

FACT Lym MF symptoms. A large proportion (>50%) reported no problems (ceiling effects) in QLQ-C30 dimensions (nausea/vomiting, constipation/diarrhoea). 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 itching and night sweats which are important MF symptoms. The QLQ-C30 pain dimension showed less responsiveness than the MF specific pain dimensions. QLQ-C30 dimensions related to constipation and diarrhoea 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 USING THE EORTC QLQ-30 AND QLQ-BR 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-30) were used to estimate a preference-based measure for health state utility derivation (Rowen et al. 2011). This study sought to apply a modified Rowen framework to identify EORTC QLQ-30 and the breast module (QLQ-BR23) items amenable to valuation to estimate a preference-based measure in metastatic breast cancer (MBC). **METHODS:** Exploratory factor analysis, Rasch analysis and other psychometric analyses were undertaken on the 53 item EORTC tools using baseline Phase 3 clinical trial data on 1063 patients with MBC to identify items amenable to valuation. Criteria for item identification were: factor loading > 0.4; < 50% of respondents at ceiling/floor; mean square fit statistics between 0.5 and 1.5; and ordered category response. **RESULTS:** Nine dimensions were identified on the EORTC dataset via exploratory factor analysis. Potential items, stratified by dimension, deemed useful for valuation include: physical (QLQ-30 items 1, 2, 6, 7, 27 and QLQ-BR23 item 6), cognitive/emotional (QLQ-30 items 21, 22, 23 and 24), self-image (QLQ-BR23 items 9, 10, 11 and 12), breast symptoms (QLQ-BR23 item 20), fatigue/sleep disturbance (QLQ-30 items 10, 12 and 18), arm pain (QLQ-BR23 item 17), and general pain (QLQ-30 item 9). Items related to gastrointestinal and sexual symptoms were not considered due to the measurement criteria. **CONCLUSIONS:** Twenty of 53 items suitable for valuation were identified over seven dimensions of the EORTC QLQ-30 and QLQ-BR 23. Items that did not meet the specified criteria for inclusion may be utilized for health state derivation if they represent clinically significant components of MBC. Results of the created health state classification system for valuation and derivation of a preference-based measure for metastatic breast cancer will be presented.

PCN125

IMPACT OF ENZALUTAMIDE OR ABIRATERONE ACETATE + PREDNISONE (AbP) ON QUALITY OF LIFE (QoL) IN THE TREATMENT OF METASTATIC CASTRATION-RESISTANT PROSTATE CANCER (mCRPC) THAT HAS PROGRESSED ON OR AFTER DOXETAXEL: A COMPARATIVE EFFECTIVENESS STUDY

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OBJECTIVES: Two effective therapies, enzalutamide and AbP, emerged simultaneously for treating patients with mCRPC that has progressed on or after docetaxel (post-chemotherapy setting) and yet are not compared head-to-head. This study aims to assess the comparative effectiveness of these treatments on QoL. **METHODS:** A systematic literature review of MEDLINE, Embase, Cochrane, and controlled trials registries was conducted to identify all evidence on the treatment effect of enzalutamide and AbP on patients' QoL in the post-chemotherapy setting. Since there are no trials directly comparing these treatments, an adjusted indirect comparison (Bucher et al. 1997) was performed on improvement and time to deterioration in FACT-P total score and subdomains. Results are expressed as odds ratio or hazard ratio with corresponding 95% confidence intervals (CIs). **RESULTS:** Two randomized, placebo-controlled, Phase III studies (AFFIRM and COU-AA-301) were identified and included in the analysis. The studies had similar study populations and designs but used different comparators (placebo in AFFIRM; prednisone in COU-AA-301) which were assumed to be similar. The same pre-specified criteria for clinically meaningful improvement and deterioration in FACT-P outcomes were used in both studies (Cella et al. 2009). Compared with AbP, enzalutamide significantly increased the likelihood of QoL improvement on the FACT-P total score (odds ratio [95% CI]: 1.94 [1.15; 3.27]), functional wellbeing (1.85 [1.09; 3.14]), and prostate cancer subscales (PCS) (1.79 [1.10; 2.90]). Enzalutamide significantly decreased the risk of QoL deterioration in FACT-P total score (hazard ratio [95% CI]: 0.72 [0.54; 0.95]) and PCS (0.75 [0.58; 0.98]) vs. AbP. **CONCLUSIONS:** The impact of enzalutamide on QoL in the post-chemotherapy setting compares favorably with AbP, with significantly higher odds of QoL improvement and significant delay in QoL deterioration, subject to study assumptions. The adjusted indirect comparison method can shed light on relative benefits of effective therapies that have not been formally compared.

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HEALTH-RELATED QUALITY OF LIFE IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: A CRITICAL LITERATURE REVIEW

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OBJECTIVES: Survival is the predominant measure of metastatic castration-resistant prostate cancer (mCRPC) treatment benefit, but it does not account for the

impact on how patients feel or function, which summarizes health-related quality of life (HRQoL). Contemporary mCRPC therapies have shown survival improvements 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 MEDLINE publications reporting on HRQoL (including pain) in ≥50 mCRPC patients using predefined search terms: prostate, prostate cancer, castrate- or hormone-resistant, hormone refractory, androgen-independent, androgen independence and quality of life, HRQoL, pain, bone or cancer-related pain, fatigue, and weight loss. **RESULTS:** Forty-four mCRPC studies were identified that met prespecified criteria and included 14 unique HRQoL instruments. Important HRQoL issues for mCRPC patients included pain, nausea/vomiting, and insomnia. The most commonly used measures were EORTC QLQ-C30, FACT-P, and the BPI/McGill pain questionnaires. Most of these instruments were not specifically developed for mCRPC patients and may not comprehensively capture symptoms important to this population. Further, identified studies did not use consistent definitions of clinically meaningful differences. Since 2010, using a variety of instruments in pivotal studies, 3 treatments (mitoxantrone, estramustine phosphate and docetaxel, and cabazitaxel) had no statistically significant impacts on HRQoL or pain, whereas 4 other treatments (abiraterone, enzalutamide, radium-223, and sipuleucel-T) reported statistically significant benefits for HRQoL or pain. **CONCLUSIONS:** HRQoL is an important complement to survival and other clinical endpoints to best understand treatment benefit in mCRPC. 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 mCRPC.

PCN127

EXPLORATORY PSYCHOMETRIC ANALYSIS OF THE EQ-5D IN A MYELOFIBROSIS 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 Myelofibrosis (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 by comparing it to a condition-specific measure, the MF Symptom Assessment Form (MFSAF) in 48 patients with MF with repeated measurement over 48 weeks using data from the ROBUST study. Convergent validity was based on correlation analysis between EQ-5D utility scores and dimensions (mobility, usual activities, self-care, pain/discomfort and anxiety/depression) and MFSAF 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 MFSAF 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 MF-SAF. A large proportion (15.56%) reported no problems in EQ-5D dimensions at baseline. The MFSAF total score did not show comparable ceiling effect (4.76%). There was however some indication of ceiling effect for some of the individual dimension of the MFSAF indicating that patients in this sample did not all have the common MF symptom. **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 READMISSION

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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 cancer patients. A secondary aim was to observe if the increased number of outpatient clinic admissions resulted an increased number of hospitalizations. **METHODS:** We evaluated QoL (EORTC QoL Questionnaire-C30) and hospital admissions in 350 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 domains associated with readmissions within 3 months were, emotional functioning ($r=0.42$, $p=0.003$) and global health status ($r=0.51$, $p<0.001$) for gastric cancers. For readmissions within 1 year they were nausea/vomiting symptom scales ($r=0.44$, $p=0.002$) for colorectal cancer and global health status ($r=0.46$, $p=0.001$) for gastric cancers. Constipation ($r=0.32$, $p=0.025$) and nausea/vomiting scales ($r=0.32$, $p=0.024$) for breast cancers were associated with hospitalizations within 3 months. Diarrhea symptom scale ($r=0.35$, $p=0.013$) for colorectal cancers and appetite loss scale ($r=0.55$, $p=0.016$) for prostate cancers were 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 QoL 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.