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Safety and efficacy of venoplasty in MS

A randomized, double-blind, sham-controlled phase II trial

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Study objective

To evaluate the safety and efficacy of balloon venoplasty for treating patients with multiple sclerosis (MS) through correction of narrowed extracranial jugular and azygos veins.

Summary results

Balloon venoplasty was not superior to sham venoplasty in improving clinical outcomes in patients with MS.

Classification of evidence

Class I.

What is known and what this paper adds

Chronic cerebrospinal venous insufficiency as a result of venous narrowing has been posited as a pathologic mechanism of MS; however, venous narrowing is observed with similar frequency in healthy volunteers and patients, and the utility of venous dilation in patients with MS is unclear. The present study provides clinical trial evidence that extracranial venoplasty is not associated with disease-modifying or subjective patient benefits in MS.

Participants and setting

The study enrolled 104 patients (mean age, 50.5 years; range 33–65 years) diagnosed with relapsing-remitting, secondary, or primary progressive MS from 4 Canadian centers. Participants had >50% narrowing of at least 1 extracranial vein on catheter venography.

Design, size, and duration

The study was a randomized, sham-controlled, double-blind, interventional trial with a follow-up period of 48 weeks after randomization and treatment.

Primary outcome measures

The primary efficacy outcome was change in MS Quality of Life questionnaire (MSQOL-54) scores from baseline to week 48. The primary safety outcome was the number of adverse events during follow-up.

Main results and the role of chance

Forty-nine patients were randomized to receive balloon venoplasty and 55 were assigned to sham. There were no differences in mean improvement from baseline to week 48 in MSQOL-54 physical (+1.3 vs +1.4, $p = 0.95$) or mental score (+1.2 vs −0.8, $p = 0.55$) or secondary clinical or imaging outcomes between the sham and venoplasty groups.

Table Improvements in patient-reported and clinical outcomes from baseline to week 48

Outcome	Sham	Balloon venoplasty
MSQOL-54 physical	1.3 ± 11.5	1.4 ± 14.0
MSQOL-54 mental	1.2 ± 15.2	−0.8 ± 18.7
NARCOMS	0.1 ± 1.7	−0.2 ± 1.0
MSFC	0.0 ± 0.7	−0.4 ± 1.5
EDSS	0.0 ± 0.9	−0.2 ± 0.8

Abbreviations: MSQOL-45, MS quality of life questionnaire; NARCOMS, North American Research Committee on MS pain scale; MSFC, Multiple Sclerosis Functional Composite score; EDSS, Expanded Disability Status Score.

Harms

Serious adverse events were reported in 1 patient undergoing sham and 5 patients undergoing balloon venoplasty.

Bias, confounding, and other reasons for caution

The study did not evaluate the use of stents due to reports of serious complications.

Generalizability to other populations

The results are generalizable to patients with MS in North America.

Study funding/potential competing interests

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Trial registration number

NCT01864941 (Clinicaltrials.gov).

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