tional research and clinical trials. These results contribute to a better understanding of how QOL issues are perceived by head and neck patients in India, strengthening the cross-cultural comparability of this instrument.

PCNS0

CHALLENGES AND LIMITATIONS OF IDENTIFYING PRESCRIPTION TREATMENT PATTERNS FOR PATIENTS WITH METASTATIC BREAST CANCER USING COMMERCIALLY INSURED CLAIMS DATABASES

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OBJECTIVES: The objective of this study was to illustrate the challenges and limitations of using claims data and developing algorithms to study prescription patterns for metastatic breast cancer (MBC) in patients previously treated with anthracycline and taxane. METHODS: Extract from the PharMetrics Integrated Outcomes Database between January 1999 and June 2005 was used. Lacking a diagnosis code for MBC, we defined the condition as 2 ICD-9 codes for breast cancer (BC) and 1 ICD-9 code for distant metastases. Drug exposure was defined as \( \geq 1 \) NDC/J-code for anthracycline and taxane. A treatment interval of 21 days was created to account for a high proportion of missing or zero values for days supply of chemotherapy agents. RESULTS: Among 38,588 patients with \( \geq 1 \) BC diagnoses, 5017 (13%) exhibited \( \geq 1 \) diagnoses for distant metastasis, 1121 (3%) were previously exposed to an anthracycline and a taxane, and 1028 met other criteria (age \( \geq 18 \) years and eligibility \( \geq 1 \) year). Of the 1028, 67% did not receive sequential therapy, and 80% of these had non-chemotherapy claims 90 days following last chemotherapy, with a mean post chemotherapy duration of 430 days. Among the 33% who received sequential therapy, the mean number of sequential therapies was 2.8 \( \pm \) 2.7 with mean duration of 66 \( \pm \) 82 days. CONCLUSION: The current analysis illustrates a method of using algorithms to define MBC diagnoses and treatment duration in claims-based treatment pattern studies. However, such algorithms must be validated against the patients’ medical records in order to assess the respective accuracy of disease and treatment pattern identification.

PCNS5

METHODS AND APPLICATION OF DATA COLLECTION TECHNOLOGY IN THE ELECTRONIC VELCADE® OBSERVATIONAL STUDY (eVOBS)

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OBJECTIVES: eVOBS is an international, non-interventional, observational study of clinical and economic outcomes in patients who receive VELCADE for the approved indication in multiple myeloma. METHODS: Patients who initiate VELCADE therapy for the approved indication are eligible for the study. Retrospective treatment data from 12 months prior to study entry and prospective treatment data for 36 months are collected via a secure, privacy-protected website. At study entry, submitted data are electronically screened against validation rules that have been prospectively established in consultation with multiple myeloma treatment specialists and data analysis specialists. These rules were designed to prevent missing data, duplicate data and data outside pre-established, logical ranges. Initial inputs require study center confirmation before the system uploads data to the central database. During the study, if there is any data that is inconsistent with previously submitted entries, study sites submit corrections via an audited online data change request system. Finally, an ongoing audit process is used to validate the quality of the data uploaded to the central database. This process uses monthly reports to identify potential inconsistencies within the dataset after data has been validated at entry. RESULTS: Uploaded data undergoes quality control checks, requiring adjustment by physicians to be minimal. Audit reports help to redress data entry training issues, further enhancing data accuracy. Analysis is only conducted on patients after resolution of outstanding supplemental data queries. CONCLUSION: The goal of this study is to document outcomes in a generalizable, representative patient cohort. This information will broaden our understanding of the use of VELCADE in typical clinical practice, outside of the interventional clinical trial setting. This largely automated three-stage quality control process streamlines the implementation of this non-interventional, observational research and permits the inclusion of patients from a broad geographic region. The study method allows for faster analysis and presentation of robust, pragmatic outcomes data.

CANCER—Patient-Reported Outcomes

PCNS2

COMPARISON OF IMPACT OF ELEVEN TYPES OF ADVANCED CANCER ON QUALITY OF LIFE

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OBJECTIVES: To compare the impact of 11 types of cancer on different domains of HRQL using the FACT-G and EQ-VAS. METHODS: Patients diagnosed with advanced cancer of the bladder, brain, breast, colorectal, head/neck, hepatobiliary/pancreas, kidney, lung, lymphoma, ovary or prostate completed HRQL assessments. HRQL was compared between patient groups for each subscale of the FACT-G, i.e., physical well-being (PWB), social/family wellbeing (SWB), emotional well-being (EWB) and functional well-being (F WB), and EQ-VAS, unadjusted and adjusted for age/gender using regression models. RESULTS: Approximately 50 patients were recruited for each cancer group (total n = 534). Mean age (SD) ranged from 52(11) (brain) to 70(8) (prostate). Unadjusted mean (SD) scores for PWB ranged from 66.8(17.2) (head/neck) to 78.1(21.3) (prostate); for SWB ranged from 81.4(19.1) (brain) to 90.6(22.0) (kidney); for EWB ranged from 61.7(16.0) (breast) to 72.0(16.9) (prostate); and F WB ranged from 54.7(20.2) (head/neck) to 67.8(18.5) (prostate). EQ-SD VAS mean scores were lowest for head/neck [61.8(21.7)] and highest for colorectal [72.0(17.1)]. Compared to lymphoma, adjusting for age/gender, PWB mean scores (SE) were significantly lower for patients with head/neck \( [-10.9(4.0)] \), hepatobiliary \( [-10.9(4.0)] \), and kidney \( [-8.7(4.0)] \). F WB mean scores were significantly lower for head/neck \( [-10.3(2.2)] \), hepatobiliary \( [-8.9(3.1)] \), bladder \( [-7.7(3.6)] \), and lung \( [-6.7(3.1)] \). Patients 65 years and older had mean (SE) scores for PWB = +9.2(2.1), EWB = +2.9(1.0), F WB = +3.1(1.6), and EQ VAS = +4.5(2.1) compared to patients aged 45 to 64. For median rank across all FACT subscales, hepatobiliary ranked worst and prostate the highest. Adjusting for age and gender, hepatobiliary ranked worst and lymphoma highest based on FACT median scores, while breast ranked lowest and colorectal highest based on mean VAS scores. CONCLUSION: Older
cancer patients generally report greater well-being across all domains, but age-adjusted results suggest hepatobiliary and head/neck cancer have significantly worse HRQL among different types of cancer, particularly in terms of PWB and FWB.

PCNS3
A COMPARISON OF THE PSYCHOMETRICS PROPERTIES OF HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS USED IN GLOIOBLASTOMA MULTIFORME PATIENTS
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OBJECTIVES: To evaluate brain cancer specific health related quality-of-life (HRQOL) instruments used in glioblastoma multiforme (GBM) patients for group and individual level decision-making. METHODS: An extensive literature search was conducted to identify brain cancer specific HRQOL instruments using several databases including Medline, PsycINFO, and Health and Psychosocial Instruments. Key search terms included “quality of life” and “glioblastoma”. Only brain cancer specific HRQOL instruments evaluating GBM patients were retained for evaluation of item information, practicality, breadth, depth, reliability (group level based on Nunnally & Bernstein 1994 and individual level based on McHorney & Tarlov 1995 criteria), validity and responsiveness. RESULTS: Four instruments were identified: extended Rotterdam Symptom Checklist (e-RSCL); European Organization for Research and Treatment of Cancer quality-of-life core 30 (EORTC QLQ C30) with brain cancer module (BCM20); EORTC QLQ C30+3 with BCM20; and a newly developed instrument deriving its core from the Sickness Impact Profile (SIP) with addition of a brain cancer module (BC). The EORTC QLQ C30 was the most widely used instrument and satisfied practicality, breadth and validity criteria (convergent: \( r = 0.61-0.70 \), \( p < 0.05 \); known-groups: \( p < 0.05 \)). This instrument offered the most extensive reliability information with 4 of 9 domains meeting the 0.70 criterion for group level decision-making. The SIP core with BC was notable for high levels of missing psychometric data. CONCLUSION: Measuring the impact of treatment on HRQOL is critical, especially in terminal conditions. However, none of the instruments in this study met the criteria for individual level decision-making. This was due in part to unavailability of psychometric data as well as data not meeting study criteria. Based on the results from this study, the EORTC QLQ C30 is recommended for use in group level decision-making in conjunction with another HRQOL instrument, for example a generic instrument. Further studies are required to evaluate the psychometric properties of the BCM20.

PCNS4
HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA TREATED WITH AXITINIB (AG-013736)
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OBJECTIVES: To assess health-related quality of life (HRQOL) in patients with metastatic renal cell carcinoma (mRCC) treated with axitinib (AG-013736), a potent vascular endothelial growth factor receptor inhibitor. METHODS: In a single-arm phase II trial, mRCC patients who had received one prior cytokine-based therapy were treated with axitinib 5 mg orally BID until disease progression or no response (46% of patients had a PR, and 40% had stable disease). HRQOL, a secondary endpoint, was measured using the European Organization for the Research and Treatment of Cancer Quality of Life Questionnaire-Core 30 (EORTC-QLQ-C30). The QLQ-C30 consists of 30 questions, rated on a 0-4 scale, measuring functional status, symptoms, and global health. Higher scores on the functional status and global health scales reflect better HRQL, whereas higher scores on the symptom scales indicate more severe symptoms. QLQ-C30 was completed at baseline, monthly for the first two cycles, every 2 cycles thereafter, and at follow-up. Longitudinal analyses were used to evaluate HRQOL data through 36 cycles of treatment. RESULTS: Fifty-four patients completed baseline HRQOL assessments. Statistically significant changes (\( P < 0.05 \)) were observed in average scores from baseline to post-treatment in the role, cognitive and social functioning scales, and the nausea/vomiting, pain and diarrhea symptoms. These changes were approximately <1/4 of a response category. The exception was diarrhea, with a 1/2 category change, which equated to a change from “no” to “a little” diarrhea. CONCLUSION: Although some measures of functioning and symptoms are statistically significant, interpretation of QLQ-C30 scores from the current literature (King 1996 Qual Life Res; Osoba 1998 JCO) indicate that changes observed in the study are, overall, too small to reflect a palpable change in patient functioning and symptoms. Thus, treatment with axitinib demonstrated minimal disruptions in HRQOL compared to baseline levels in mRCC patients.

PCNS5
TRANSLATION AND CULTURAL ADAPTATION OF HEALTH UTILITIES INDEX (HUI) FOR ASSESSING EFFECTS OF NEUTROPENIA AMONG PEDIATRIC ONCOLOGY PATIENTS IN TURKEY
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OBJECTIVES: HUI is a family of multi-attribute, health-status classification and preference scoring systems for general population health surveys and clinical research studies including cost-utility economic evaluations of alternative treatments. It has been translated and culturally adapted into many languages. This is the first report of HUI in Turkish. METHODS: The original English-language health-status classification system was translated into Turkish by 3 physicians from the pediatric oncology clinic in Istanbul. The consensus forward translation was independently back translated and then reviewed by HUInc staff. It provides the keywords for subsequent HUI questionnaire translation. The same forward/backward translation strategy with all-party consensus produced the interviewer-administered questionnaire for proxy assessments (HUI23P1Tr.40Q). The questionnaire was evaluated for acceptability and construct validity by interviewing parents of patients who developed neutropenia during their first chemotherapy cycle. Parents were interviewed twice at the Istanbul clinic, during and again after the neutropenic episode. Upon completion of the first interview, parents were asked informally about the questionnaire readability and suitability. Utility scores are from the original published functions based on general population preference measurements and differences in mean utility scores were tested using ANOVA. RESULTS: Parents of 50 newly diagnosed patients (26 males, mean age 91.3 months) were interviewed. The questionnaire was reported by all parents to be understandable and acceptable. Overall utility scores of health-related quality of life (HRQL) during neutropenic episodes (HUI2 mean = 0.65, SD = 0.251; HUI3 mean = 0.60, SD = 0.328) were significantly and importantly lower (HUI2 p = 0.008, HUI3 p = 0.034) than after recovery (HUI2 mean = 0.79, SD = 0.244; HUI3 mean = 0.75, SD = 0.315) as were the single-attribute scores for HUI2 and HUI3.