PCN82

HPS 14A: A SPECIFIC QUALITY OF LIFE INSTRUMENT FOR PATIENTS WITH HAND-FOOT SYNDROME

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Hand-foot syndrome or palmar-plantar erythrodysesthesia is a common adverse effect of certain chemotherapeutic agents, such as capcitabine or pegylated doxorubicin, but it is estimated to occur in 50% of cases. It is also frequently reported with some new targeted antitumor therapies such as sorafenib or sunitinib, although its clinical presentation is slightly different. OBJECTIVES: To develop and validate a hand-foot syndrome-specific quality of life scale in order to be able to measure the impact of the condition on patients and to be able to assess the value of certain specific treatments in this indication. METHODS: The questionnaire was developed after conducting a series of structured interviews with patients with forms of hand-foot syndrome of varying severity, which yielded a detailed and rigorous collection of verbatim transcripts. RESULTS: Thirty-one items were identified, and 14 items were selected as being relevant and non-overlapping after initial evaluation. The first question in the HFS14-items addresses which member is affected (hand, foot or both). The second question addresses the pain with three possible responses (very, moderately or not painful). The 14 items can be organised in 2 modules: the first module more specifically assesses the handicap generated by involvement of the feet and the second assesses the handicap generated by involvement of the hands. Six items are considered common to both modules, four are hand-specific and four are foot-specific. Psychometric validation confirmed the internal consistency and very high reproducibility of the questionnaire.

CONCLUSIONS: The hand-foot syndrome-specific HFS14 scale is easy to use and meets the quality of life scale. This scale now needs to be tested in longitudinal studies for example in clinical trials to confirm its ability to measure a change in status.

PCN83

A MULTINATIONAL STUDY OF PATIENT PREFERENCE VALUES FOR HEALTH STATES FOR CHRONIC MYELOGENOUS LEUKAEMIA

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OBJECTIVES: Studies of preferences in many disease areas show that patients value health states higher than general public respondents. We previously elicited general public preferences for chronic myelogenous leukemia (CML) health states. The objectives here were to 1) estimate preferences for CML health states from US, UK, Canadian, and Australian patients, and 2) determine if adjusted point estimates for CML health states were higher than those estimated by general public respondents. METHODS: Time trade-off preference values for six CML health states were elicited from CML patients by trained interviewers using a script. Standardized health state descriptions were derived in consultation with a panel of oncologists. Mean health state preferences were calculated and a generalized linear model used to determine significant predictors. While statistical comparisons were not appropriate, point estimates of patient preferences were compared against known general public preferences for CML health states. RESULTS: Ninety-three patients were included; from the US (n = 33, 35%), UK (n = 11, 12%), Canada (n = 24, 26%), and Australia (n = 15, 16%). The mean age was 52 years (range, 29-79) and 63% were men. Significant differences were observed in mean patient preferences between the countries. After adjustment for country, age and sex, mean patient preferences were: 0.95 for chronic phase responding (CR); 0.76 for chronic phase non-responding (CNR); 0.94 for accelerated phase responding (AP); 0.92 for accelerated phase non-responding (ANR); 0.38 for blast phase responding (BR); and 0.27 for blast phase non-responding (BNR). Except for BR, all point estimates of general public preferences were lower than patient values, and were: 0.91 (CR); 0.73 (CNR); 0.78 (AP); 0.49 (ANR); 0.48 (BR); and 0.22 (BNR). CONCLUSIONS: This study provides evidence that preferences for oncological health states follow the pattern expected if habituation were taking place, and patients report higher preferences than general public representatives.

PCN84

VALIDATION OF THE EUROQOL EQ-5D IN PATIENTS WITH RELAPSED/REFRACTORY MANTLE CELL LYMPHOMA (RR MCL)

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OBJECTIVES: Health utilities, measured by the EQ-5D, have not been reported for MCL, an aggressive form of non-Hodgkin's lymphoma. This research aimed to explore the validity of the EQ-5D in patients with RR MCL and to estimate minimally important differences (MIDs). METHODS: Data were collected in a phase II, single-arm, open-label study of enzastaurin in RR MCL patients (Morschhauser et al, Ann Oncol 2008). Criterion validity was assessed by grouping patients by International Prognostic Index (IPI) and by Eastern Cooperative Oncology Group performance status (PS). Responsiveness to change was assessed by grouping patients according to changes in PS (improved/stable or worse) and disease status. Distribution-and-anchor-based methods were used to estimate MIDs. RESULTS: EQ-5D data were available for 58 of 60 enrolled patients at baseline and for 38 patients at discontinuation. Median age was 66 years, 70% were male, 88% had a baseline PS of 0 or 1, and 52% had an IPI score 52. There was a statistically significant (p < 0.05) difference in baseline EQ-5D index (0.81, 0.63, 0.58) and visual analogue scale (VAS) (66.9, 36.4, 44.7) by PS group (0, 1, 2, respectively) and at discontinuation by PS group for the index (0.77, 0.61, 0.28). There were no significant differences for the index or VAS scores by IPI group. Those patients with worsened PS (n = 12) had significantly worse index and VAS scores than those patients with improved/stable PS (n = 18). The estimated MID ranges across the varying methodologies were 0.03-0.10 for the IPI and 5.2-10.0 for the VAS. CONCLUSIONS: This retrospective study provides evidence that the EQ-5D is a valid instrument to assess health status in patients with RR MCL, based on differentiation of patients by clinical status. The estimated MIDs are consistent with those reported for other cancers and will be helpful in designing future studies.

PCN85

TESTING THE MEASUREMENT EQUIVALENCE OF PAPER AND INTERACTIVE VOICE RESPONSE (IVR) VERSIONS OF THE EORTC QLQ-C30

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OBJECTIVES: When migrating existing patient-reported outcome measures to electronic data capture technologies, it is critically important that the new modes of administration provide comparable results to the original. The objective of this study was to evaluate the measurement equivalence of an interactive voice response (IVR) version to the original paper-based version of the EORTC QLQ-C30. METHODS: The QLQ-C30 is a cancer-specific health-related quality of life measure consisting of nine multi-item scales (physical, role, emotional, cognitive and social functioning, fatigue, pain, nausea and vomiting, insomnia, appetite loss, constipation, diarrhea, and financial problems). This study utilized a crossover design with subjects randomly assigned to one of two assessment orders: 1) paper then IVR, or 2) IVR then paper. Cancer patients receiving treatment as an outpatient basis (n = 139) were included. Both versions are scored in two days apart. Equivalence between the two administration modes was established by comparing the 95% lower confidence interval (CI) of the intraclass correlation coefficients (ICCs) for each scale, with a critical value of 0.70. RESULTS: The ICCs for the nine multi-item scales were all above 0.79, ranging from 0.791 to 0.889 (ICC 95% lower CI range: 0.726 to 0.861), and significantly different from our threshold reliability of 0.70. The ICCs for the six single items ranged from 0.689 to 0.898 (ICC 95% lower CI range: 0.611 to 0.888). Two of the items, insomnia and appetite loss, were not statistically different from 0.70. Thus, we do not denote equivalence based on the ICCs for these two items. However, when taken together, the results support the equivalence of the scores between the paper and IVR versions of the QLQ-C30. CONCLUSIONS: This analysis provides evidence that the scores obtained from the IVR version of the QLQ-C30 are equivalent to those obtained with the original paper version.

PCN86

TESTRETEST RELIABILITY OF AN INTERACTIVE Voice RESPONSE (IVR) VERSION OF THE EQ-5D IN A SAMPLE OF CANCER SURVIVORS

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OBJECTIVES: The objective of this study was to assess the test-retest reliability of an interactive voice response (IVR) version of the EQ-5D. METHODS: The EQ-5D self-report questionnaire consists of a descriptive system and a visual analog scale (EQ VAS). Responses on the descriptive system classify the respondent into one of 243 unique health states. A preference weight is assigned to the health state, resulting in an EQ-5D index score on a scale where 1 = perfect health and 0 = death. Cancer patients were complete the IVR-based twice, two days apart. The analyses tested for mean differences (paired t-test) and test-retest reliability (ICC) to assess measurement stability over time. Equivalence of the means was established if the 95% confidence interval (CI) was within the minimally important difference (MID) interval, namely <0.025 to 0.025 for the index and <3 to 3 for the EQ-VAS. Adequacy of the ICC was established by comparing the ICC 95% lower CI with a critical value of 0.70. RESULTS: Both administrations were completed per protocol by 110 subjects (EQ-5D index) and 114 subjects (EQ VAS). For the EQ-5D index, the means (SD) of the first and second administrations were 0.871 (0.138) and 0.868 (0.153), respectively. The 95% CI of the mean difference was −0.012 to 0.017, which was within the equivalence interval. The ICC was 0.858 (0.800 – 0.909) and was significantly different from 0.70 (p < 0.001). For the EQ VAS, the means (SD) were 81.34 (17.46) and 80.83 (17.52), respectively. The 95% CI of the mean difference was −0.598 to 0.167, which was within the equivalence interval. The ICC was 0.944 (0.919 – 0.961) and was significantly different from 0.70 (p < 0.001). CONCLUSIONS: This analysis provides substantial evidence that the scores obtained from the IVR version of the EQ-5D are reliable upon repeated administrations.

PCN87

TESTRETEST RELIABILITY OF AN INTERACTIVE voice RESPONSE (IVR) VERSION OF THE EORTC QLQ-C30

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OBJECTIVES: The objective of this study was to assess the test-retest reliability of an interactive voice response (IVR) version of the EORTC QLQ-C30. METHODS: A convenience sample of outpatient cancer clinic patients (n = 127) was asked to complete the IVR version of the QLQ-C30 twice, two days apart. The QLQ-C30 is a 30-item, cancer-specific questionnaire composed of single-items and multi-item scales. The