TASTE DYSFUNCTION AFTER HEAD AND NECK CANCER TREATMENT: A META-ANALYSIS
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OBJECTIVES: Taste dysfunction is a common, debilitating problem for head and neck cancer treatment survivors (HCNTS). When taste is impaired eating is not as enjoyable, appetite is diminished and overall health related quality of life (HRQoL) is diminished. However, the extent to which impairment in HCNTS remains altered over time is not well understood.
METHODS: The Ovid MEDLINE®, SCOPUS, and CINAHL data bases were searched for reports of HCNTS in which taste function was measured. Eligible studies reported taste scores baseline to five years post treatment. WF8 reports were identified in the search and 20 studies were suitable for inclusion in the final analysis. Estimates of effect size of head and neck cancer therapy on taste dysfunction were extracted from each study. A descriptive meta-analysis was conducted to determine the overall mean effect size. PCN118
RESULTS: The meta-analysis included data on 1526 subjects. The sample was predominantly young in age (mean age is 59.11 years) and 66.8% male. Head and neck cancer treatment survivors reported statistically significantly worse taste scores 6 months or longer after completing all cancer treatment. The summary effect for the standard measure difference between pretreatment and post-treatment taste scores was 0.331 (p<0.001). The sample was highly heterogeneous in terms of country, tumor site, and therapy, so a random effects model was chosen for data analysis. Heterogeneity testing supported this decision (Q=82.08, df=18, p<0.001). CONCLUSIONS: Assessment of HRQoL in HCNTS should include questions on taste function. With the global increase in HPV related head and neck cancers, the pool of treatment survivors is expected to increase over the next decade. The Taste dysfunction is a long-term complication for HCNTS and clinicians should screen survivors for this sensory dysfunction.
THE EMERGING ROLE OF PATIENT-REPORTED OUTCOMES (PROs) IN FDA HEMATOLOGY AND ONCOLOGY PRODUCT LABELS
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OBJECTIVES: The US Food and Drug Administration (FDA) did not approve any PRO labels for cancer treatments between 2006 and 2010. In December 2009, the agency published guidance on the use of PROs to support label claims, and in 2012 the Center for Medical Technology Policy (CMTP) called for all prospective observational studies of oncology drugs in adults to include PRO measures. The current study sought to identify how many PRO claims have been approved as part of the FDA’s Drug Development Tool (DDT) Qualification Program.
METHODS: A search of Citeline’s Trialtrove was conducted using the search criteria of “Ovarian Cancer” as the disease, drugs tested was “any,” and if the disease type was other than ovarian cancer. Study designs were clinical trial and observational studies. This resulted in 182 trials. Study design included clinical trials (double-blind, open-label) and observational studies. Start dates ranged from 1985-2014. Trials were included if the disease SQA was ovarian cancer specific measures, 27 (40%) were specific to Bladder Cancer, 1 (3%) was generic (e.g., SF-36), and the remaining 15 (21%) were not specified. Among the symptom measures, 3 (60%) were specific to bladder cancer and 2 (40%) were generic.
RESULTS: Of the 189 studies reviewed, 102 (54%) included PROs. For these 102 trials, a total of 148 PROs were included, and an average of 1.5 PROs were used per study. Fourty (40%) of the 102 trials included 2 PROs, 26 (26%) included 3 or more PROs. One hundred twenty-six (85%) of these PROs measured Health-Related Quality of Life (HRQL) and 5 (13%) were symptom-based measures. Within the HRQL measures, 9 (26.5%) were cancer general, 9 (26.5%) were specific to Ovarian Cancer, 1 (3%) was generic (e.g., FACT-Ne), and the remaining 15 (44%) were not specified. Among the symptom measures, 3 (60%) were specific to bladder cancer and 2 (40%) were generic. Conclusions: Indicate that the presence of PROs in bladder cancer trials is low compared to other disease areas. The majority of measures assess HRQL and are specific to ovarian cancer and other diseases despite their importance in evaluating impact of disease and treatment benefit. The type of PRO most commonly indicated was a bladder cancer disease-specific measure of HRQL. Findings show the need to highlight the value and relevance of PRO data to increase incorporation of PROs in bladder cancer trials.
PCN121
PATIENT-REPORTED OUTCOMES (PROs) IN BLADDER CANCER TRIALS
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OBJECTIVES: To assess frequency and type of Patient-Reported Outcomes (PROs) in studies of Ovarian Cancer. METHODS: A search of Citeline’s Trialtrove was conducted using the search criteria of “Ovarian Cancer” as the disease, drugs tested was “any,” and if the disease type was other than ovarian cancer. Study designs were clinical trial and observational studies, and both double-blind and open-label studies were included. Target accrual for all studies was ≥53. Start dates ranged from 1990 to 2014. The remaining 189 trials were then assessed for prevalence and type of PROs. RESULTS: Of the 189 studies reviewed, 102 (54%) included PROs. For these 102 trials, a total of 148 PROs were included, and an average of 1.5 PROs were used per study. Fourty (40%) of the 102 trials included 2 PROs, 26 (26%) included 3 or more PROs. One hundred twenty-six (85%) of these PROs measured Health-Related Quality of Life (HRQL), 10 (7%) measured QoL/Utilities, 9 (6%) measured Symptoms, 2 (1%) measured activities of Daily Living and 1 (1%) was categorized as other. Thirty-three (33%) were symptom measures, 15 (15%) were HRQL measures, 9 (9%) were generic measures and 1 (1%) was chemotherapy treatment specific. The remaining 55 (43%) HRQL endpoints were unspecified. The majority of PROs were specific to Ovarian Cancer (55 (43%) were not specified. Among the symptom measures, 3 (60%) were specific to bladder cancer and 2 (40%) were generic.
CONCLUSIONS: Indicates that the presence of PROs in Ovarian Cancer trials is low compared to other disease areas. The majority of measures assess HRQL and are specific to ovarian cancer. Including HRQL in ovarian cancer studies can support the value of progression free survival to patients. PROs can be used to show the value of new ovarian cancer drug therapies.
PCN123
DOES THE GENERIC CANCER OUTCOME MEASURE EORTC QLQ-C30 WORK IN MYELOBLASTOSIS?
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OBJECTIVES: The EORTC QLQ-C30 is a validated patient reported outcome measure for cancer patients but there is limited evidence on its validity in Myeloblastosis (MF), a rare but serious bone-marrow cancer. This study aimed to provide evidence of its validity in MF. METHODS: QLQ-C30 was compared to MF specific measures (MF-SAF 2.0 and FACT-myel) using trial data of MF patients (CDMF 1 = 59, CDMF 2 = 44). Two meta-analyses were conducted to support concept elicitation and content validity. RESULTS: QLQ-C30 dimensions (physical, role, emotional and social functioning, pain and fatigue) were strongly correlated (r >0.5) with equivalent items/dimensions in the MF-SAF and FACT-Myel but all QLQ-C30 dimensions were weakly correlated (r<0.3) to MF symptoms such as weight loss, itching and night sweats. RESULTS: QLQ-C30 dimensions were able to discriminate between MF-SAF (scores 0-10, 11-20, 21-30, 31-60) with better discrimination for the mild severity low score groups (0.2<ES<0.7) compared to high score groups (ES>0.2) who had higher severity and the FACT-myel (scores 0-30, 31-45, 46-51, 52-60) groups. ESs were <0.2 for most QLQ-C30 dimensions including pain but >0.2 for MF-SAF and
FACT Lym MF symptoms. A large proportion (n>50%) reported no problems (ceiling effect) in FACT-Lym MF dimensions (nausea/vomiting, constipation/ diarrhea). There was some evidence of ceiling effects in MF symptoms in COMFORT II due to missing data which affects the analysis. CONCLUSIONS: QLQ-C30 reflected functional and fatigue effects of MF but was less associated with MF specific symptoms such as itch and night sweats which are important MF symptoms. The QLQ-C30 MF symptom dimension showed less responsiveness than the MF specific dimensions. QLQ-C30 dimensions related to constipation and diarrhea were less relevant in this population than has been found in other cancer populations.

PCN124
DERIVATION OF A PREFERENCE-BASED MEASURE FOR METASTATIC BREAST CANCER PATIENTS USING THE EORTC QLQ-C30 AND QLQ-SSR 23
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OBJECTIVES: Psychometric analyses to derive a health state classification system in multiple myeloma using the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30) were used to estimate utility values. MFSAF has been shown to be valid and responsive and varying HRQoL impacts. In order to understand the true burden of illness (BOI) in these patients and how it is impacted by treatment, it is critical to understand how patient-centered outcomes are measured and interpreted. METHODS: This literature review identified 13 studies that reported MFSAF treatment impact on HRQoL among patients with advanced cancer. A total of 25 studies were identified that met prespecified criteria and included 14 unique HRQoL instruments. Important HRQoL issues for mCRC patients included pain, nausea/vomiting, and insomnia. The studies were EORTC QLQ-C30, FACT-P, and the BPI/ McGill pain questionnaires. Most of these instruments were not specifically developed for mCRC patients and may not comprehensively capture symptoms important to cancer population. Fundamentally, the instrument definitions of clinically meaningful differences. Since 2010, using a variety of instruments in pivotal studies, 3 treatments (mitoxantrone, estramustine phosphate and docetaxel, and cabazitaxel) has nonstatistically significant impacts on HRQoL or pain, but CAB has shown both improvements in health status and pain. CONCLUSIONS: HRQoL is an important complement to survival and other clinical endpoints to best understand treatment benefit in mCRC. To give context to the relative impact of treatments on HRQoL, it is critical to understand the underlying BOI in this patient population and to standardize methods for measuring and quantifying the assessment of HRQoL in mCRC.

PCN127
EXPLORATORY PSYCHOMETRIC ANALYSIS OF THE EQ-5D IN A MYEOLOBIROSIS POPULATION
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OBJECTIVES: There is no evidence about the appropriateness of the EQ-5D (a generic preference-based measure of health) in Myelobrosis (MF), a rare but serious bone-marrow cancer. This study aimed to provide psychometric evidence of its appropriateness. METHODS: Convergent validity and responsiveness of the EQ-5D was assessed in three pivotal studies that evaluated the HR of QoL. Assessment Form (MSAF) in 48 patients with MF with repeated measurement over 48 weeks using data from the ROBUST study. Convergent validity was based on the regression between EQ-5D utility scores and dimensions (mobility, usual activities, self-care, pain/discomfort and anxiety/depression) and MSAF total score and symptoms (pain, early satiety, night sweats, itching and bone or muscle pain). Responsiveness was based on change in EQ-5D compared to change in MSAF using standardized response mean (SRM) and Cohen’s effect size (ES). Moderate to strong correlations (rho>0.3) and comparable SRM and ES would indicate that EQ-5D was appropriate. RESULTS: EQ-5D had poor associations with key symptoms in MF (rho<0.3), except for the ‘pain/discomfort’ and ‘anxiety/depression’ health dimensions (rho>0.4). SRM and ES at week 4 for EQ-5D was 0.270 and 0.343 compared to SRM and ES of 0.911 and 0.826 for the MSAF. A large proportion (15.56%) reported no problems in EQ-5D dimensions at baseline. The MSAF total score did not show consistent treatment effect for most cancer types. Moderate to strong correlation (rho>0.3) and comparable SRM and ES would indicate that EQ-5D was appropriate. CONCLUSIONS: This exploratory analysis suggests that the EQ-5D’s ability to capture the effect of key symptoms in MF is limited to pain rather than the specific MF symptoms such as night sweats and itchiness. However, results of this analysis need to be interpreted with caution due to the small number of patients.

PCN128
QUALITY OF LIFE DOMAINS ASSOCIATED WITH READMISSIONS AMONG PATIENTS WITH HEMATOLOGICAL CANCER
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OBJECTIVES: The aim of this study was to evaluate the associations between quality of life (QoL) domains and frequency of readmission to hospitals for different patients. A secondary aim was to observe if the increased number of outpatient clinic admissions resulted in an increased number of hospitalizations. METHODS: We evaluated QOL (EORTC Qol Questionnaire-C30) and hospital admissions in 255 patients with lung, breast, hematological, head and neck, colorectal, gastric, gynecological, and prostate cancers. The outpatient clinic admission and hospitalization data for each patient within 1 year of QoL assessment was obtained from the hospital finance database. Statistical analyses used nonparametric correlation coefficients to flag associations (r>0.3 and p<0.05) between overall, functional or symptom scales and number of hospitalizations or outpatient clinic admissions. RESULTS: QoL total domain scores were correlated with readmissions within 3 months for prostate cancer (rho=0.34, p<0.001) and colorectal cancer (rho=0.37, p<0.001) after adjusting for Charlson co-morbidities. Emotional functioning (rho=-0.42, p<0.001) and global health status (rho=-0.51, p=0.001) for gastric cancers. For readmissions within 1 year they were nausea/vomiting symptom scales (rho=0.44, p<0.001) for colorectal cancer and global health status (rho=-0.46, p<0.001) for gastric cancer and usual activities scale (rho=-0.39, p=0.001) for prostate cancer. Emotional functioning scale (rho=-0.32, p=0.024) for breast cancers were associated with hospitalizations within 3 months. Diarrhea symptom scale (rho=0.35, p=0.013) for colorectal cancers scales were more likely less scale (rho=0.52, p=0.016) for prostate cancer. Conclusions: Emotional functioning and global health status are associated with hospitalizations within 1 year. In general, number of hospitalizations and admissions were not significantly correlated except for the head and neck cancers (r=0.32, p=0.022, within 1 year). CONCLUSIONS: Several quality of life domains might be associated with hospital admissions and hospitalizations. Although they may not always reflect causal relations, these QLQ-C30 evaluations may be used to flag possible increases in contact with health care system and to timely notify the patient or their relatives of this possibility. Increased number of clinic visits does not necessarily result in increased hospitalizations for most cancer types.