A multicenter randomized controlled trial evaluating balneotherapy in patients with advanced chronic venous insufficiency


Patrick H. Carpentier, MD<sup>a</sup>,<sup>b</sup> · Sophie Blaise, MD<sup>a</sup> · Bernadette Satger, MD<sup>a</sup> · Céline Genty, MSc<sup>c</sup> · Carole Rolland, MSc<sup>c</sup> · Christian Roques, MD<sup>d</sup> · Jean-Luc Bosson, MD, PhD<sup>c</sup>

Background
Apart from compression therapy, physical therapy has scarcely been evaluated in the treatment of chronic venous disorders (CVDs). Spa treatment is a popular way to administer physical therapy for CVDs in France, but its efficacy has not yet been assessed in a large trial. The objective was to assess the efficacy of spa therapy for patients with advanced CVD (CEAP clinical classes C4-C5).

Methods
This was a single-blind (treatment concealed to the investigators) randomized, multicenter, controlled trial (French spa resorts). Inclusion criteria were primary or post-thrombotic CVD with skin changes but no active ulcer (C4a, C4b, or C5). The treated group had the usual 3-week spa treatment course soon after randomization; the control group had spa treatment after the 1-year comparison period. All patients continued their usual medical care including wearing compression stockings. Treatment consisted of four balneotherapy sessions per day for 6 days a week. Follow-up was performed at 6, 12 and 18 months by independent blinded investigators. The main outcome criterion was the incidence of leg ulcers at 12 months. Secondary criteria were a modified version of the Venous Clinical Severity Score, a visual analog scale for leg symptoms, and the Chronic Venous Insufficiency Questionnaire 2 and EuroQol 5D quality-of-life autoquestionnaires.

Results
Four hundred twenty-five subjects were enrolled: 214 in the treatment group (Spa) and 211 in the control group (Ctr); they were similar at baseline regarding their demographic characteristics, the severity of the CVD, and the outcome variables. At 1 year, the incidence of leg ulcers was not statistically different (Spa: +9.3%; 95% confidence
interval [CI], +5.6 - +14.3; Ctr: +6.1%; 95% CI, +3.2 - +10.4), whereas the Venous Clinical Severity Score improved significantly in the treatment group (Spa: −1.2; 95% CI, −1.6 - −0.8; Ctr: −0.6; 95% CI, −1.0 - −0.2; \( P = .04 \)). A significant difference favoring spa treatment was found regarding symptoms after 1 year (Spa: −0.03; 95% CI, −0.57 - +0.51; Ctr: +0.87; 95% CI, +0.46 - +1.26; \( P = .009 \)). EuroQol 5D improved in the treatment group (Spa: +0.01; 95% CI, −0.02 - +0.04) while it worsened (Ctr: −0.07; 95% CI, −0.10 - −0.04) in the control group (\( P < .001 \)). A similar pattern was found for the Chronic Venous Insufficiency Questionnaire 2 scale (Spa: −2.0; 95% CI, −4.4 - +0.4; Ctr: +2.4; 95% CI, +0.2 - +4.7; \( P = .008 \)). The control patients showed similar improvements in clinical severity, symptoms, and quality of life after their own spa treatment (day 547).

Conclusions

In this study, the incidence of leg ulcers was not reduced after a 3-week spa therapy course. Nevertheless, our study demonstrates that spa therapy provides a significant and substantial improvement in clinical status, symptoms, and quality of life of patients with advanced venous insufficiency for at least 1 year.

Author conflict of interest: none.

Additional material for this article may be found online at www.jvascsurg.org.

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

Reprint requests: Patrick H. Carpentier, MD, Clinique Universitaire de Médecine Vasculaire, Département Pluridisciplinaire de Médecine, Centre Hospitalier Universitaire de Grenoble, F-38043, Grenoble, France.

Copyright © 2014 Society for Vascular Surgery. Published by Elsevier Inc. All rights reserved.
A multicenter randomized controlled trial evaluating balneotherapy in patients with advanced chronic venous insufficiency
A multicenter randomized controlled trial evaluating balneotherapy in patients with advanced chronic venous insufficiency