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OBJECTIVES: To characterize patients suffering from restless legs syndrome (RLS) and assess their annual health care resources consumption in comparison with a population of average ambulatory patients seen by General Practitioners (GPs), in France. METHODS: This study was based on anonymous individual longitudinal medical records of adult patients suffering from RLS provided by physicians from a permanent panel of representative French GPs. RLS was defined accordingly to established diagnostic criteria. Patients with at least one complaint of legs and/or sleep symptoms suggestive of RLS in 2003 were included. Data about patients' socio-demographic characteristics, clinical status, medical resources consumption and sick leaves over one year were collected retrospectively. For the cost comparison, RLS patients were matched for sex and age to a corresponding random population of patients followed by the same GPs. Average annual costs in € were estimated from the perspective of Health Insurance. RESULTS: A total of 515 RLS patients were included. Mean age was 63.8 years and 76% were female. 14% of patients had both complaints of leg and sleep symptoms, 59% only leg troubles and 27% only sleep disturbances. All together, RLS patients consumed significantly (p < 0.0001) more health care resources than those from the comparison group. On average in 2003, they saw 11.6 times their GPs (versus 4.6 in the comparison group), 7 investigations were prescribed (versus 4.3) and they had had 46.8 drug prescriptions (versus 16.5). The mean annual medical cost of RLS patients' follow-up by GPs was twice higher than that of average consulting patients (840€ versus 391€, p < 0.0001). CONCLU-SIONS: This study shows that patients satisfying to validated diagnostic criteria consumed significantly more medical resources than "ordinary" patients in primary care bearing in mind that RLS remains an unknown and under-diagnosed condition. This population deserves thus a special attention in order to optimize the treatment.

PNL14

THE COST-EFFECTIVENESS OF TREATING PATIENTS WITH RESTLESS LEGS SYNDROME (RLS) USING ROPINIROLE Moore AP¹, Lloyd A², Scott DA², Connolly M³, Dixon S⁴

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OBJECTIVES: Idiopathic RLS (Ekbom syndrome) is a sensorimotor disorder that leads to disrupted sleep and poor quality of life. Until now, there have been no internationally approved treatments for this disorder. This study evaluated costs and outcomes resulting from the use of ropinirole in patients with RLS. METHODS: Data were combined from 553 patients enrolled in two matching, pivotal, randomized, 12-week, double-blind, placebo-controlled studies. Patients with moderate-to-severe RLS received ropinirole or placebo, with a maximum allowable dose of 4 mg/day. The primary outcome measure was the International Restless Legs Scale (IRLS). IRLS scores at baseline and study endpoint were mapped to the multi-attribute utility instrument EQ-5D based on expert opinion to derive Quality-Adjusted Life Years (QALYs). Costs of study drug, concomitant neurological medications and cost of adverse events were applied in the model from the perspective of the UK NHS. Lower cost per QALY gained indicates better cost-effectiveness. RESULTS: Based on combined analysis of the entire treatment population over 12 weeks, the QALYs gained for ropinirole and placebo were 0.095 (0.082-0.106) and 0.075 (0.063-0.086), respectively. The mean costs per patient for ropinirole and placebo were £210.52 (£197-£223) and £42.34 (£34-£53), respectively. The incremental QALYs and costs were 0.020 (0.002-0.037) and £168.18 (£150-£187), respectively, resulting in an incremental cost per QALY of £8405 (£4557-£41,524). Extrapolation of IRLS scores at trial endpoint to 52 weeks improved the incremental QALY to £6748. For patients reporting more severe sleep disturbance or more severe symptoms at baseline, the cost-effectiveness ratios improved to £5810 (£3210-£20,177) and £4587 (£2881-£10,508), respectively. CONCLUSIONS: In the absence of an active-treatment comparator, this analysis found that treatment of moderate-to-severe RLS with ropinirole is cost-effective compared with placebo using conventional UK cost-effectiveness standards, particularly in patients with more severe sleep disturbance and severe RLS symptoms at baseline.

PNL15

RETROSPECTIVE EVALUATION OF THE DOSE OF DYSPORTÒ AND BOTOXÒ IN THE CLINICAL MANAGEMENT OF CERVICAL DYSTONIA OR BLEPHAROSPASM—THE REAL DOSE STUDY EXPANSION—COST CONSIDERATIONS BASED ON DRUG START

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OBJECTIVE: Assess utilization of Dysport and BOTOX for cervical dystonia and blepharospasm and compute the cost consequences of toxin selection. METHODS: Six European study sites abstracted drug utilization data from the records of their patients who had received Dysport then BOTOX or BOTOX then Dysport in a drug crossover that occurred in clinical practice. To reduce potential selection bias and confounding variables, patient records were screened for study inclusion/exclusion criteria during scheduled clinic visits. Patients were screen-qualified if they were 18 years of age, medically stable, responsive to persistent toxin therapy for 1 year before and after drug crossover, did not receive other medications that affect neuromuscular transmission, and were not involved in another drug study. **RESULTS:** A total of 132 screen-qualified patients were assessed. Ratios of mean dose (units) Dysport: BOTOX ranged from 2:1 to 11:1, with 88% of patients greater than or equal to 3:1, regardless of study site or direction of drug crossover. When current UK pricing for BOTOX and Dysport is applied to distribution of ratios, patients started on Dysport and switched to BOTOX (N = 94) result in an incremental net savings of £1572.4 or an average savings of £16.7 per patient. When patients were started on BOTOX and switched to Dysport (N = 38), an incremental net cost of £252.9 or an average cost of £6.7 per patient is realized. CONCLUSION: BOTOX utilization likely leads to net cost savings compared with Dysport based on utilization and current pricing for the UK.

PNL16

A COMPARATIVE STUDY ON RESOURCE USE, COSTS AND CAREGIVER BURDEN BETWEEN RASAGILINE AND ENTACAPONE IN FLUCTUATING PARKINSON'S DISEASE (PD) PATIENTS

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OBJECTIVES: To compare the costs of PD when using rasagiline and entacapone to treat patients that experienced motor fluctuations. **METHODS:** An 18-week randomised double-blind controlled clinical trial (RCT) LARGO, evaluating the safety and efficacy of rasagiline 1 mg/d, entacapone 200 mg with levodopa