OBJECTIVES: To estimate the cost-consequences of treating women for Stress Urinary Incontinence (SUI) with a pharmacological intervention—Duloxetine—from the perspective of the statutory health insurance in Germany. METHODS: A decision-tree was developed by a panel of clinical experts to model biannual cost-consequences of three treatment strategies: 1) initial Duloxetine treatment, followed either by continuation of Duloxetine, no further treatment or surgical intervention(s); 2) initial placebo treatment (physician visits), then no further treatment or surgical intervention(s); and 3) Standard treatment including surgical intervention(s). Pelvic Floor Exercises were considered in all arms. Model input for the first three months were taken from one phase 2 and three phase 3 placebo-controlled studies assessing the efficacy and safety of Duloxetine. 930 patients with moderate to severe SUI (Incontinence Episodes Frequency, IEF >= 14/week) were included in the analysis. Success of treatment was classified as “full response” (100% reduction in IEF) and “successful treatment but not dry” (50.0%-99.9% reduction in IEF). The likelihood of continuation of Duloxetine beyond three months was based on the patient’s perception of improvement as assessed by a validated questionnaire. Success rates for the considered surgical procedures were drawn from the literature and expert opinion. Diagnosis Related Groups (2004) for surgery and the Einheitliche Bewertungsmaßstab (EBM) (2003) for outpatient resource use were taken to derive costs. Placebo will not present an option in routine practice, but is presented because of the clinical trial design. RESULTS: Expected biannual costs per women are: Duloxetine treatment 2205€, placebo treatment 2034€, and 2092€ for standard treatment. Duloxetine generates a higher probability of avoiding surgery (36%), compared with placebo (24%) and standard treatment (20%). CONCLUSIONS: Treating SUI in women with Duloxetine leads to comparable costs to standard treatment. Model limitations include extrapolation of clinical trial data and parameter input by clinical experts.

LONG-TERM COST-EFFECTIVENESS MODELLING OF FEEDBACK MICROWAVE THERMOTHERAPY VERSUS DRUG TREATMENT IN PATIENTS WITH BENIGN PROSTATIC HYPERPLASIA AND LOWER URINARY TRACT SYMPTOMS

Hyggenbrand J1, Malmberg L2, Ragnarsson-Tennwall G1

1The Swedish Institute for Health Economics (IHE), Lund, Sweden
2Lund University Hospital, Lund, Sweden

OBJECTIVES: The purpose was to develop an economic model for simulation of the long-term cost-effectiveness of treatment with ProstaLund Feedback Treatment (PLFT) versus alpha-blockade in patients with benign prostatic hyperplasia (BPH) and lower urinary tract symptoms (LUTS). The model was applied using information about Swedish treatment practice.

METHODS: Data from published literature, treatment programs, and official Swedish price lists was used to develop a disease progression model for patients with BPH and LUTS according to the International Prostate Symptom Score (IPSS). Three important time-dependent features of disease progression were regarded in the model: 1) a phase where initial symptoms are reduced; 2) a stationary post-treatment phase; and 3) a phase where the probability of a re-intervention will increase. All the three phases could be adjusted in the model to capture differences in treatment effects between different treatment options. Costs and quality adjusted life years (QALY) were calculated for a period of three years and discounted at 3%. The calculations were made in Euro (2003 prices). A sensitivity analysis was performed where scenarios regarding baseline disease severity, treatment effects, time horizon, discount rate, age at initiation of treatment, QALY weights, and assumption about the probability of re-treatment were altered. RESULTS: The total three-year cost of PLFT (including re-treatment) and alpha-blockade was estimated to 2059€ and 1411€, respectively. According to the model PLFT would result in 0.07–0.10 more QALYs compared to alpha-blockade resulting in a cost-effectiveness ratio of €6600–9500. Due to lower future expected costs of PLFT compared to alpha-blockade the results indicate that PLFT would be cost-saving if the time perspective is extended to five years. CONCLUSIONS: According to the assumptions made in the model, PLFT is cost-effective compared to alpha-blockade. The main conclusion remained stable in the sensitivity analysis.

URINARY/KIDNEY DISEASES/DISORDERS

URINARY/KIDNEY DISEASES/DISORDERS—Quality of Life/Utility/Preference Studies

García-Mendoza M, Valdés C, Rebollo P, Ortega T, Ortega F

Hospital Universitario Central de Asturias Institute, Oviedo, Spain

OBJECTIVES: To prospectively evaluate the survival of patients <65 years who initiated hemodialysis (HD) in our region and to investigate factors associated with survival. METHODS: All patients < 65 years who started HD in our region between January, 2001 and September, 2002 and who remained in renal replacement therapy (RRT) at least 3 months were included and followed-up to March, 2004 (N = 78). Patients with severe cognitive deterioration were excluded (n = 1). The health related quality of life (HRQoL) was evaluated using the SF-36 Health Survey (Physical-PCS and Mental-MCS Component Summary Scores) and the Kidney Disease Questionnaire (Physical Symptom scale-PSS) at 3 months from start and at 1 and 2 years later. Sociodemographic and clinical data, the Karnofsky Scale score and a comorbidity index were also collected. SF-36 scores were standardized using the Spanish general population norms. Kaplan-Meier survival curves and Cox Proportional hazard regression model were used for the survival analysis. In order to adjust the effect of age on mortality the Relative Risk of Mortality (RRM) was calculated using the population rates. RESULTS: At the end, the 2-year survival rate was 88.3%, but the RRM fell progressively from 30 in the younger patients (34–43 years) to 6.33 in the older ones (55–64 years). Kaplan-Meier analysis showed that those with MCS lower than 40 at 3 months from start and those who had not received a kidney transplant at the second year of the follow-up had lower survival (p = 0.0074 and 0.0008 respectively). Cox Proportional hazard regression model with both variables showed that patients with MCS lower than 40 had higher mortality risk: hazard ratio = 6.94 (95%CI = 1.34–35.99) p = 0.021. CONCLUSIONS: Patients between 34 and 43 years showed higher RRM. The mental aspects of the HRQoL could have an important role in the survival of patients on RRT under 65 years.

ELDERLY PATIENTS STARTING RENAL REPLACEMENT THERAPY (RRT) HAVE LOWER LOSS OF HEALTH RELATED QUALITY OF LIFE (HRQOL) THAN YOUNGER ONES DURING THE FIRST TWO YEARS

García-Mendoza M, Valdés C, Ortega T, Rebollo P, Ortega F

Hospital Universitario Central de Asturias Institute, Oviedo, Spain

OBJECTIVES: There is already some degree of evidence about the greater capacity of adaptation to RRT of elderly patients vs. the
younger ones. The objective of the present study was to assess the differences between elderly and younger patients on hemodialysis. HRQoL was assessed using the SF-36 health survey at three, 12 and 24 months from the start of RRT. PCS, MCS and standardised scores by age and sex were obtained using Spanish general population norms. The results emphasize the importance of using, in comparative studies, specific scales for patients on dialysis.

CONCLUSIONS: Patients undergoing DP show similar status of general health as those of HD, but seem to have a better perceived health in several specific problems related with renal disease. Results emphasize the importance of using, in comparative studies, specific scales for patients on dialysis.

VALIDATION OF TWO QUESTIONNARIES ON SYMPTOMS AND QUALITY OF LIFE IN ITALIAN WOMEN WITH LUTS: THE FLOW STUDY

Simoni L1, Rizzi CA2, Santini A2, Sgarbi S1, Tubaro A1, Preziosio D1, Zattoni F1, Artibani W1, Pesce F1, Scarpa RM1

1MediData srl, Modena, Italy; 2Boehringer Ingelheim, Milan, Italy; 3Hospital S. Andrea, Roma, Italy; 4University “Federico II”, Naples, Italy; 5Az Osp. S. M. Misericordia, Udine, Italy; 6Policlinico G. Rossi, Verona, Italy; 7University of Torino, Turin, Italy

OBJECTIVES: No validated questionnaires are available for assessing symptoms and quality of life (QoL) in Italian women with lower urinary tract symptoms (LUTS). In a large multicentre observational study of women with LUTS (FLOW-Female LUTS: Observational Study in Women), we translated into Italian and validated the long and short forms of female-specific questionnaires (ICIQ-LF and ICIQ-SF). METHODS: The validation process consisted of forward and backward translation, test of comprehension, discriminant validity, test-retest reliability. A first set of women was interviewed after they had filled in the questionnaires. A comprehension rate was built as the percentage of correctly understood questions and pre-coded answers of all items by all patients. A case-control study was then performed. Cases were women aged >18 year affected by LUTS from at least 3 months and with negative dipstick. Controls were defined as healthy women of comparable age. All women were enrolled consecutively. In order to evaluate reliability, cases were retested after seven days and a correlation analysis was performed between the first and the second measurement (Pearson’s r). Discriminant validity was assessed by comparing the scores of cases and controls with ANOVA. RESULTS: The comprehension rate was 99.4% for ICIQ-LF and 99.1% for ICIQ-SF. Four out of 16 patients did not correctly understand 1 item (hesitancy) of ICIQ-LF, which was changed. Cases and controls were respectively 42 and 47 (ICIQ-SF), 80 and 61 (ICIQ-LF). All the ICIQ-SF patients were valuable for test-retest, while only 25 patients for ICIQ-LF. Pearson coefficient between ratings was >0.93 for 23 out of 48 items of ICIQ-LF and 0.86 for ICIQ-SF total score (p < 0.001). Cases and controls were discriminated at ANOVA (p < 0.001) with both questionnaires. CONCLUSIONS: These data show that ICI questionnaires are generally easy to understand, have a good to excellent reliability and a high discriminant validity.

EVALUATION OF TREATMENT OF FEMALE URINARY INCONTINENCE WITH THE ICIQ-UI SF QUESTIONNAIRE

Espuña-Pons M1, Rebollo P2, Puig M3

1Hospital Clinic i Provincial. Universidad de Barcelona, Barcelona, Catalonia, Spain; 2Hospital Universitario Central de Asturias, Oviedo, Asturias, Spain

OBJECTIVES: To evaluate the sensitivity to change of the Spanish version of the ICIQ-UI SF questionnaire, in order to recommend its use in clinical practice to evaluate treatment outcome for Urinary Incontinence (UI). METHODS: Prospective study of 115 women with diagnosis of Stress UI (SUI) who received treatment for their incontinence: Pelvic floor training (PFT) or surgery. All the patients had clinical and udynamic...