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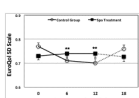
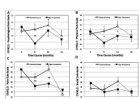
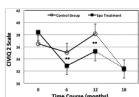
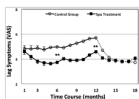
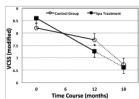
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Table II



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Clinical research study

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

Presented as a poster display at the Twenty-fifth Annual Meeting of the American Venous Forum, Phoenix, Ariz, February 28, 2013.

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## 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.

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