclerosis (AOR=0.89; 95%CI=0.82, 0.97). **CONCLUSIONS:** Pre-existing T2DM was not associated with emergency surgery after controlling for a comprehensive list of risk factors.

PCN10

PATTERNS OF CARE IN THE WORKUP AND MANAGEMENT OF NON-METASTATIC AND METASTATIC COLORECTAL CANCER

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OBJECTIVES: NCCN guidelines recommend that non-metastatic colorectal cancer (CRC) patients receive a comprehensive work-up including detailed imaging studies. The purpose of this study was to evaluate physician concordance to NCCN guidelines in terms of the receipt of tests and procedures during the 6-month period prior to a patient's CRC diagnosis. **METHODS:** A large integrated claims database spanning January 2008 to September 2013 was used to identify patients ≥50 years old diagnosed and treated for CRC. Patients were required to be continuously enrolled for ≥6 months pre- (baseline period) and ≥3 months post-diagnosis. Eligible patients were stratified into cohorts based on the occurrence and timing of metastatic (M) disease: no metastases (NM), ≤90 days (M1), and ≥90 days (M2) from initial diagnosis. Tests evaluated included disease-appropriate CT or MRI, ultrasound, blood and fecal screenings, baseline biopsy, CEA, endoscopy, PET-CT, proctoscopy, sigmoidoscopy, and colonoscopy. **RESULTS:** There were 15,182 patients meeting study criteria, with 77.8% being NM, 11.2% M1, and 11.0% M2. Over 75% of patients had a health physical in the baseline period but only 43.3% received fecal or blood-based screenings. The most common invasive procedure was colonoscopy, occurring in 9.6% of M1, 13.7% of M2, and 11.7% of NM patients. Less than 20% of NM patients (17.8%) received a chest, abdominal, or pelvic CT or MRI compared to 20.7% of M1 and 33.8% of M2 patients. Twice as many M2 patients (30.9%) received a CEA test compared to 15.1% of M1 and 24.6% of NM patients. Biopsy, ultrasound (including endorectal), proctoscopy, and sigmoidoscopy were documented in less than 5% of all patients. **CONCLUSIONS:** In this population of CRC patients, concordance to NCCN guidelines was low, with NM patients receiving a lesser degree of complete work-up per guidelines compared with M patients.

PCN11

THE BURDEN OF AML WITHIN THE

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OBJECTIVES: While cancer registries such as SEER currently serve as the largest source of cancer epidemiology, recent research (Cogle, et al., 2012) has suggested that these registries may be underreporting AML due to methodological limitations. Using a claims-based algorithm, we estimated the incidence of acute myeloid leukemia (AML) in the <65 year-old US population. **METHODS:** A retrospective analysis of claims was performed using 2010-2012 IMS Health LifeLink PharMetrics Plus (LifeLink), a longitudinal medical claims dataset comprised of adjudicated claims of >150 million unique enrollees. LifeLink is representative of the US commercially-insured population aged ≤65. AML diagnoses were identified using ICD-9 codes and AML treatments were identified using CPT/HCPCS codes and ICD-9-CM infusion codes. Patients with ≥2 claims including AML diagnoses codes OR one AML medical claim and one AML treatment in 2012 were defined as prevalent AML patients. A sub-population of all prevalent AML patients without historical AML diagnoses or treatments during the prior two years were identified as new (incident) AML patients. Results were stratified by gender and age (<18, 18-39, 40-49, 50-59, 60-64 years). **RESULTS:** The overall 2012 incidence of the <65 population was 5.4 per 100,000 (95% CI: 5.2, 5.6), with incidence incrementally increasing with age (i.e., lowest in the <18 cohort [3.2 per 100,000] and highest in the 60-64 cohort [12.3 per 100,000]). Incidence among males was slightly higher than among females, 5.7 (95% CI: 5.3, 6.0) and 5.2 (95% CI: 4.9, 5.5) per 100,000, respectively. Males 60-64 had the highest incidence rate, 13.5 per 100,000 (95% CI: 11.7, 15.2). **CONCLUSIONS:** Our 2012 AML incidence estimates are substantially higher than published SEER estimates for the <65 population: 5.4 per 100,000 vs. SEER's 1.8 per 100,000, respectively. Thus, the current AML burden of disease may be underestimated, further justifying the need for earlier detection and more efficacious treatment options.