ent cost-containment policies, i.e. restriction for use of DES, along with the uncertainty surrounding the estimate.

**QUALITY OF LIFE I**

**QL1**

**AGREEMENT BETWEEN PATIENTS’ AND CLINICIANS-REPORTED OUTCOMES IN LIPODYSTROPHY (HIV/AIDS)

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**OBJECTIVES:** Lipodystrophy may greatly impair quality of life (QoL). Nevertheless, the recognition of the scientific value of QoL and more broadly the patient’s perspective in evaluating therapies is questioned. It may be useful to quantify the added value of the patient’s perspective, using correlations between patient-reported outcomes (PROs) and clinician-reported and biological outcomes.

**METHODS:** We performed a cross-sectional survey in 143 HIV French outpatients with lipodystrophy. Clinical and demographic data were collected. Patients completed a new specific lipodystrophy questionnaire “Assessment of Body Change and Distress” (ABCD), consisting of three parts: signs of lipodystrophy (six items), global satisfaction (n = 1) and 20 items evaluating QoL. An HIV specific (MOS-HIV) and generic (SF-12) QoL questionnaires were also filled-in.

**RESULTS:** Mean age was 43 ± 10yrs (71% of men), and mean duration of HAART was 4.5 ± 1.7yrs. ABCD QoL score is weakly or no associated with viral load (r = 0.03), CD4 count (r = 0.13) and CDC classification (p = NS). Its correlation with the clinician’s report of number of sites of lipodystrophy is weak (r = 0.17). Correlations between different PRO’s are logically higher. ABCD QoL score is more correlated with the patient’s report of number of sites of lipodystrophy (r = 0.39) and with satisfaction (r = 0.58). ABCD QoL score is correlated with health distress and social dimensions of the MOS-HIV (r > 0.6) and with mental component of the SF-12 (r = 0.65), but not with physical dimensions of these questionnaires (r < 0.2).

**CONCLUSIONS:** PRO’s are weakly correlated with biological markers, and although overlapping, each one of PRO’s measures a distinct concept. clinicians cannot infer the QoL of their patients neither from a viral load nor from a clinical exam. The patient’s perspective is essential in medical decision making and so it is with lipodystrophy.

**QL2**

**THE HEALTH RELATED QUALITY OF LIFE IN PARKINSON’S DISEASE IN GERMANY**

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**OBJECTIVES:** To prospectively evaluate the health-related quality of life of patients with Parkinson’s disease (PD) in Germany over a 12 months observation period. **METHODS:** The study included 145 patients with PD (mean age: 67.3 ± 9.6 years) in Germany. Patients were asked to complete the EQ-5D, Parkinson’s Disease Quality of life questionnaire (PDQL) and the Parkinson’s Disease questionnaire-39 (PDQ-39). In addition, the occurrence of depression and dementia were investigated using the Beck’s Depression Inventory (BDI) and the Mini-Mental-State-Examination (MMSE). Evaluations were performed at baseline, three, six and 12 months. Disease severity was documented by the Unified Parkinson’s Disease Rating Scale (UPDRS) and the Hoehn & Yahr (HY) scale.

**RESULTS:** At baseline mean VAS-value was 59.9 ± 18.0 and mean EQ-5D index was 0.74 ± 0.25. HRQoL of patients suffering from dyskinesias (47.5) were lower than in patients without dyskinesias (61.7). In HY-stage 1 mean VAS was 72.8 ± 16.9 yrs. V4 45.7 ± 10.6. At 12 months the overall PDQ-39 score declined slightly from baseline 29.4 ± 17.4 (n = 137) to 25.6 ± 16.2 (n = 128). Similar results were found for the PDQL overall score (118.6 ± 27.5 (n = 87) compared to 122.8 ± 26.1 (n = 72)) and the EQ-5D index (0.74 ± 0.25 (n = 115) compared to 0.74 ± 0.25 (n = 115). No significant changes were found for the clinical scores (UPDRS and Hoehn & Yahr scale) and the psychometric questionnaires (MMSE and BDI).

**CONCLUSIONS:** The PDQ-39, PDQL and the EQ-5D are instruments delivering stable test results for PD patients. There is no significant change during the 12-months observation period in all used instruments. As this study will have a follow-up up to three years a more detailed analysis of time-dependent changes of HRQoL will be possible. Depression and motor complications are the factors with the highest impact on health-related quality of life in PD patients.

**QL3**

**QUALITY OF LIFE OF GASTROESOPHAGEAL REFLUX DISEASE PATIENTS**

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**OBJECTIVES:** Gastroesophageal Reflux Disease is a chronic condition whose symptoms cause great impairment on a patient’s quality of life. Our aim was to evaluate GERD patients Health Related Quality of Life (HRQoL) and its association to clinical status. **METHODS:** A cross-sectional observational multicentre cost of illness study was conducted in the urban area of Milan. The study involved 317 patients (mean age 59 years, 58% female) sequentially enrolled by 47 General Practitioners. Information was collected investigating demographic, clinical, economic and quality of life variables. To assess QoL in GERD patients we used a generic (EuroQol) and a specific (Quality of Life in Reflux and Dyspepsia, QOLRAD heartburn version) questionnaire. We report on QoL data. **RESULTS:** A strong impairment in the HRQoL was documented both with EQ-5D and QOLRAD instruments. Patients reported an average value of 64.4 in the EQ-VAS, significantly lower compared to general population. The EQ-profile indicated that “pain/discomfort” and “anxiety/depression” were the most impaired domains. We converted the EQ-profile in economic utility score by means of values from UK and Catalonia. Using the UK conversion values we had a utility mean score of 0.70 (±0.23), using the Catalonia conversion values the mean score was 0.79 (±0.21). The EQ-VAS value significantly decreased with age, heartburn, epigastric pain, odynophagia, globus sensation, relapse of symptoms and with all the QOLRAD domains. The most impaired QOLRAD domain was “food/drink problems”, the less one was “physical/social functioning” with a mean value of 4.95 and 5.74 respectively (one worst, seven best imaginable health state). The internal consistency tested with Cronbach’s alpha was >0.8 for all domains. Results with QOLRAD were confirmed by those with EQ-5D. **CONCLUSIONS:** Conclusions: This is the first Italian study on quality of life of GERD patients visited by GPs, highlighting that this disease significantly impairs global patients’ HRQoL.

**QL4**

**PATIENT-RATED UTILITIES IN POSTMENOPAUSAL EARLY BREAST CANCER (EBC): A CROSS-COUNTRY COMPARISON**

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**OBJECTIVES:** To investigate the impacts of early breast cancer (EBC) on HRQoL, one of the main objectives of this study was to compare utility values reported in the United Kingdom (UK) with those of the Catalonia and Spain. These values were used to estimate costs of illness study was conducted in the urban area of Milan. The study involved 317 patients (mean age 59 years, 58% female) sequentially enrolled by 47 General Practitioners. Information was collected investigating demographic, clinical, economic and quality of life variables. To assess QoL in GERD patients we used a generic (EuroQol) and a specific (Quality of Life in Reflux and Dyspepsia, QOLRAD heartburn version) questionnaire. We report on QoL data. **RESULTS:** A strong impairment in the HRQoL was documented both with EQ-5D and QOLRAD instruments. Patients reported an average value of 64.4 in the EQ-VAS, significantly lower compared to general population. The EQ-profile indicated that “pain/discomfort” and “anxiety/depression” were the most impaired domains. We converted the EQ-profile in economic utility score by means of values from UK and Catalonia. Using the UK conversion values we had a utility mean score of 0.70 (±0.23), using the Catalonia conversion values the mean score was 0.79 (±0.21). The EQ-VAS value significantly decreased with age, heartburn, epigastric pain, odynophagia, globus sensation, relapse of symptoms and with all the QOLRAD domains. The most impaired QOLRAD domain was “food/drink problems”, the less one was “physical/social functioning” with a mean value of 4.95 and 5.74 respectively (one worst, seven best imaginable health state). The internal consistency tested with Cronbach’s alpha was >0.8 for all domains. Results with QOLRAD were confirmed by those with EQ-5D. **CONCLUSIONS:** This is the first Italian study on quality of life of GERD patients visited by GPs, highlighting that this disease significantly impairs global patients’ HRQoL.
OBJECTIVES: The purpose of this study was to estimate the preferences of postmenopausal women for disease states associated with EBC. METHODS: Preferences for relevant health states and demographic information were obtained from women aged 55–70 years in the UK and the USA with a history of stage one or two operable EBC and experience with adjuvant hormonal therapy. The 14 health states included in the study, which were compiled from literature and input from oncologists, reflected the major disease states of breast cancer and the adverse events reported in the ATAC trial (Cancer 2003; 98:1802–10). A chained standard gamble (SG) technique was used to compare health states to perfect and worst health (WH) and then WH against perfect health and death. WH values were used to rescale values (0 = death, 1 = perfect health). Poole and country-specific utilities were analysed and compared. RESULTS: A total of 67 subjects (UK = 23, USA = 44) successfully completed the SG interviews. There were few differences between country samples. For the pooled sample, mean age was 67.8 years, 49% were retired, 61% were living with someone, and 51% had arthritis. More US than UK women had received radiotherapy and/or chemotherapy. Raw WH values differed significantly between country samples (UK = 0.844, USA = 0.455; p < 0.001). Adjusted mean SG scores were 0.432–0.974 for the pooled sample, 0.710–0.989 for the UK sample, and 0.288–0.965 for the US sample. Mean current health values for the pooled, UK and US samples were 0.907, 0.933 and 0.893, respectively. CONCLUSIONS: The order of adjusted and unadjusted SG scores within each country was consistent, with the metastatic breast cancer and disease-free survival with no adverse events health states being the least and most preferred, respectively. When comparing utilities across countries, care must be taken in cases of significantly different WH values.

Session II

CARDIOVASCULAR II

THE COSTS AND EFFECTS OF CLOPIDOGREL IN COMPARISON TO ASA OR PLACEBO FOR SEVERAL PATIENT POPULATIONS IN DENMARK

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BACKGROUND: CAPRIE was an international randomized double blind trial comparing clopidogrel and ASA in patients with recent MI, stroke or PAD. Post-hoc analyses of the CAPRIE database identified three high-risk subgroups in which improved risk reductions were observed of clopidogrel compared to ASA.

OBJECTIVE: To estimate the long and short term costs and effects of clopidogrel versus ASA in Denmark in the prevention of ischemic events (MI, IS, VD) in three high-risk CAPRIE sub-populations: 1) patients with a history of coronary artery bypass grafting; 2) patients with a history of ischemic events, and 3) patients with multiple vascular territory involvement respectively. The comparison of clopidogrel to no treatment for the ASA intolerant patients resulted in DKK 3093 (€416)/LYG. Cost-effectiveness ratios of this order are generally considered acceptable in modern Western societies. Internal and external validity have been tested and were ascertained. CONCLUSION: Clopidogrel may be considered a cost-effective treatment for the prevention of subsequent ischemic events in high-risk patient populations and in the general CAPRIE-population with ASA intolerance in Denmark. Extensive sensitivity analyses confirmed that these results were stable over the entire range of assumptions.