Non-pharmacological treatment of Multiple Sclerosis related spasticity and pain with lower extremity intermittent negative pressure; The FlowOx study

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Introduction:

Spasticity is a common cause for discomfort and pain in Multiple Sclerosis (MS), having great influence on quality of daily living.

Method:

This was a randomized, controlled, double blind clinical trial. Fifty-six MS patients, with a self-reported spasticity in the most affected leg ≥4 rated according to the numeric rating scale (NRS), and spasticity related pain or discomfort, completed a 4-week multicenter treatment trial, in which they daily applied 1 hour of intermittent negative pressure (INP). Patients were randomized to treatment with FlowOx with either -10 mmHg INP (lower dose group) or -40 mmHg INP (higher dose group).

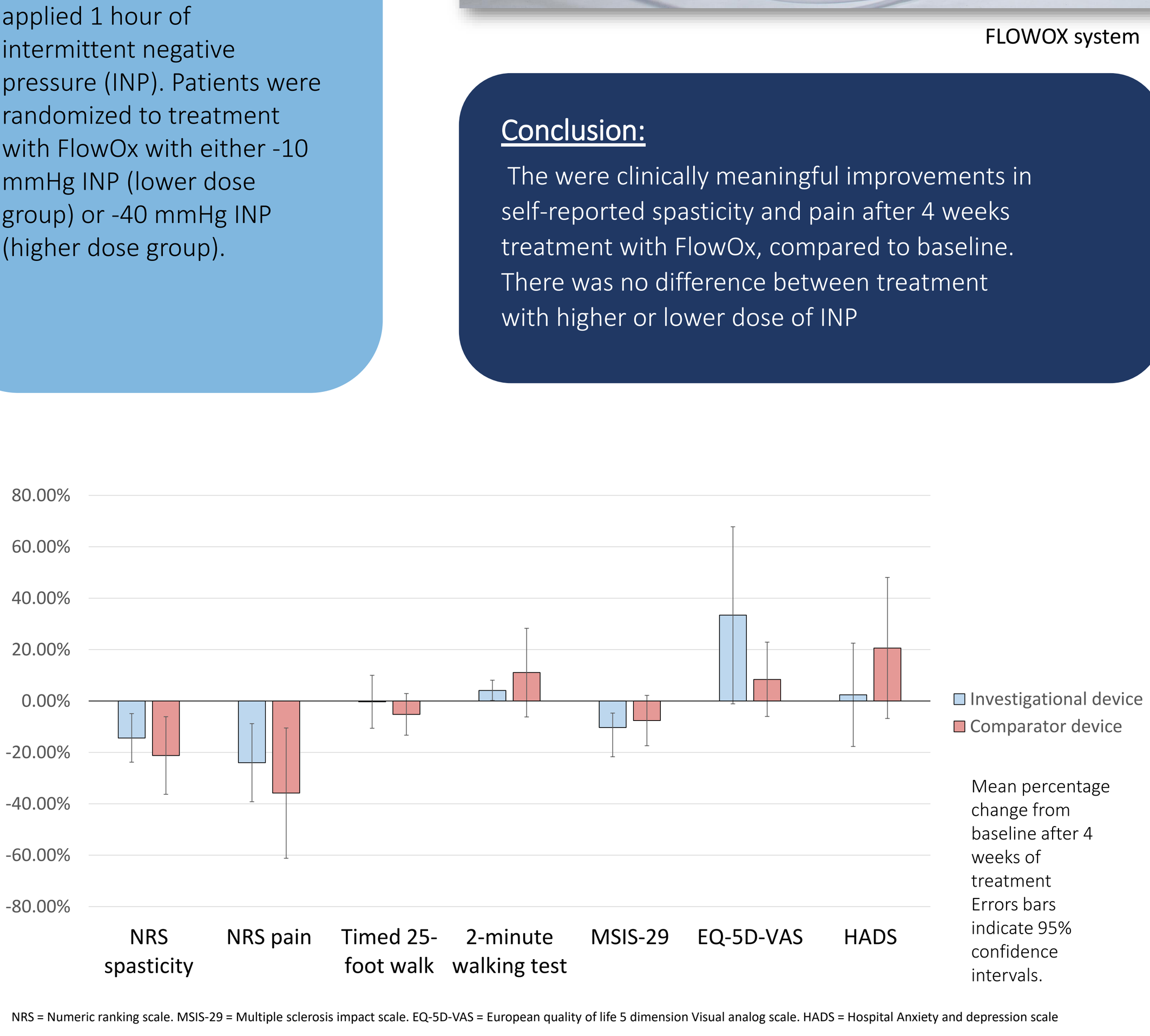
Results:

There was no difference in NRS spasticity score between the higher dose group and the lower dose group after 4 weeks of treatment. At baseline, mean (SD) NRS spasticity score was 6.6 (1.4) in the higher dose group and 6.1 (1.5) in the lower dose group. The mean (95% CI) changes in NRS spasticity score were -14% (-24, -5) in the higher dose group, and -21% (-36, -6) in the lower dose group after 4 weeks, compared to baseline. Further, there was no difference in NRS pain score between the two groups after 4 weeks. The change in NRS pain score were -24% (-39, -9) in the higher dose group and -36% (-61, -11) in the lower dose group, respectively.

FLOWOX system

Conclusion:

The were clinically meaningful improvements in self-reported spasticity and pain after 4 weeks treatment with FlowOx, compared to baseline. There was no difference between treatment with higher or lower dose of INP



Mean percentage change from baseline after 4 weeks of treatment
Errors bars indicate 95% confidence intervals.

NRS = Numeric ranking scale. MSIS-29 = Multiple sclerosis impact scale. EQ-5D-VAS = European quality of life 5 dimension Visual analog scale. HADS = Hospital Anxiety and depression scale