PCN108 QUALITY OF LIFE AND PATIENT PREFERENCES IN PLATINUM SENSITIVE OVARIAN CANCER
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OBJECTIVES: Although ovarian cancer has been widely studied, there is very little documentation of patient reported outcomes (PROs) for patients with platinum-sensitive ovarian cancer (PSOC). Initial therapy for ovarian cancer typically consists of surgery followed by platinum-based chemotherapy. Patients are considered platinum-sensitive if disease recurrence occurs more than 6 months after completion of first-line platinum-based treatment. The objective of this literature review was to obtain a clear picture of patient reported outcomes (PROs) including health related quality of life (HRQol), patient preferences, and health status utility for patients with PSOC. METHODS: A systematic literature review of the peer-reviewed literature was conducted in Medline and Embase using the Cochrane approach. Studies reporting and analyzing PROs, HRQol, patient preferences, and health status utility in patients with PSOC over the past 10 years were identified. RESULTS: The review identified 19 studies reporting PROs for PSOC patients, of which 9 were PSOC only, 7 were a combination of platinum-sensitive and resistant patients and 3 were platinum resistant patients. Of the 19 studies, there was evidence of participanta tion, with limited commonality, on the types of treatment regimens reported. In general, Qol did not differ between therapies for PSOC patients. However, in one study when docetaxel and carboplatin were given sequentially vs. in combination, an improvement in Qol was demonstrated. Another study showed that statistically significant higher Qol scores were found in pegylated liposomal doxorubicin treated patients than in gemcitabine patients. CONCLUSIONS: Given the limited number of PSOC references and variations in treatment regimens, it was difficult to identify common themes in patient preferences and PROs for this patient popula tion. PSOC patients’ preferences and perceptions of treatment are important; how ever, this information is missing in the evidence base. Further research is needed to identify treatment options which improve Qol and add value to PSOC patients treatment experience.

PCN109 QUALITY OF LIFE ASSESSMENT OF CHRONIC MYELOID LEUKAEMIA PATIENTS IN AUSTRIA: CROSS-SECTIONAL PILOT STUDY USING THE EQ-5D
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OBJECTIVES: Chronic Myeloid Leukemia (CML) is a hematological, mostly fatal cancer. With the introduction of the targeted therapies for CML, patients for these therapies dramatically increased (Garciá-Manero, 2003, Deininger, 2008). Therefore, the assessment of quality of life (Qol) is increasingly important to CML patients taking a lifelong medication. The aim of our cross-sectional pilot study was to assess CML patient Qol using the Euro Quality of Life-5 Dimensions (EQ-5D) and derive utility values for each patient. METHODS: Patients with CML in Innsbruck, Austria completed the EQ-5D either on a tablet PC or via postal survey. According to the ethic committee vote, inclusion criteria were: prior diagnosis of CML, fluency in the German language, age between 18 and 80 years, and expected survival time of at least three months. The analysis included descriptive statistics of the sample and derivation of a utility value for each patient. RESULTS: Out of the 47 questionnaires that were sent out via mail, 31 were returned. An additional 4 patients completed the EQ-5D using a tablet PC. Nine patients were excluded due to lack of clinical data and/or failure to complete the questionnaire. Of the 26 patients in the final sample, 21 patients (81%) were in the chronic phase of disease and five (19%) had undergone allogeneic stem cell transplantation (SCT). Patients who had undergone SCT had a median utility of 0.701 (range 0.197-0.937). Patients in the chronic phase had a median utility of 0.887 (range 0.262-1.0). The difference between these two groups was not statistically significant (p = 0.345). CONCLUSIONS: Due to limited sample size, our results should be interpreted with caution. It is important for clinicians and health policy decision makers to consider mortality reductions, but also consider the patients’ Qol and patient preferences in a stan dardized and systematic way to optimize patient care.

PCN110 DIFFERENCES IN HEALTH-RELATED QUALITY OF LIFE BETWEEN CHILDREN TREATED FOR ACUTE LYMPHOBlastic LEUKAEMIA (ALL) ON DANA FANER CANCER INSTITUTE (DFC) PROTOCOLS
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OBJECTIVES: To identify differences in health-related quality of life (HRQoL) between 2 consecutive Dana Farber Cancer Institute (DFC) protocols to treat acute lymphoblastic leukemia (ALL) diagnosed during childhood. METHODS: Children diagnosed with high risk ALL and treated according to DFC protocol 95-01 or 00-01 at 5 and 9 Centres, respectively, in Canada and the USA were eligible for study. Patients of completed Health Utilities Index (HUI) questionnaires for each and for 4 major phases of therapy (induction of remission, postcentral nervous system prophylaxis, consolidation, and intensification), and at 2 years post-treatment. Differences between protocols in mean HUI score for each phase were assessed using a t-test for independent groups. Quality-adjusted life years (QALYs), based on mean HUI scores for each protocol phase, were used to determine the importance of differences. RESULTS: A total of 95-001 patients (n = 1000) and 375 (n = 285) were randomized to the 2 protocols. Differences between groups were found in mean HUI scores for each phase, with statistically significant higher QoL scores for 95-001 patients (0.17 vs. 0.15). CONCLUSIONS: Although there is no significant difference between groups in any of the four phases of post-treatment. Over the 5 year period, 95-001 patients experienced 0.06 greater QALYs, or 3 quality-adjusted life weeks (QALW), than 95-001 patients. RESULTS: The difference in mean HUI score for each phase were assessed using a t-test for independent groups. Quality-adjusted life years (QALYs), based on mean HUI scores for each protocol phase, were used to determine the importance of differences. RESULTS: A total of 95-001 patients (n = 1000) and 375 (n = 285) were randomized to the 2 protocols. Differences between groups were found in mean HUI scores for each phase, with statistically significant higher QoL scores for 95-001 patients (0.17 vs. 0.15). CONCLUSIONS: Although there is no significant difference between groups in any of the four phases of post-treatment. Over the 5 year period, 95-001 patients experienced 0.06 greater QALYs, or 3 quality-adjusted life weeks (QALW), than 95-001 patients.
move, but some had ascites, pleural effusion, jaundice, dyspnea (3–10%), and used nargile, as old as age 97. Lung cancer (19–49%) /H11011 ranged 1–97), and lung, hepatobiliary, colon, gastric, breast and pancreatic cancer were comprised of 80% of cancers. Among these about 40–50% had poor performance status (ECOG 2–4). CONCLUSIONS: In consideration of the size of the center and non-insured, offering cytostatic therapy with remembered by the patients associated with cytostatic therapy. Further research is needed to investigate cons and pros of cytostatic therapy.

PCN113 ASSESSING HEALTH-RELATED QUALITY OF LIFE (HRQOL) FOR ADVANCED BASAL CELL CARCINOMA (aBCC) AND BASAL CELL CARCINOMA NEVUS SYNDROME (BCNSS): DEVELOPMENT OF THE FIRST DISEASE-SPECIFIC PATIENT-REPORTED OUTCOME (PRO) QUESTIONNAIRE

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OBJECTIVES: In some BCC patients, tumors may progress to locally advanced disease or become metastatic (aBCC). BCNSS (Gorlin syndrome) is a rare genetic condition associated with life-long occurrence of multiple BCCs. Surgical treatments may cause disfiguring scars. The patient experience for those with aBCC and BCNSS is not well understood. Qualitative research was conducted to develop a PRO questionnaire for this population.

METHODS: Concept elicitation interviews were conducted in aBCC or BCNSS patients > 18 yr and physicians using an interview guide containing open-ended questions about symptom impact on functioning and well-being. Results from patient interviews were used to develop draft questionnaires. Cognitive debriefing interviews were conducted to finalize the questionnaires. RESULTS: Thirty patients were interviewed [14 aBCC (8 locally advanced, 6 metastatic; 73% male, mean age 64) and 16 BCNSS (50% male, mean age 51)]. Patients experience a variety of disease symptoms including pain, swelling, bleeding, itching. Physical appearance, specifically scarring and disfigurement, affected 73% of patients. 80% of patients made lifestyle changes (avoided outdoor activities and intimate relationships). Emotional effects, including worry about when/where the next BCC would appear, were evident in BCNSS patients (80%). Physicians (n = 4) noted aBCC patients worry about cancer and the possibility of more tumors, while BCNSS patients are concerned about tumor recurrence, mutilating surgery, and disfigurement. Based on interview results, separate aBCC and BCNSS questionnaires were developed. Ten cognitive-debrief interviews were conducted to evaluate content and clarity of draft questionnaires. The questionnaires were easy to complete and items were relevant. Minor revisions were made.

PCN114 DEVELOPING REGULATORY SUCCESS FOR PATIENT-REPORTED OUTCOMES (PROS) IN ONCOLOGY

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OBJECTIVES: FDA and EMA have created guidelines for PRO label claims. However, there have been few PRO-based claims in oncology (Gnanasakthy, et al., 2012) since the US has not required PRO labeling. The objective of this research was to explore factors that might predict regulatory success for PROs. We developed a regulatory success gradient, and used factors based on literature review, expert interviews, and the FDA guidelines to predict success. METHODS: Using a case-control approach, 10 oncology medications with PRO labels came from two sources: 1) a review of PROs in oncology labels (Gondek et al, 2007), and 2) a proprietary database (http://www.mapi-pros.org) containing a list of PRO-based labels. Six controls were oncology medications with the same indication and mechanism of action, but without PRO data in the label. Regulatory success was defined from no (no PRO in the label), through minimal, mild, and moderate, to great success (PRO labeling in the indication section). Independent factors, derived from literature review, expert interviews, and the PRO Guidelines, possibly related to regulatory success included concordance with PROs, content validity, appropriateness, and robustness (coefficient 0.0001) and functional (0.011, p < 0.0001) well-being subscales. The objective of this research was to explore factors that might predict regulatory success for PROs. We developed a regulatory success gradient, and used factors based on literature review, expert interviews, and the FDA guidelines to predict success.

RESULTS: Significant: Concordance with PROs, content validity, appropriateness, and robustness (coefficient 0.011, p < 0.0001) and functional well-being subscales. The objective of this research was to explore factors that might predict regulatory success for PROs. We developed a regulatory success gradient, and used factors based on literature review, expert interviews, and the FDA guidelines to predict success.

PCN115 QUALITY OF LIFE IN LUNG CANCER PATIENTS DURING ADJUVANT OR PRE-ADJUVANT CHEMOTHERAPY

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OBJECTIVES: Lung cancer is one of the most common high incidence and mortality cancers. Many lung cancer patients (LPs) receive chemotherapy not only for curative treatment, but also to palliate symptoms and maintain or even improve their quality of life (QOL). Though the impact of substantiated adjuvant chemotherapy on progress-free and overall survival is intensively investigated, there is currently only little knowledge on patients’ QOL in regard to the number of CT- lines administered. METHODS: By means of computer-based patient-reported outcome monitoring LCPs receiving adjuvant chemotherapy (adjuvant or palliative) completely validated EORTC QLC-C30, 11 additional questions concerning taste alterations. Statistical analysis comprised mixed linear models to calculate change rates over time and differences between chemotherapy lines. RESULTS: A total of 175 LCPs (92% female, on average 68 years old (± 10.4 years), and (± 4.5 SD)) assessed their QOL before adjuvant chemotherapy assessment during ambulatory chemotherapy administration. Twenty percent of LCPs received adjuvant chemotherapy, 73.1% 1st line palliative chemotherapy and 6.9% 2nd or above line chemotherapy. 70.7% were diagnosed with NSCLC, 21.0% with SCLC and 8.3% with other types of lung cancer. Symptom trajectories during adjuvant chemotherapy did not show a significant change in QOL-scores. LCPs receiving 1st line palliative chemotherapy experienced improvement concerning sleep disturbances (-1.9 points/month, p < 0.009), but deteriorations in regard to appetite loss and taste alterations (-2.8 points/month, p < 0.001, respectively), constipation (+1.8 points/month, p = 0.20) and financial impact (+1.3 points/month, p = 0.038). 2nd or above line palliative chemotherapy was associated with stronger symptom burden than adjuvant or 1st line palliative chemotherapy in most of the EORTC QLC-C30 dimensions (physical, emotional, cognitive and functional well-being). CONCLUSIONS: Though aggressive, adjuvant treatment did not endanger patients’ QOL. 1st line palliative chemotherapy proved to be helpful in maintaining and stabilizing patients’ QOL since deteriorations have been limited.

PCN116 MAPPING FACT-P TO EQ-SD IN A LARGE CROSS-SECTIONAL STUDY OF METASTATIC CASTRATE-RESISTANT PROSTATE CANCER PATIENTS

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OBJECTIVES: To construct and validate a prediction model of preference-adjusted health status (EQ–SD) for metastatic castration-resistant prostate cancer (mCRPC) patients using FACT-P (Functional Assessment of Cancer Therapy-Prostate).

METHODS: Observational study conducted in 47 centres across 6 countries (Belgium, France, Germany, Sweden, The Netherlands, UK) collected HRQoL data for 659 mCRPC patients with confirmed mCRPC and documented disease progression. Utility values were derived from EQ–SD profiles based on a UK-specific EQ–SD value set (5). Predictive validity of the 5 FACT-P subscales, patient demographics, co-morbidities and prior chemotherapy for utility values was tested using ordinary least square (OLS) model, Gamma and Tobit multivariate regression models. RESULTS: At the time of measurement, mean age was 74.5 years, 71% had prior chemotherapy and 5% had been treated with chemodeprivation therapy were 72.1, 6.6 and 4.1 years respectively; 32% of patients were treated with chemotherapy, 24% had prior chemotherapy, and 43% were chemotherapy naive. At diagnosis, 35.9% of patients had metastases and 84.1% had Gleason score 7 or less. Mean FACT-P scores varied from 76.8 to 126.2 depending on the patients’ utility. OLS-regression was the best-performing model, explaining 61% of the observed EQ–SD variation. All FACT-P subscales were significantly predictive. The coefficient (0.023, p < 0.0001) and functional (0.012, p < 0.0001) well-being subscales had the highest explanatory value. Age, co-morbidities and prior chemotherapy did not add additional explanatory value. CONCLUSIONS: The developed algorithms enable translation of cancer-specific health-related quality of life measures to preference-adjusted health status in mCRPC patients. Findings will help to develop health status adjustments in cost-utility analyses used in future HTA’s.

PCN117 QUALITY OF LIFE IN PATIENTS WITH MALIGNANT ASCITES AFTER TREATMENT WITH CATUMAXO: A MULTICENTER PHASE II/III STUDY COMPARING PARACENTESIS PLUS CATUMAXOMAB WITH PARACENTESIS ALONE

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OBJECTIVES: Malignant ascites (MA) is associated with poor prognosis and limited palliative therapeutic options. Therefore a change in patients’ health-related quality of life (HRQoL) is of particular importance to demonstrate added value of a new treatment compared to the patient-reported outcomes (PRO). Moreover how fast the change occurs can be as important as the simple occurrence of a meaningful change in HRQoL. Following demonstration of superiority on puncture-free survival of catumaxomab plus paracentesis vs paracentesis alone, this study aimed to compare time to deterioration in HRQoL between both treatment groups by using survival analysis techniques. METHODS: In a randomized, multi-center, phase II/III study in patients with MA, HRQoL was measured by using the European Organization for