PCN113

TREATMENT PATTERNS AND OUTCOMES IN THE FRENCH COHORT OF PATIENTS WITH UNRESECTABLE STAGE III OR STAGE IV MELANOMA (MELODY STUDY): A RETROSPECTIVE LONGITUDINAL SURVEY

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OBJECTIVES: Melanoma is the first mortality cause by skin cancer. The more advanced stages prognosis is remaining poor. The MELODY study had as primary objectives to describe the disease characteristics, treatment modalities/outcomes, and resources use in patients with unresectable Stage III-Stage IV (UNRSIII-SIV) melanoma. **METHODS:** MELODY was a three-country (France, Italy, UK) longitudinal, retrospective, observational survey. In the French cohort, 10 expert dermatology departments had to register all melanomas seen between July 2005 and June 2006. The UNRSIII-SIV cases, with minimum 2-month follow-up, were extracted for detailed description of the disease characteristics, treatments (systemic, local, supportive care), and outcomes and resource use, until May 1, 2008 or death. **RESULTS:** In France, 1224 patients (pts) were registered, in which 278 UNRSIII-SIV cases were extracted. At initial diagnosis, 34/1224 pts (2.8%) were UNRSIII-SIV; 253 pts (91%) received systemic treatment, while 230 (91%) had a chemotherapy of any line. In first-line systemic (n = 249), 198 pts (80%) were treated outside clinical trials, in whom 119 (60%) were on dacarbazine (D) and 35 (18%) on fotemustine (F) monotherapy; complete/partial response was noted for 21 pts (11%), with 2.9-month median response duration, median of progression-free survival (PFS) was 2.8 months (2.6; 3.5). In second line, 159 pts (57%) were treated, in whom 139 (87%) outside of clinical trials, with 75 (54%) on F, and 16 (12%) on D; median PFS was 2.5 months (2.1; 3.9). In case of systemic treatment/supportive care, there was a median of 20 (11; 30) hospitalization days (13 [6; 22] days for first line systemic) and 3 [1; 6] outpatient visits (1.5 [1.0; 5.0] for first-line systemic). **CONCLUSIONS:** In the French cohort of MELODY, chemotherapy treatments gave modest results in terms of complete/partial response and PFS, at a high cost of resource use, highlighting the unmet medical need.

CANCER – Patient-Reported Outcomes Studies

PCN114

VISITING DOCTORS WITH MALIGNANT MELANOMA

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OBJECTIVES: The incidence of malignant melanoma has been continuously growing; however, early identification contributes significantly to its effective treatment. As a prerequisite, the individual needs to see a specialist soon after the recognition of the first symptoms. Therefore, the aim of our study is to disclose the factors and patient attitude behind seeing a specialist in case of skin deformation in order to establish the method for effective treatment. **METHODS:** Retrospective cross-sectional study was carried out among patients in four cities (n = 280) who had been diagnosed with malignant melanoma within 5 years. Besides sociodemographic data, the questionnaire focused on the awareness and knowledge of the patient regarding melanoma, on risk factors, the general attitude of seeing doctors, and that of delaying factors in respect of melanoma. Single and multiple logistic regression were used in statistical analysis. **RESULTS:** After the recognition of skin deformation, only half of the patients visit a doctor within 1 year. The increase of latency (seeing a specialist more than 3 months after the incidence of the first symptoms) was four to seven times more frequent among those who demonstrate anxiety and distress, feel exposed to doctors, lie in the sun without any control, lack awareness of the disease, and have a lower rate of social support ($P < 0.01$). The study also revealed the shortages of primary care (e.g., insufficient examination, lack of information supply). Seeing a specialist in most of the cases was motivated by external factors. **CONCLUSIONS:** To estimate the benefit of developing programs focusing on health behavior and awareness building of the prevalence and incidence of malignant melanoma instead of facilitating several preventive interventional projects based on the screening of the population.

PCN115

EVALUATION OF SUPPORT SERVICES TO COLORECTAL CANCER PATIENTS IN MEXICO

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OBJECTIVES: To identify the association of sociodemographic, resource use, and adverse events variables with adherence to measure the return on investment of a patient education service for colorectal cancer patients taking capecitabine.

METHODS: This was a prospective intervention of government patients in the country of Mexico of any age, with colorectal cancer and capecitabine treatment. The intervention group had access to a hot line, booklets, nutritional and psychological support; control group patients did not. a structured ad-hoc questionnaire applied the Morisky–Green Test to determine adherence to therapy via follow-up phone calls. Associations between variables and adherence between intervention group and controls were assessed using chi-square test. Emergency rooms (ER) visits were the economic indicator to establish cost differences between groups. Power analysis was conducted using PS Power and Sample Size Calculations version 3.0, January 2009. **RESULTS:** A total of 220 patients were included in this study (mean age 58.4 [26 to 89] years), 121 intervention patients (48 responded to first call; 70% adherence) and 99 control patients (30 responded to first call; 57% adherence). If the true odds ratio for adherence in intervention relative to control is 1.86, a power analysis projects statistical significance with 290 intervention patients and 181 controls to reject the null hypothesis with a probability (power) of 0.8. The reason for nonadherence "Does not know administration regime" did show statistical significance ($P = 0.019$) between the intervention (10% n = 2) and control group (47% n = 7). For ER visits related to adverse events, the control group rate was 13.33% (n = 4) versus 2.32% (n = 1) in the intervention group ($P = 0.067$). The cost for ER/day is $Mex 1,144.44 (USD 86.82). **CONCLUSIONS:** These preliminary results indicate that patients who receive intervention services may have improved adherence to medication and therefore fewer ER visits and costs. Continued enrollment will be able to determine true significance.

PCN116

ANALYSIS OF THE EQ-5D QUESTIONNAIRE FOR PATIENTS WITH ADVANCED HER2-POSITIVE GASTRIC CANCER (HER2+ AGC) BASED ON THE TRASTUZUMAB FOR GASTRIC CANCER (TOGA) STUDY

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OBJECTIVES: In the ToGA study, patients with HER2+ aGC (n = 584) who received trastuzumab + chemotherapy achieved significantly improved overall survival compared to patients receiving chemotherapy alone (HR = 0.74 (95% CI 0.60; 0.91, $P =$ 0.0046; van Cutsem et al. 2009). Since published utilities in gastric cancer are rare, we report results of the EQ-5D analysis from ToGA here, particularly the obtained utility for progression-free-survival (PFS). **METHODS:** The EQ-5D was provided to patients at baseline and every 3 weeks until disease progression. The questionnaire was completed by the patient prior to any study specific assessment or discussion with their study care provider. Patients' EQ-5D responses were scored using UK-tariffs, according to the guidelines of the EuroQol group. Only fully completed questionnaires were included. Mixed effects random slope models in SAS v8.2 were developed to estimate the health state utility. The intercept and day of assessment were incorporated as random effects. Covariance structures were assessed for goodness of fit using Akaike Information Criteria. Secondary analyses that included a treatment indicator were performed to explore a possible treatment effect. EQ-5D analysis of a patient subgroup (with tumors highly expressing the HER2-protein, i.e., IHC3+ or IHC2+ and FISH+, metastatic at screening, n = 431), was also conducted. **RESULTS:** The unstructured covariance matrix was found to be the best fit and resulted into a PFS-utility of 0.73 (95% CI: 0.71; 0.75). The treatment effect was not found to be significant ($P =$ 0.1542); i.e., no difference between the two treatment regimens was identified. Results were confirmed for the subgroup. **CONCLUSIONS:** Although only HER2+ patients were included in ToGA, the obtained utility value is in line with other published PFS-utilities in aGC. Given the large patient numbers, 0.73 can be regarded as a robust estimate of a patient-reported outcome. Further studies in aGC should attempt to assess the utility in patients following disease progression.

PCN117

UTILITY ELICITATION STUDY IN THE UK GENERAL PUBLIC FOR LATE STAGE CHRONIC LYMPHOCYTIC LEUKEMIA

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OBJECTIVES: In the UK, chronic lymphocytic leukemia (CLL) makes up 40% of all leukemias in patients over 65 years. The objective of this UK-based study was to obtain societal preferences for "progression-free" and "progressive" stages of late-stage CLL, and selected treatment-related adverse events. **METHODS:** A utility study, using the time-trade off (TTO) method, was conducted in the UK with 110 members of the general public for a baseline disease state (before treatment), three primary disease states (progression-free survival [PFS] response, PFS non-response, and disease progression) and four adverse event (AE) substates (PFS response with thrombocytopenia, neutropenia or severe infection, and PFS non-response with severe infection). Disease state vignettes were developed using literature and validated by expert CLL clinicians. Face-to-face interviews were conducted by trained interviewers. The TTO scores were converted into a utility value for each disease state and disutilities were calculated for AEs. Visual analogue scale (VAS) scores were also obtained. **RESULTS:** All participants were included in the analysis. The mean utility scores from the TTO for the primary disease states were: baseline: 0.549; PFS response: 0.671; PFS nonresponse: 0.394; and progression: 0.294. The mean TTO utility (disutility) scores for the AEs were: PFS response with thrombocytopenia, neutropenia, or infection, 0.563 (–0.108), 0.508 (–0.163), 0.476 (–0.195), respectively; PFS nonresponse with infection, 0.333 (–0.061). The VAS results were in line with the TTO results. **CONCLUSIONS:**

Overall, the utility was higher for the PFS state than for baseline, but decreased below baseline in nonresponse and disease progression states. AEs had an important impact on utility within the PFS response state. The severe infection AE appeared to have a greater impact on patients responding to treatment compared to nonresponders, which may be related to the quality of life which is already low for the latter.

PCN118

UTILITY VALUES FOR CHRONIC MYELOID LEUKAEMIA-CHRONIC PHASE (CML-CP) HEALTH STATES FROM THE GENERAL PUBLIC IN THE UNITED KINGDOM

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OBJECTIVES: To estimate utility values associated with CML-CP health states among members of the general public in the UK. **METHODS:** Interviewer-administered time trade-off utilities were elicited for four CML-CP health states related to risk of progression, from a random sample of 241 members of the general public from eight cities across the UK, using health-state descriptions validated by clinicians and members of the general public. Mean utility values with 95% confidence intervals (CI) were calculated for each health state. **RESULTS:** The respondents' mean age was 45 years and 51% were female. Seven percent (n = 18) of respondents had a cancer at the time of the interview which had been diagnosed for a mean 7.0 ± 6.5 years. The mean utilities with 95% CI were: 0.72 (0.69; 0.75) for untreated chronic phase CML, 0.80 (0.79; 0.82) for hematologic response, 0.89 (0.87; 0.90) for cytogenetic response, and 0.94 (0.94; 0.95) for molecular response. The utility values for each state are significantly different from one another ($P < 0.001$). The respondents' preference values for any of the states were not significantly affected by their demographics or whether they had cancer. Nevertheless, the values elicited from respondents with cancer were lower than those elicited from respondents who did not have cancer: 0.65 versus 0.73 for chronic phase CML; 0.72 versus 0.81 for hematologic response; 0.83 versus 0.89 for cytogenetic response; and 0.89 versus 0.95 for molecular response. **CONCLUSIONS:** The health states with poorer outcome (e.g., hematologic response) were associated with a lower preference value than the state with the best outcome (i.e., molecular response). The data demonstrate the impact that different treatment responses may have on the health-related quality of life of patients with chronic phase CML and can be used to estimate the outcomes of interventions in terms of quality-adjusted life-years.

PCN119

COMPARISON OF EQ-5D SCORE BETWEEN TREATMENT WITH 4 CYCLES OF ANTHRACYCLINE FOLLOWED BY 4 CYCLES OF TAXANE AND 8 CYCLES OF TAXANE FOR NODE POSITIVE BREAST CANCER PATIENTS AFTER SURGERY: N-SAS BC 02 TRIAL

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OBJECTIVES: We investigated the effect of adjuvant chemotherapy regimens on utility scores assessed by the EQ-5D instrument in a randomized controlled trial for breast cancer patients after surgery. **METHODS:** In the National Surgical Adjuvant Study of Breast Cancer-02 (N-SAS BC 02), 1060 patients were randomly assigned to the following four chemotherapy groups: 1) four cycles of anthracycline (ADM 60 mg/m² or EPR 75 mg/m² + CPM 600 mg/m², q3 wks x 4) followed by paclitaxel (175 mg/m², q3 wks x 4) (ACP); 2) four cycles of anthracycline followed by docetaxel (75 mg/m² q3, wks x 4) (ACD); 3) eight cycles of paclitaxel (175 mg/m², q3 wks x 8) (PTX); and 4) eight cycles of docetaxel (75 mg/m², q3 wks x 8). The first consecutively registered 300 women were the subjects of the present utility study. Utility scores were assessed using the EQ-5D instrument at baseline, 3rd cycle, 5th cycle, 7th cycle, 7 months, and 1 year. The obtained data were analyzed using a linear mixed model with baseline, time, group, and interaction between time and group as explanatory variables. **RESULTS:** Missing data was observed between 1.9 and 6.1% of cases depending on the time of measurement. The utility score was significantly lower in the DTX group than in the ACP and ACD groups. In the DTX group, the mean utility score was lowest at 7 months, and it tended to remain low for a long time. In a comparison of the anthracycline and taxane groups, the anthracycline group had significantly higher utility scores. There were no significant differences depending on the type of taxane. The estimated mean utility scores were 0.81, 0.83, 0.79, and 0.76 (ACP, ACD, PTX, and DTX group). **CONCLUSIONS:** The results of this study will be beneficial not only for clinical decision-making but also for appropriate allocation of medical resources.

PCN120

UTILITY AND WORK PRODUCTIVITY DATA FOR ECONOMIC EVALUATION OF BREAST CANCER THERAPIES IN THE NETHERLANDS AND SWEDEN

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OBJECTIVES: Survival and quality of life (utility) are often the main measure of benefit used in an economic evaluation. Additionally, some decision-makers will consider benefits in terms of work productivity. The present study was designed to estimate utilities and productivity loss for women with metastatic breast cancer (MBC)

which is Human Epidermal Growth Factor Receptor 2 positive (HER 2+). **METHODS:** Health-state vignettes describing MBC progressive disease, stable disease, and seven grade 3/4 adverse events (diarrhea, fatigue, anemia, leukopenia, anorexia, decreases in left ventricular ejection fraction [LVEF], and skin rash) were developed based on interviews with women with MBC in the The Netherlands and Sweden and clinicians. a general public sample rated the states (100 men and women in NL; 100 women aged 50+ in Sweden) using the time trade off method. Women (161 The Netherlands, 52 Sweden) who were currently or recently treated for MBC were surveyed using the Work Productivity and Activity Impairment scale regarding the impact of disease on their ability to work. **RESULTS:** MBC progressive disease and stable disease were rated more highly in Sweden (0.61, 0.81) than the The Netherlands (0.50, 0.69). Utilities for toxicities ranged from 0.52 to 0.69 (Sweden), and 0.47 to 0.66 (NL). The productivity survey identified that women currently receiving treatment reported that their overall productivity was reduced by 69% (NL) and 72% (Sweden); while those who had recently completed therapy reported reductions of 41% (NL) and 40% (Sweden). **CONCLUSIONS:** This study captured utility and productivity data for the The Netherlands and Sweden regarding the impact of HER 2+ MBC. Important differences in utilities emerged in the study which could impact cost-effectiveness estimates. The productivity survey demonstrated how the negative impact of breast cancer on productivity persists after women have completed their treatment.

PCN121

CONFIRMATION OF BRIEF PAIN INVENTORY SHORT FORM (BPI-SF) "WORST PAIN" ITEM CUT-POINT FOR THE ASSESSMENT OF PAIN PROGRESSION IN CASTRATION-RESISTANT PROSTATE CANCER (CRPC)

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OBJECTIVES: Previous studies in cancer patients have found scores of ≥5 on 11-point pain scales to indicate pain that has a significant impact on patients' lives. This study sought to confirm the adequacy of a ≥5 cutpoint on the BPI-SF "worst pain" item for defining pain progression in CRPC patients using data collected as part of a multinational phase III clinical trial. **METHODS:** Patients with a BPI-SF worst pain score ≥5 were compared with patients with a score <5 in terms of Functional Assessment of Cancer Therapy—Prostate (FACT-P) subscales and total score and EQ-5D item scores. Exploratory analyses were also conducted to investigate any potential differences within designated regional subgroups of patients. All analyses were performed using treatment-blinded data collected at the first post-baseline trial visit including the above assessments (Week 12). **RESULTS:** A total of 464 patients completed the BPI-SF at W12 (<5 n = 411, ≥5 n = 53). Mean FACT-P total scores for patients with a BPI-SF worst pain score ≥5 were 24.5 points lower than for patients with a score <5 (91.1 vs. 115.6, $P < 0.0001$), indicating poorer well-being. Patients with BPI-SF worst pain scores ≥5 consistently had lower scores for all FACT-P subscales ($P < 0.0001$) except for social well-being. The magnitude of these differences, for all scales, was considerably greater than reported thresholds for meaningful difference. Results for EQ-5D item scores were in a similar direction with significantly greater impairment reported in patients with a BPI-SF worst pain score ≥5 compared with patients with a score <5 ($P < 0.0001$). Exploratory analyses also revealed similar results across all regional subgroups of patients. **CONCLUSIONS:** Patient scores ≥5 on the BPI-SF "worst pain" item are associated with significant and meaningful impairments in CRPC patients, thus supporting the adequacy of this cutpoint as an appropriate definition of pain progression in this population.

PCN122

DEVELOPMENT OF THE PATIENT-REPORTED VERSION OF THE COMMON TERMINOLOGY CRITERIA FOR ADVERSE EVENTS (PRO-CTCAE)

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OBJECTIVES: The standard lexicon for reporting adverse events in National Cancer Institute (NCI) sponsored clinical trials is the Common Terminology Criteria for Adverse Events (CTCAE), which consists of 790 individual items. Currently, all adverse events are reported by clinicians. However, multiple studies have found that clinicians tend to underreport symptom severity and onset compared with patient self-reports. In 2008, the NCI contracted a multi-institution consortium to develop patient versions of CTCAE items and an electronic platform for capturing symptoms from patients and reporting data to health care providers and researchers. **METHODS:** A committee including clinical investigators, methodologists, patients, and representatives of NCI and FDA systematically identified CTCAE items with a subjective component amenable to patient reporting. Systematic review and analyses of publications and existing symptom survey data sets and questionnaires were conducted to determine optimal formats for questions, response options, and terms for new PRO-CTCAE items. **RESULTS:** 81 symptoms were identified in the CTCAE to be amenable to patient reporting. The format and content of these items were found to be inappropri-