[P7.304] First 1-year Real-life Study to Assess Management of Augmentation of Restless Legs Syndrome by Switching to Rotigotine Transdermal System

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OBJECTIVE: To assess effect of switching to rotigotine transdermal system on severity of restless legs syndrome (RLS) in patients who experienced augmentation with prior oral dopaminergics.
BACKGROUND: Augmentation (worsening of RLS symptoms) can be a major complication of long-term dopaminergic therapy. Clinical studies indicated low augmentation rates with rotigotine (only long-acting dopaminergic approved for RLS). Transdermal delivery maintains stable plasma levels over 24h.
DESIGN/METHODS: AURORA (NCT01386944) was a 13-month non-interventional study. Patients with moderate-to-severe RLS and augmentation with oral dopaminergics were switched to rotigotine (physician's independent decision). Primary outcome: Clinical Global Impression severity score (CGI-1). Secondary: treatment regimen for switch. Other: RLS-6, International RLS Rating Scale (IRLS), Augmentation Severity Rating Scale (ASRS), adverse events (AEs). Study completers were assessed for effectiveness.
RESULTS: 102 patients enrolled, 99 (mean age±SD:64.2±11.1 years; female:68) received rotigotine. 46 patients completed the study; 3 were excluded from effectiveness analyses due to concomitant Parkinson's disease. Most common discontinuation reasons: AEs (26 [primarily application site reactions: ASR]), lack of efficacy (14); 8 patients lost to follow-up. Among 43 completers, prior dopaminergics were: benserazide/levodopa (19); pramipexole (19); ropinirole (7); carbidopa/levodopa (2); levodopa (1). Mean±SD baseline CGI-1 was 5.3±0.7; median change in CGI-1 was -2.0[-2.5,-1.5] (Hodges Lehman estimate [95%CI]). 16/43 patients were CGI-1 responders (≥50% improvement). 5 patients switched to rotigotine after >1-day drug holiday, 23 switched overnight, 9 had overlapping switch, and 6 received ongoing oral dopaminergics with rotigotine on Day 28. RLS-6 decreased with rotigotine. Mean±SD change in IRLS:-12.7±7.5. At final visit, patients had median ASRS=0 (i.e. no worsening/occurrence of augmentation); mean±SD:1.2±2.7. AEs: ASR (33), nausea (13), fatigue (9), depression (7), headache (6).
CONCLUSIONS: Switching to 24h therapy with rotigotine (continuous dopaminergic stimulation) was effective in improving RLS severity among severely affected patients who tolerated rotigotine and remained on therapy for 13 months.
Study Supported by: UCB Pharma
Category - Sleep: Sleep Related Movement Disorders and Restless Leg Syndrome

Session: P7: Poster Session VII: Sleep: Restless Legs and REM Disorders (2:00 PM-6:30 PM)
Date/Time: Thursday, April 23, 2015 - 2:00 pm