

with the physician/Less than 6 months of survival/Intravenous administration). The factors that influence more on the treatment preferences were, symptoms' control (31% of the patients), confidence with the physician (21.6%) and immediate toxicity (18.7%). **CONCLUSION:** Through a conjoint analysis we may conclude that the most important attributes for the patients were symptoms' control followed by confidence with their physician.

PCN72

HEALTH-RELATED QUALITY OF LIFE (HRQOL) AND KIDNEY CANCER-RELATED SYMPTOMS IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA (mRCC) TREATED WITH SUNITINIB VERSUS INTERFERON (IFN)-ALFA IN A RANDOMISED, MULTINATIONAL PHASE III TRIAL: RESULTS FOR EUROPEAN AND US SUBSAMPLE ANALYSES

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OBJECTIVES: Sunitinib malate is an oral, tyrosine kinase inhibitor that targets VEGFRs, PDGFRs, KIT, RET and FLT3, with antitumour and antiangiogenic effects. Sunitinib demonstrated statistically superior efficacy and HRQOL over IFN- α as first-line mRCC therapy ($P < 0.001$) in an international, randomised phase III trial [Motzer et al. *NEJM* 2007;356:115–24]. These analyses examine the association between geography and treatment effect on patient-reported outcomes (PROs). **METHODS:** Patients with mRCC ($N = 750$) were randomised 1 : 1 to sunitinib 50 mg/day orally in 6-week cycles (4 weeks on, 2 weeks off) or IFN- α (9 MU SC TIW). HRQOL was assessed on days 1 and 28 of each cycle using the following instruments: 1) FACT-Kidney Symptom Index (FKSI) and its disease-related symptom subscale (FKSI-DRS); 2) Functional Assessment of Cancer Therapy-General (FACT-G) and its 4 subscales; and 3) population-preference-based health state utility score (EQ-5D Index) and patient self-rated overall health state (EQ-VAS) from the EQ-5D self-report questionnaire. Data were analysed using repeated-measures mixed-effects models for the EU+ (France, Germany, Italy, Poland, Russia, Spain, UK, plus Australia and Canada; $n = 400$) and US ($n = 346$) subsamples. **RESULTS:** Sunitinib provided a significant benefit compared with IFN- α in the overall post-baseline least-square means for in all 9 PRO endpoints ($P < 0.05$), except EQ-5D in the US subsample ($P = 0.4105$). Most of the 9 FKSI-DRS items also favoured sunitinib. These findings were consistent with the overall sample results. Larger between-treatment differences were generally observed in the EU+ subsample compared with the US subsample. **CONCLUSION:** In both Europe and the US, sunitinib offers consistent HRQOL and kidney cancer-related symptoms advantages compared with IFN- α in the first-line treatment of mRCC. These advantages were more pronounced in the EU+ sample and may reflect differences in treatment experience or underlying differences in HRQOL reporting.

PCN73

LINGUISTIC VALIDATION OF THE HOT FLASH DIARY FOR PROSTATE CANCER PATIENTS IN EIGHT LANGUAGES FOR NINE COUNTRIES

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OBJECTIVES: Hot flashes are important adverse effects of androgen deprivation therapies (ADT) in prostate cancer

patients. The prevalence of hot flashes in patients undergoing ADT is approximately 70–80%. Fifty-five percent of patients report distress due to their hot flashes. The Hot Flash Diary (HFD) developed by the North Central Cancer Treatment Group/Mayo Clinic measures patient's daily assessment of hot flash frequency and severity and enables calculation of a hot flash score. Severity is measured on a scale from 1 ("Mild") to 4 ("Very severe"). To measure hot flashes in prostate cancer patients cross-culturally, we performed the translation/adaptation and linguistic validation of the HFD for use in 9 countries: Canada (French/English), Czech Republic, France, Germany, Hungary, The Netherlands, Spain (Catalan/Spanish), US (Spanish), and UK. **METHODS:** The translation/adaptation and linguistic validation of the HFD followed an established and rigorous method to ensure conceptual equivalence between the original and translated versions. The methodology consisted of 10 steps: 1) item definition development; 2) two forward translations; 3) reconciliation; 4) back-translation; 5) source and back-translated text comparison; 6) bilingual expert review; 7) finalization; 8) harmonization; 9) comprehension testing with patients; and 10) post-testing review/revision. **RESULTS:** Linguistic and conceptual issues were identified during translation. It proved difficult to find precise equivalents for adjectives describing the degree of hot flash (e.g. 'mild', 'moderate', 'severe') in several languages. Additional problems were mainly related to semantics and syntax. Overall, the HFD was well understood by the patients and they encountered little difficulty in its completion. **CONCLUSION:** Linguistic validity of the HFD for 9 countries was confirmed. International prostate cancer trials are currently underway and cross-cultural data on hot flashes will be available to provide international comparison of this very bothersome adverse effect of ADT.

PCN74

PSYCHOSOCIAL CONSEQUENCES OF ABNORMAL AND FALSE-POSITIVE RESULTS IN LUNG CANCER SCREENING: ADAPTATION OF A QUESTIONNAIRE

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OBJECTIVES: The *Consequence of Screening in Breast Cancer* questionnaire (COS-BC) assesses the psychosocial consequences of abnormal and false-positive screening mammography. It has two parts; one covering the period between abnormal screening and final diagnosis and one relating to the period following being declared free from cancer. The first aim of the study was to assess if COS (i.e. COS-BC without the breast specific items) was relevant for persons having false-positive lung cancer screening results. The second was to develop new items specifically relevant to participants in lung cancer screening. **METHODS:** A randomised study of lung cancer screening was launched in Denmark in 2005. Five focus groups were held with 20 people (13 women and 7 men; mean age 60.0 years) who had received an abnormal screening result in the prevalence round and were recalled for a scan after 3 months. They discussed their thoughts and feelings after being recalled and after receiving the final false-positive diagnosis. They completed the COS and discussed its relevance to their own experiences. The face and content validity of new items developed after the focus groups was tested by means of interviews with 6 participants from the focus groups. **RESULTS:** The items in the COS were all relevant for lung cancer screening. Three themes were extracted from the audio-taped interviews. *Stigmatisation*, *Self-blame* and *Focus on symptoms*. Twenty-six new items for part I and 16 for part II of the questionnaire (COS-LC) were generated. **CONCLUSION:** There are many common psychosocial consequences of abnormal and