OBJECTIVES: Lower urinary tract symptoms (LUTS), such as detrusor instability or urinary retention, strongly impacts quality of life, involving economical aspects and social living. The aim of our investigation is to record changes in hospitalizations, urological, and general practitioner visits before and after sacral nerve stimulation therapy. Expenses for pads, catheters, and drugs are also investigated. METHODS: From February 2000 to September 2002 we enrolled 62 patients in the economic session of the Italian Sacral Nerve Modulation Registry (mean age 50 years old, from 22 to 70). Economic data was recorded in order to compare costs with clinical results of sacral nerve modulation therapy in patients with LUTS. In this group 41 were incontinent patients (61% female) mean age 53; 21 patients (71% female) mean age 46 had urinary retention. RESULTS: We performed a quarterly analysis, comparing the baseline data to the last follow up available (12 month). Visits to the general practitioner decreased from 1.1 to 0.05 (p < 0.01), visits to the urologist did not change significantly from baseline (1.5 to 1.2). Diagnostic tests decreased from 2 to 0.8 (p < 0.01). In the use of pads we observed a major change from 2.1/day (3 months expenses per patient of €120.96) to 0.5 (3 months expenses per patient of €28.8) (p = 0.08); For urinary retention the use of catheters decreased from 1.1 baseline (3 months expenses per patient of €178.2) to 0.1 at 12 months (3 months expenses per patient of €16.2) (p = 0.09). Drug consumption decreased significantly (p < 0.05) from €47.24 to €10.53. CONCLUSIONS: The reduction in daily consumption of pads and catheters (which is the major cost-driver of urinary disorders), but also the reduction of costs due to general practitioner visits, diagnostic tests, and drug consumption are significantly changed.

A COST ANALYSIS OF ALFUZOSIN IN THE MANAGEMENT OF ACUTE URINARY RETENTION

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OBJECTIVES: An important complication of Benign Prostate Hyperplasia, a bothersome condition of ageing men, is Acute Urinary Retention (AUR). This condition needs acute catheterisation and is a predisposing factor for surgery. Removal of the catheter is only possible in a minority of patients if no drugs are used. Alpha-blockers may increase the success rate of removing the catheter and decrease the need for future surgery. This study assessed the costs of treating patients with AUR with alfuzosin, watchful waiting or immediate prostatectomy in Belgium. METHODS: According to a randomised controlled trial (ALFAUR study) removing the catheter is successful in 47.9% of patients treated with watchful waiting and 61.9% of those treated with 3 days of alfuzosin (cost €0.92 per day). Based on the treatment path and immediate clinical outcome in the ALFAUR study, a medical decision model to compare the costs and health effects of the three possible strategies was built in Excel MS 2000, whereby follow-up results were obtained from epidemiological data. The cost of events was based on a patient chart review (n = 63) in patients with a first episode of AUR and conducted from the health care payer’s perspective. The time horizon of the model was 6 months. RESULTS: At 6 months, 32.3% of patients who initially voided successfully were re-hospitalised to undergo a prostatectomy. Six-month cost of patients treated with alfuzosin, watchful waiting and immediate prostatectomy were respectively €4175, €4758, and €6036. These results were robust under a wide range of plausible assumptions. CONCLUSIONS: Based on the current available clinical data, a very small investment (3 units of alfuzosin) can lead to important savings for the public health care payer by treating all patients hospitalised with AUR with alfuzosin. Further research on utilities in these patients is expected to strengthen this conclusion.

SURVIVAL IN END-STAGE RENAL DISEASE (ESRD) PATIENTS: ECONOMIC CONSEQUENCES OF THE LACK OF AUTOLOGOUS ARTERIOVENOUS FISTULAE (AVF) AT THE START OF HEMODIALYSIS

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AVF are recommended over catheters because they have lower morbidity and costs. OBJECTIVES: The aim was to evaluate the cost effectiveness according to patient’s survival and the difference caused by the delay of an adequate AVF implementation when starting periodical haemodialysis PHD. Pts included: all pts but 19 pts starting PHD during 1996–2000 (n = 133). One defined three groups of pts according to the time in having definitive AVF: Group 1 (G1) having an adequate functioning AVF before initiating PHD and it lasting at least three months (53%); G2 not having a AVF at the beginning of PHD, but in the first 3 months of the entrance in PHD (25%) and G3 being using catheters for more than 3 months (22%). Studied resources cost: the AVF execution and patient’s medical care, the mean hospital admissions (HA) and their mean length stay (LS), catheter cost and time of personnel as direct and indirect costs. Benefits were calculated evaluating patient’s survival and drugs were not included by the complexity and patient’s diversity. RESULTS: G1 were younger than G2 and G3, had lower infections and less attributable death, lower CI, less HA and LS. Total AVF costs were estimated in €3071. It could have been avoided about 11–15% because of catheter infections and 12 attributed deaths. So mean benefits could have been €5400 respect to G2 and €6860 to G3.
Keeping in mind that the benefits were measured by survival groups, the cost effectiveness was: €57/month of life for G1, 181 for G2, and 222 for G3. CONCLUSIONS: not having an adequate vascular access in order to start PHD, causes not only an important decrease of survival but more indirect costs as less benefit too.

**COMPARISON OF TACROLIMUS WITH CYCLOSPORIN IN KIDNEY TRANSPLANTATION: COST-MINIMIZATION AND COST-EFFECTIVENESS ANALYSES**

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**OBJECTIVES:** The costs associated with kidney transplantation are substantial, not only because of transplantation surgery but also due to the life-long need for immunosuppressive medication to prevent graft rejection. We analyzed the clinical and economic consequences of the use of the two baseline immunosuppressants, tacrolimus (Tac), and cyclosporin (CyA), currently administered in clinical practice. METHODS: A retrospective economic analysis was performed from a hospital perspective in Italy, Spain, and Germany. The analysis was conducted on the ITT-population comprising 557 patients from 7 European countries. Thus, the clinical and medical resource information for the pharmacoeconomic analysis was pooled multi-country data, the cost data was country specific. Costs were calculated on the actual resources used by each patient and assigned to the treatment group to which the patient was randomized. Direct medical resource use costs was covered over 6 months post transplantation. A local health economist collected cost information from published sources and personal interviews with clinicians. Costs were collected on study drug, concomitant medication, hospitalization, dialysis, and rejection episodes. To explore the impact of any variability of costs, a one-way sensitivity analysis was conducted. RESULTS: Six months after transplantation, patient survival was 99.3% (Tac) and 98.5% (CyA), p = 0.366; graft survival was 94.6% (Tac) and 91.9% (CyA), p = 0.139. The incidence of acute graft rejection was 32.5% (Tac) and 51.3% (CyA), p < 0.0001. Cost-minimization analysis revealed savings for tacrolimus (per patient) of €583–1874 for surviving patients, and €781–2305 for patients with functioning grafts. Tacrolimus was cost-effective for patients with rejection-free grafts; savings per patient were €4627–9919. The tacrolimus group consistently had lower total costs than the cyclosporin group. The cost advantages for tacrolimus were a result of lower overall hospitalization costs and lower incidences of dialysis and graft rejection. A sensitivity analysis regarding the main cost drivers (hospitalization, study drug, and concomitant medication) generally confirmed the robustness of this finding in all 3 countries.

**URINARY/KIDNEY DISEASES OR DISORDERS—Quality of Life Studies**

**COMPARISON OF THE PERFORMANCE AND DATA QUALITY OF ELECTRONIC AND PAPER DIARIES FOR BENIGN PROSTATIC HYPERPLASIA (BPH)**

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**OBJECTIVE:** Use of electronic data capture (EDC) in the assessment of patient status is increasing, however it must be determined how data collected electronically correlates with similar data collected using the standard “paper” method. Our objective was to compare paper and electronic administrations of a urinary voiding and symptom diary for use in a population with benign prostatic hyperplasia (BPH). METHODS: Using a crossover design, men aged 45–83 with a diagnosis of BPH and IPSS scores of 8 or greater were recruited from clinics. Subjects completed either the paper or electronic version of the diary (depending on randomized arm) for 7 consecutive days and then the opposing version for the following 7 consecutive days. Data quality was assessed for both versions. Intraclass correlation coefficients (ICC) and t-test comparisons were calculated to compare EDC and paper versions for the mean number of urinary events, symptoms, and severity of urgency. Ease of use, preference, and demographic items were also collected. RESULTS: A total of 28 subjects were assessed with 14 in each group. Mean age and IPSS for the total sample was 63.8 and 17.3, respectively. Data quality concerns were minimal with both versions. Mean differences in urinary events, symptoms and severity were not significantly different (p-values > 0.29, ICC > 0.70). Participants who took the electronic version first thought the paper version was considerably less convenient to keep with them and more difficult to use. The majority of the sample (64%) would prefer, if given a choice, the computerized version of the diary compared with 29% opting for the paper version (7% indicated no real preference for either). CONCLUSION: As in previous studies comparing electronic to paper assessments, this study revealed statistical evidence to support the use of EDC of a patient urinary diary. While some difficulties existed, the electronic version produced good data with low data management burden.

**“EFFECT SIZE” OF HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WITH CHRONIC ALLOGRAFT NEPHROPATHY AND ANEMIA TREATED WITH RH-EPO**

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