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A single center, open, non-controlled pilot investigation to evaluate the effects of intermittent negative pressure on spasticity and concomitant pain in patients with multiple sclerosis

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Introduction: A novel non-invasive medical device applying intermittent negative pressure (INP) to the lower leg have shown promising effects on spasticity and pain in single patients with multiple sclerosis (MS).

Aims: To assess the safety and potential clinical benefit of INP treatment on spasticity, pain, and quality of life in patients with MS.

Methods: This was a prospective, non-controlled clinical pilot investigation of patients diagnosed with MS with spasticity and concomitant pain. Patients with a numeric rating scale (NRS) reported spasticity ≥ 4 , combined with pain in the lower extremities were included. Self-reported spasticity, pain, and sleep (NRS) over the last 24 hours and 7 days, multiple sclerosis impact scale (MSIS 29), hospital anxiety and depression scale (HADS), fatigue scale for motor and cognitive function (FSMC), modified Ashworth scale, expanded disability status scale (EDSS), two-minute walk test, and 25-foot walk test were assessed at baseline and after 4 weeks of INP treatment.

Results: In total 43 patients were assessed for eligibility, 10 patients were enrolled, and 8 patients completed the 4-week treatment period. After four weeks of treatment, median change (range) in in spasticity was -2 (-5, 3) NRS points reported over the preceding 24 hours, and 7 days. Pain was reduced by -1.5 (-4, 0) points reported over the preceding 24 hours, and -1.5 (-5, 1) points over the preceding 7 days. Sleep remained unchanged. There was a change in MSIS 29 total score of -3.5 (-36, 19), and a change in HADS of -3 (-6, 3) after 4 weeks of treatment. No change in FSMC was observed. There was an improvement in two-minute walk test of 8.5 m (-20, 75), and a change in the timed 25-foot walk of -0.4 s (-2.0, 1.2) after 4 weeks of treatment. No changes in Ashworth Scale and EDSS was observed after 4 weeks of treatment. No serious adverse events were reported during the study.

Conclusion: The results from this pilot investigation indicate that INP treatment may improve spasticity, pain, quality of life and walking ability in patients with MS. INP treatment seems to be safe and well tolerated in this patient group.

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