Longer-term effects of treatment with FlowOx on self-reported spasticity, pain and quality of life in patients with multiple sclerosis

J. Nørregaard* M. Blinkenberg* I. Mathisen H. Hoel

* Danish Multiple Sclerosis Center, Department of Neurology, Copenhagen University Hospital – Rigshospitalet Glostrup, Denmark
** .

Introduction:

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

We wanted to evaluate the long-term clinical effects of treatment with intermittent negative pressure (INP), applied by FlowOx, on spasticity, pain and quality of life in patients with multiple sclerosis (MS).

Method:

This was a 6 months optional extension study (OES), following a 4 week randomized controlled trial (RCT), in which treatment of MS spasticity was performed with a negative pressure of -10 mmHg compared to -40 mmHg applied by FlowOx. The OES investigated the longer-term effects of treatment with INP of -40 mmHg, on self-reported spasticity, pain and quality of life. Included patients were instructed to treat the lower limb most affected by spasticity for one hour daily during the study period. Self-reported spasticity and pain according to the numeric rating scale (NRS) were recorded weekly. Multiple Sclerosis Impact Scale (MSIS-29) was recorded at baseline and after 6 months.

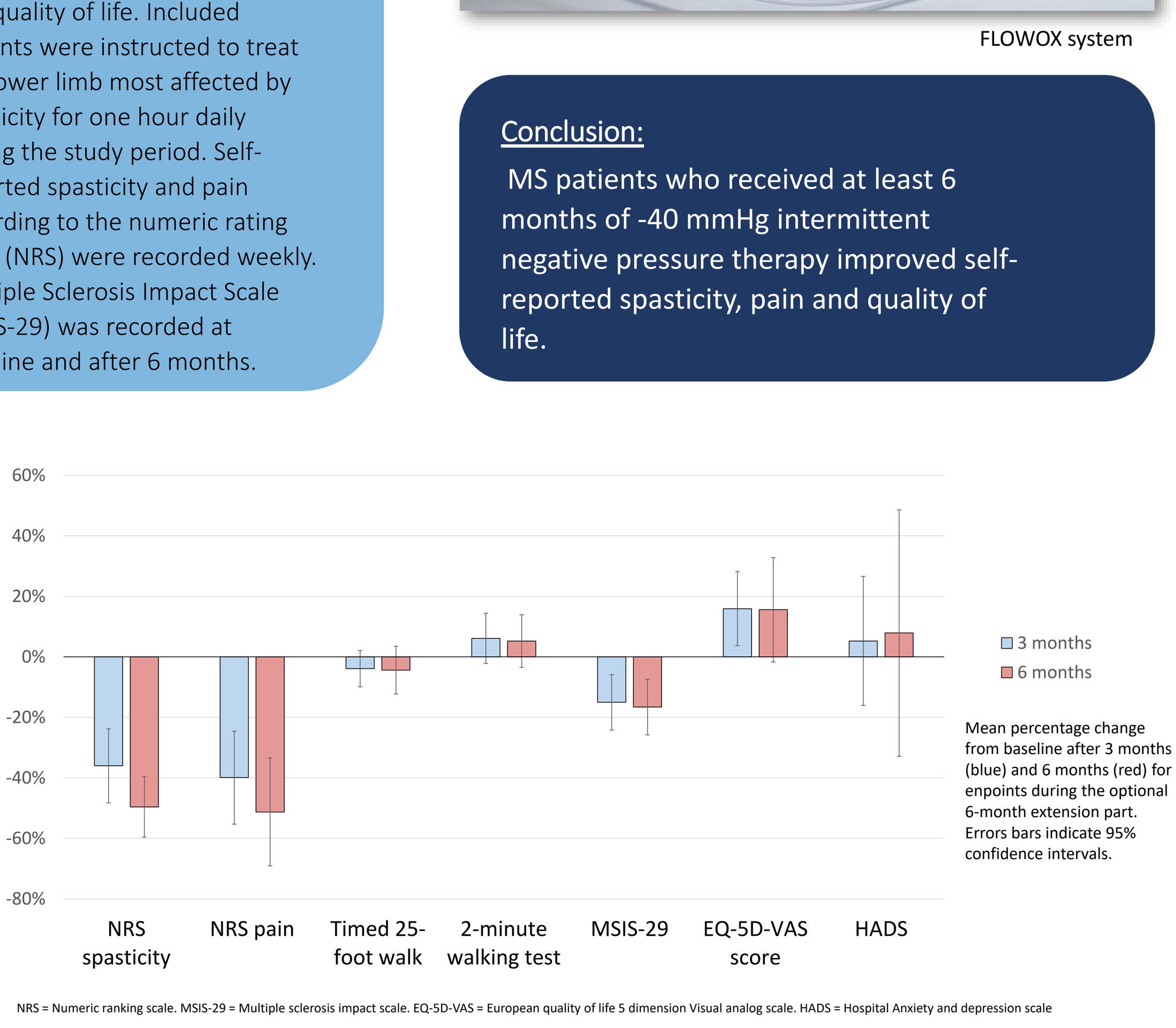
Results:

In total, 43 patients who completed the 4 week RCT chose to continue in the OES. Of those, 36/43 (84%) participated after 3 months, and 25/43 (58%) completed the 6 months. At baseline, mean (SD) NRS spasticity score was 6.3 (1.5) and NRS pain score was 6.4 (1.6). There was a significant reduction in NRS spasticity score from baseline to 6 months (mean change -3.2, 95% CI [-3.8, -2.5]). There was also a significant reduction in NRS pain score from baseline to 6 months (mean change -3.4, 95% CI [-4.7, -2.1]). The MSIS-29 total score, physiological score and psychological score also improved significantly after 6 months (mean change -9.2, 95% CI [-14.4, -4.0]), mean change -6.3, 95% CI [-9.9, -2.8], and mean change -2.9, 95% CI [-5.0, -0.8], respectively).

FLOWOX system

Conclusion:

MS patients who received at least 6 months of -40 mmHg intermittent negative pressure therapy improved self-reported spasticity, pain and quality of life.



Mean percentage change from baseline after 3 months (blue) and 6 months (red) for enpoints during the optional 6-month extension part. 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