Keeping in mind that the benefits were measured by survival groups, the cost effectiveness was: €37/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.

**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 was costed 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 €781–2305 for months 7–12. Keeping in mind that the benefits were measured by survival groups, the cost effectiveness was: €37/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.

**RESULTS:**

<table>
<thead>
<tr>
<th>Country</th>
<th>Cost Savings (€)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Italy</td>
<td>781</td>
</tr>
<tr>
<td>Spain</td>
<td>2305</td>
</tr>
<tr>
<td>Germany</td>
<td>1,200</td>
</tr>
</tbody>
</table>

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.

**CONCLUSIONS:**

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 €781–2305 for survival 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)**

**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**

**OBJECTIVE:**

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.

**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.
OBJECTIVE: With the progression of the renal insufficiency (RI) produced in the chronic allograft nephropathy (CAN), the patients’ HRQoL worsens. The treatment of the anemia associated to the RI with rh-EPO improves the HRQoL. The objective of present study was to evaluate the HRQoL of kidney transplant patients with CAN and anemia associated to the RI, and the effect of the treatment with rh-EPO on the HRQoL. METHODS: Prospective study of 24 kidney transplant patients with RI caused by CAD and anemia who received rh-EPO to treat the anemia. The hemoglobin target was 12 gr/dL. HRQoL was evaluated with the SF-36 Health Survey at start treatment, 3 months later and at the end of follow-up. SF-36 scores (8 dimensions, Physical-PCS and Mental Component Summary-MCS) were standardized by age and gender using the Spanish general population norms. The “Effect Size” was also calculated for each dimension and for summary scores. RESULTS: Hemoglobin statistically improved from start to third month (p < 0.01). SF-36 scores of studied patients were worse than those of the general population and that those of a transversal sample of transplant patients with good renal function: PCS = 36.08 ± 12.83 vs. 48.68 ± 9.86; MCS = 47.16 ± 14.46 vs. 51.91 ± 10.25. Three SF-36 dimensions statistically improved with the correction of anemia with the rh-EPO treatment: Role Physical, Vitality and Mental Health. The “Effect Size” was very small for Physical Functioning and Pain and negative (NPV) predictive value with respect to clinical diagnostic and that of the urodinamic study were also calculated. RESULTS: Mean time of administration was 3 minutes. All patients answered all the items of the ICIQ-SF. According to clinical diagnostic, patients with UI showed higher score on the ICIQ-SF (11.6 ± 5.9) than women without UI (4.5 ± 6.3) (p = 0.000). The same occurs with the scores according to the urodinamic study (11.1 ± 6.3 vs. 6.2 ± 6.5; p = 0.000). A higher severity degree was associated to a higher score on the ICIQ-SF: low degree (10.47 ± 5.61) vs. intermediate (12.4 ± 5.72) vs high degree (13.61 ± 5.42). Cronbach’s alpha was 0.89. The values of Se, Sp, PPV and NPV were 92.1%, 55.6%, 88.3% y 65.9% with respect to clinical diagnostic and 87.7%, 40.8%, 85.1% y 46.2% with respect to the urodinamic study. CONCLUSIONS: This is the first questionnaire design for diagnostic of UI validated in Spain. The psychometric properties of the ICIQ-SF are satisfactory and allow to recommend the use of the questionnaire in the clinical practice.

VALIDATION STUDY OF THE SPANISH VERSION OF THE ICIQ-SHORT FORM. A USEFUL INSTRUMENT IN DETECTING URINARY INCONTINENCE

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OBJECTIVE: A great proportion (50–70%) of patients with urinary incontinence (UI) do not ask for medical advise. Symptom questionnaires may help in detecting the UI. The objective of present study was to analyze the psychometric properties of the Spanish version of the questionnaire of UI symptoms “ICIQ-SF”. METHODS: A total of 500 women who consulted at a UI-specialized unit answered the questionnaire. Urodynamic study was carried out, and sociodemographic and clinical data were also collected including the symptoms expressed by the patients. So there were two diagnostic tools for the assessment: clinical and that of the urodinamic study. Feasibility, validity (comparing the scores between groups according to both diagnostic methods, between groups of different sort of UI and between groups of different severity degrees) and reliability (Cronbach’s alpha) were assessed. Sensitivity (Se), specificity (Sp), positive (PPV) and negative (NPV) predictive value with respect to clinical diagnostic and that of the urodinamic study were also calculated. RESULTS: Mean age = 66.8 ± 13.1 years (elderly 71.2%); 56% men. The main analytic and clinical parameters did not change after one year: hemoglobin = 11.5 ± 1 versus 11.1 ± 1.5 gr./dL.; Albumin = 3.6 ± 0.2 versus 3.6 ± 0.4 gr./L.; Creatinine = 8.13 ± 2.39 versus 7.87 ±