tension and glaucoma. Validation is currently underway to examine the psychometric properties of the EDSQ questionnaire.

NEUROLOGICAL DISORDERSE

META-ANALYSIS OF THE EFFICACY AND TOLERABILITY OF PRAMISEPOXLE AND ROPINROLE IN RESTLESS LEGS SYNDROME (RLS)

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OBJECTIVES: In the absence of comparative trials, to perform a direct and indirect meta-analysis of the efficacy and tolerability of pramipexole (PPX) and ropinrole (RPR), both widely approved treatments in RLS. METHODS: Clinical trials were identified from a systematic search and clinical reports. Study inclusion criteria: studies in idiopathic RLS, randomized, double-blind, placebo-controlled, parallel group, primary endpoint: International Restless Legs Rating Scale (IRLS). Pre-specified analyses were: fixed and random-effects models for direct comparisons and a Bayesian approach for the indirect comparison, PPX vs. RPR, using placebo as the common comparator. Non-inferiority of PPX vs. RPR was tested first and then superiority. Efficacy criteria were: IRLS mean change from baseline and percentage of responders on the Clinical Global Impressions-Improvement scale (CGI-I). Tolerability criteria were: incidence of withdrawal and incidence of AEs occurring in >5% of patients. RESULTS: Two trials were eligible for inclusion for PPX (n = 689) and three for RPR (n = 931). The direct meta-analysis, using random-effects model, confirmed superior efficacy for both treatments vs. placebo measured as change on the IRLS (PPX: −5.5; 95% CI: −7.7; −3.2; RPR: −3.2; 95% CI: −4.3; −2.1) and for the CGI-I (PPX: OR = 3.0; 95% CI: 2.1; 4.3; RPR: OR = 2.0; 95% CI: 1.5; 2.6). Compared to placebo the incidence of nausea was significantly higher for PPX (p < 0.01), whereas dizziness, nausea, somnolence and vomiting were significantly higher for RPR (all p < 0.01). The Bayesian indirect comparison showed a superior reduction on the IRLS for PPX vs. RPR of -2.3 points, and an OR = 1.5 for the CGI-I responders. The superior reduction on the IRLS, the higher CGI-I responder rate and the reduced incidence of nausea and vomiting for PPX vs. RPR were observed with a probability of 99.7%. CONCLUSIONS: Results of the indirect meta-analysis were in favour of PPX vs. RPR for IRLS and CGI-I and for the tolerability outcomes nausea and vomiting.

ESTIMATING THE BUDGET IMPACT OF LEVETIRACETAM AS ADJUNCTIVE THERAPY IN CHILDREN WITH REFRACTORY PARTIAL ONSET SEIZURE IN THE UK

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OBJECTIVES: With about 33 million children affected worldwide, epilepsy is a common neurological disorder creating significant socio-economic costs. This study aims to estimate the additional costs or savings generated by the introduction of levetiracetam for refractory partial onset seizure (POS) in paediatric patients in the UK. METHODS: A budget impact model was built from the UK NHS perspective, for a 5-year time period. Levetiracetam adjunctive therapy was compared with standard treatments (ST): lamotrigine, oxcarbazepine, valproic acid, carbamazepine and topiramate. Epidemiological paediatric population data such as prevalence of refractory POS cases were obtained from the published literature and combined with UK population projections for 2005 from official statistics sources. Patients on levetiracetam were divided into three groups: new, existing and withdrawing patients to reflect the progressive adoption of the treatment. The cost of medications and hospitalizations were included and expressed in 2005 UK£. RESULTS: During the first year, the number of paediatric patients with refractory POS was estimated to be 7205. The annual cost per patient for current ST was £1593, resulting in a total budget of £11.5 million. Within the next five years, the number of paediatric patients will increase to 7267, resulting in a total budget of £11.6 million. Adding levetiracetam to ST increased the yearly drug costs by £1089 per patient. This additional cost was partly offset by lower hospitalization costs (£332 and £815 per patient for levetiracetam and ST respectively). Introducing levetiracetam resulted in a budget increase to £11.7 million (+1.8% compared to current budget) during the first year and £12.1 million (+4.7%) over the next five years. CONCLUSION: Levetiracetam as adjunctive therapy in paediatric patients with refractory POS is predicted to result in a modest increase in UK NHS paediatric epilepsy expenditure of 4.7% within a 5-year time period.