low protein diet is cost effective relative to no-treatment in an Italian setting. Further studies should test this model in other countries with different dialysis costs and dietary support.

Puk23 Assessing the likely cost-utility of alemtuzumab versus rabbit anti-thymocyte globulin as induction therapy for high-risk kidney transplant recipients

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OBJECTIVES: Induction therapy is administered at the time of kidney transplantation to prevent acute rejections. The agent of choice depends on the degree of patient risk for acute rejection. In the US, rabbit anti-thymocyte globulin (rATG) is the standard agent administered to high-risk patients. A monoclonal antibody approved for use in chronic lymphocytic leukemia—alemtuzumab—has been shown in label-exceeding studies to have a lower incidence of acute rejection (IT) after kidney (KT) transplantation. Furthermore, alemtuzumab costs less, making it a potentially cost-effective alternative. Nevertheless, practitioners have been slow to adopt alemtuzumab as an induction agent of choice due to concerns that it may be less effective than rATG in improving long-term outcomes. The objective of this study is to estimate the incremental cost-effectiveness ratio (ICER) of alemtuzumab versus rATG in high-risk patients.

METHODS: A decision-analytic model was constructed to model costs and outcomes specific to the first 12 months post-transplantation, such as for delayed graft function and acute rejection, long-term (30-year) outcomes were estimated with a Markov model with outcomes measured in life years (LYs) and quality-adjusted life years (QALYs). Clinical probabilities were obtained from randomized controlled trials, preference weights from direct patient measures in previously published literature, and costs from previously published cost-effectiveness studies on kidney transplantation. RESULTS: In the base case, alemtuzumab was projected to yield 1.18 LYs and 1.09 QALYs gained when compared with rATG. The estimated ICER of alemtuzumab compared to rATG was $5,366 per QALY. Sensitivity analysis revealed that the ICER was most sensitive to changes in patient risk to graft rejection. CONCLUSIONS: Alemtuzumab was cost-effective across all parameter ranges, with the greatest ICER being $21,133.

Puk24 Cost-utility analysis of sacral neuromodulation versus botox in the treatment of overactive bladder in Colombia

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OBJECTIVES: A comparison of the cost-utility of Sacral Neuromodulation (SNM) vs botulin toxin type A (BotoxNTA) in Overactive Bladder (OAB) treatment in Colombia. METHODS: Through the adaptation of an HTA Consulting economic model and after data transference analysis, a cost-effectiveness analysis of SNM vs BotoxNTA 100UI in the treatment of OAB in Colombia was done. The model was constructed as a Discrete Event Simulation. The effectiveness data of SNM and BotoxNTA, defined as more than 50% improvement in urinary parameters, was based in systematic search for health-related quality of life data, and one health state transition probabilities to graft loss and death. Despite these variations, the treatment with SNM obtained yield an ICER below often-cited thresholds.

Puk25 Understanding MID for micturition frequency, a pivotal endpoint in clinical studies

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OBJECTIVES: Although pivotal studies of overactive bladder (OAB) medications frequently report micturition frequency (MF) as a primary or co-primary endpoint, few studies have examined minimal important difference (MID) values for this parameter. This study explored MID values for MF using data from a Phase IIb study in OAB patients with urge predominant incontinence along with estimates for OAB symptoms of urgency urinary (UUI), urgency incontinence (UII), and total incontinence (TI). METHODS: The endpoint was defined as the change from baseline to 8 weeks in the number of daily episodes averaged over a diary week for each parameter. Anchor- and distribution-based methods using statistical criteria (e.g. half standard deviation) were used to estimate MID ranges for all parameters. Anchors were selected as a +1 change score representing slight improvement, and data from the Phase IIb study were used to estimate MID values for MF. RESULTS: The sample included 769 OAB patients with (80.4%) and without (19.6%) incontinence. The baseline mean number of micturitions was 11 and the mean (±SD) change from baseline representing the MID for MF ranged from 2.4-2.5 (42.7-47.2%), respectively. For total incontinence, the baseline and mean (±SD) change was 3 and 1.5-1.7 (64.3-76.2%), respectively, with similar values for UUI. Distribution-based values were much smaller than those derived using anchor-based methods. CONCLUSIONS: The mean changes representing MID estimates for micturition frequency were comparable to those observed for incontinence but constituted smaller percent changes given the larger number of patients reporting incontinence.

Puk26 Immunossuppressant Therapy in Kidney Transplant Recipients

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OBJECTIVES: Adherence to immunosuppressive therapy after kidney transplantation is crucial to avoid graft rejection and optimize long term patient and graft survival. However, patient’s adherence is not always optimal. Our aim was to identify reasons for non-adherence and health-related quality of life (HRQoL) dimensions affected by immunosuppressant therapy (IT) after kidney transplantation including patient preference of once daily over twice daily immunosuppressive regimen. METHODS: A literature review on adherence to immunosuppressant therapy (IT) and impact of IT on HRQoL through the Embase database was performed. RESULTS: The results showed that non-adherence was mostly unintentional among the participants. The reason for non-adherence included forgetfulness, interference with lifestyle, being asleep at the time the medication should be taken, change in routine and side effects. The twice daily regimen was more problematic in relation to adherence. Overall, participants were of the opinion that a once daily IT regimen would help them be more adherent. Also, IT impacts on the HRQoL of the patient in a number of ways including: restricting the patients’ lifestyle, causing anxiety or impairing the patient’s ability to work. Although the patients happily obliged to the necessity of taking IT medication, patients preferred to reduce the burden associated to the administration of IT. Sensitivity analysis of this study suggested that patients strongly valued adherence to IT medication and saw a change in the regimen from twice daily to once daily as one way to improve their adherence to IT. Results also suggested that a once-daily regimen could improve patient’s HRQoL.
Objectives: Both generic and disease-specific measures can be a useful strategy for assessing HRQoL outcomes. This post-hoc analysis evaluated the ability of the generic EQ-5D-3L instrument and the OAB-5D disease-specific instrument, to assess changes in men with LUTS/BPH who have moderate-to-severe storage symptoms and voiding symptoms treated with fixed-dose combination (FDC) of solifenacin 6mg + oral controlled absorption system [OCAS™] formulation of tamsulosin (TOCAS, 0.4mg), TOCAS monotherapy, or placebo.

Methods: Data were available from a 12-week clinical trial (NEPTUNE). Patients completed the OAB-5D and EQ-5D-3L (including EQ-VAS) instruments. Analyses controlled for relevant patient characteristics. Analysis of covariance estimated and compared changes from baseline at each time point for EQ-5D-3L, EQ-VAS and OAB-5D.

Results: Statistically significant differences were seen in OAB-5D utilities with TOCAS monotherapy and FDC solifenacin 6mg + TOCAS compared with placebo after 4, 8 and 12 weeks in the overall population. When patients reporting full-health on EQ-5D-3L at baseline were excluded from the analysis to reduce the ceiling effect, the improvement from baseline (Δ0.101 for FDC solifenacin + TOCAS) with EQ-5D-3L was 1.5 fold greater than the minimally important difference of 0.074.

Conclusions: This analysis indicates EQ-5D-3L captures several improvements in HRQoL resulting from treatment of LUTS/BPH with FDC solifenacin 6mg + TOCAS. However, OAB-5D shows larger and more consistent statistically significant differences between placebo and the treatment arms, and could be considered an appropriate alternative to EQ-5D utilities in health economic modelling.