2-HOUR POST DOSE (C2) MONITORING VERSUS TROUGH (C0) MONITORING OF NEORAL: AN ECONOMIC EVALUATION
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OBJECTIVES: Monitoring of Neoral by 2-hour post-dose cyclosporine (CsA) levels (C2) is an accurate measure of CsA absorption efficiency and exposure. It is superior to trough (C0) monitoring for prediction of rejection risk and for targeting optimal CsA doses. Our goal was to assess potential economic benefits of C2 monitoring by the use of an economic model.

METHODS: Parameter estimates for key clinical events were derived from two cohorts containing 296 patients for C2 monitoring and 204 for C0 monitoring. An economic model was developed to calculate treatment costs according to different clinical outcomes. This multiple regression model is based on resource utilization records of kidney transplanted patients at Medizinische Hochschule Hannover.

RESULTS: The incidence of clinically confirmed acute rejection (CAR) at 3 months post-transplant was 28.2% for patients monitored by C0 and 15.3% for C2. Delayed graft function (DGF) and graft failure occurred in 32.4% and 4.4% of the C0 population and 36.5% and 4.9% of the C2 population, respectively. These events resulted in a highly significant increment on 3-months treatment costs, i.e. 542€ (DGF), 636€ (CAR) and 14,117€ ( graft failure) compared to problem-free patients. Average direct three-months treatment costs were 22,583€ for C0 and 20,650€ for C2 cohorts.

CONCLUSION: Use of C2 monitoring produces not only clinically important benefits but also provides an estimated saving of 1933€ during the first 3 months after transplantation. Therefore, C2 promises to be a superior patient management strategy over C0 monitoring. The model developed allows a preliminary assessment of the short-term economic impact of C2 monitoring.

EVALUATION OF THE COST UTILITY OF SIROLIMUS VERSUS TACROLIMUS FOR IMMUNOSUPPRESSION FOR RENAL TRANSPLANTATION IN THE UNITED KINGDOM
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OBJECTIVES: Immunosuppressive therapy is required to prevent graft rejection. Older medicines such as tacrolimus are paradoxically toxic to the kidney, whereas newer therapies such as sirolimus (Rapamune) are not. The purpose of this study was to evaluate the relative cost-utility of sirolimus versus tacrolimus in the UK.

METHODS: A stochastic simulation model was constructed using clinical trial and real-life data comparing the two treatments. Time duration was up to 20-years, 2003 prices, discounted at 6% for costs and 1.5% benefits and from an NHS perspective. Simulated events included patient and graft survival, haemodialysis, peritoneal dialysis, re-transplants and acute rejection. Costs were summed for events and various maintenance therapies. Utility was differentially accredited depending upon survival using the alternative renal replacement therapies. Outcome was predicted using post-transplant creatinine levels up to 3-years. Extensive statistical economic analysis and sensitivity analysis was undertaken.

RESULTS: Extensive validation demonstrated that the simulation was very reliable. Over the 10-year horizon, sirolimus gained 0.58 yrs (discounted) of functionig graft over tacrolimus, resulting in an incremental cost per year of functioning graft that was dominant (ICER was calculated at −£39,576). Over a 20-year time horizon cost effectiveness of sirolimus over tacrolimus further improved with an average discounted gain in years of a functioning graft of 1.5 yrs, resulting in an incremental cost-utility that was dominant (ICUR =£46,695). The number of haemodialysis events was 48,243 on sirolimus versus 127,829 on tacrolimus and peritoneal dialysis events 40,872 versus 105,249, respectively. Sirolimus remained dominant over tacrolimus under all scenarios. These findings were robust using statistical economic analysis and sensitivity analysis.

CONCLUSIONS: Sirolimus was far more cost effective than tacrolimus and was economically “dominant”. The magnitude of this difference indicates that this finding is likely to be geographically generalisable.

A HEALTH ECONOMIC EVALUATION OF 6 MONTHS ALFUZOSIN TREATMENT IN THE MANAGEMENT OF ACUTE URINARY RETENTION
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OBJECTIVES: An important complication of Benign Prostate Hyperplasia is Acute Urinary Retention (AUR). This condition needs acute catheterisation and is a predisposing factor for surgery. Subsequent removal of the catheter is only possible in a minority of patients. Moreover, after removing the catheter the long-term prostatectomy rate is considerable. Alfuosin increases the success rate of catheter removal, and may decrease the need for future surgery. This study assessed the cost-consequences of treating patients with AUR with alfuosin, watchful waiting or immediate prostatectomy from the perspective of the National Health Service (NHS) in the UK.

METHODS: Starting from the treatment path and the immediate and 6-month clinical outcome of the trial programme “ALFAUR”, a medical decision model to compare the cost-consequences of watchful waiting, immediate prostatectomy and alfuosin treatment was built in Excel MS 2000. The time horizon of the model was 6 months. Cost data were obtained from the NHS and resource use data gathered alongside the clinical trial. A Monte Carlo analysis, allowing variability in all uncertain parameters of the model, was performed to calculate the uncertainty surrounding the results. The unit cost of alfuosin was £0.79. Patients were continued on alfuosin for 6 months if the catheter was removed successfully.

RESULTS: Treating patients with alfuosin during initial hospitalisation for AUR and during the 6 months of follow-up after successful catheter removal generates a cost-saving of £330 (CONF INT) relative to placebo and £892 (CONF INT) relative to immediate prostatectomy. Both savings are statistically significant. Alfuosin treatment was associated with a lower rate of prostatectomy after discharge with a successful catheter removal.

CONCLUSIONS: Treating all patients hospitalised with AUR with alfuosin decreases the need for surgery and leads to important savings for the public health care payer. Future studies should explore the QoL outcomes of the different strategies.

COST-CONSEQUENCES OF TREATING WOMEN WITH STRESS URINARY INCONTINENCE WITH DULOXETINE FROM THE PERSPECTIVE OF THE STATUTORY HEALTH INSURANCE IN GERMANY
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OBJECTIVES: To estimate the cost-consequences of treating women for Stress Urinary Incontinence (SUI) with a pharmaceutical 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; 2) initial placebo treatment (physician visits), then no further treatment or surgical intervention; 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.