Adjustable topical compression foot wrap, is more effective than a dopamine agonist, ropinirole, in reducing the symptoms of moderate to severe restless leg syndrome

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The objective was to measure the reduction of symptoms with an adjustable topical compression device (RESTIFFIC™ Brand Pressure Application System; Lake Erie Research Institute, Inc., Girard, PA, USA) of the foot in patients suffering with moderate to severe Willis-Ekbom disease [restless leg syndrome (RLS)].

We designed an experimental study: a single arm, open label single center clinical trial with a repeated measures design conducted from April 2009 to August 2012. Follow-up averaged 1.3 years.

Forty-seven patients were enrolled, 11 were excluded, 7 withdrew, one with usable results. 30 otherwise healthy adults, 22 women and 8 men, mean age 51.5 years, (range 30 to 75 years) diagnosed with moderate to severe primary RLS met eligibility criteria. Each patient was provided a pair of the RESTIFFIC™ devices that applies targeted compression to the abductor hallucis and the flexor hallucis brevis muscles in the foot when worn during rest and sleep. Main measure, patient-generated International RLS study group (IRLSS) rating scale; secondary measure, physician-generated clinical global impression (CGI) scale. Patients were surveyed at period 1: baseline (no device) Day 1-7, 3 times per period; period 2: with device Days 8-28, 8 times per period; period 3: without device Days 29-35, 3 times per period; period 4: with device Days 36-56, 8 times per period. Meta-analysis used to compare RESTIFFIC™ to historic reports of ropinirole and placebo pill. Demographics, disease severity assessment tools are similar among studies.

RESTIFFIC™ IRLSS score decreased from 25.05±5.33 (a mean baseline on the Day 1) to 7.83±6.33 (a mean score on Day 56), overall reduction of 17.22±6.16 (P=0.0001) representing two levels of improvement from *severe* to *mild*. Change in mean IRLSS scores were significantly greater for RESTIFFIC™, 17.22, compared with historic reports of ropinirole, 12, and its placebo, 8.9 (P<0.05).

CGI responders were significantly increased for RESTIFFIC™, 90% (27/30), compared with ropinirole 63% (293/464) (P<0.05). Only minimal, transient side effects were reported that were relieved by loosening the straps.

RESTIFFIC™ was 1.44 times as effective as historically reported ropinirole in reducing IRLSS scores. RESTIFFIC™ represented a marked improvement over current pharmaceutical solutions in both efficacy and safety.

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