Randomized trial of balneotherapy associated with patient education in patients with advanced chronic venous insufficiency

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Objectives: **Except for compression therapy, physical therapy has scarcely been evaluated in the treatment of chronic venous disorders (CVD). Spa treatment is a popular way to administer physical therapy for CVD in France, but its efficacy has not been evaluated yet. This study aimed to assess the efficacy of balneotherapy associated with patient education, as performed in the spa resort of La Léchère, in patients with advanced chronic venous insufficiency (CEAP clinical classes C4/C5).**

Methods: **The study was a randomized controlled trial, spa therapy being administered on top of the usual medical care. Evaluation was by a blinded independent investigator. Subjects were patients with primary or post-thrombotic CVD with skin changes but no active ulcer (C4a, C4b, or C5), living in Grenoble area, and willing to undergo a spa treatment course in La Léchère. The treated group had the three week spa treatment course in La Léchère, soon after randomization; the control group also had a spa treatment, but starting at day 365. The treatment consisted of four balneology sessions per day, six days a week during three weeks, and three educational workshops. An independent follow-up was performed in Grenoble hospital every three months for 15 months. The main outcome criterion was the severity of the skin changes, as evaluated by means of malleolar chromametry. Quality of life, as measured by the Chronic Venous Insufficiency Questionnaire 2 scale, a visual analog scale (VAS) for leg symptoms, and the occurrence of leg ulcers were used as secondary criteria. The year after spa treatment in the treated group was compared with the year before spa treatment in the control group.**

Results: **Fifty-nine subjects were enrolled (29 in the treatment group and 30 in the control group). No statistically significant difference between groups was found at study onset regarding age, sex, etiology, CEAP "C" class, and the outcome variables. After treatment, chromametry showed significantly decreased pigmentation and erythema in the treatment group compared with the controls ($P < .01$). Quality of life ($P < .01$) and symptoms ($P < .001$) also improved significantly. These differences remained significant after one year follow-up. The control patients improved similarly after their own spa treatment (day 450).**

Conclusion: **This study shows that spa therapy, associating balneotherapy and patient education, is able to improve significantly the skin trophic changes of the CVD patients and their CVD related quality of life and symptoms. This effect is of large magnitude and remains significant one year after the treatment course. (J Vasc Surg 2009;49:163-70.)**

Patients with advanced chronic venous insufficiency (ie, with CEAP C4 to C6 chronic venous disorders)[1] suffer for years from a painful and disabling condition,[2] and they also experience the limitations of the present possibilities of medical care. Surgical or endovascular ablation of superficial refluxing veins is useful when there is an incompetence of the superficial venous system,[3] but few among the numerous patients with deep vein damage are eligible for surgery.[4] The documented impact of venoactive drugs is limited to an improvement of symptoms.[5] Most patients have to wear compression stockings and the poor compliance of this treatment shows by itself that it is not the perfect answer to their expectations.[6] In this context, any possibility of a treatment able to improve the function and quality of life of the patients is welcome.

Although poorly evaluated in this condition, rehabilitation and physical therapy aiming at a restoration of calf muscle pump function offer the potential for a useful adjunctive treatment, and a randomized study by Padberg et al showed promising results.[7] Patient education is also usually considered as useful in patients with such chronic disabling conditions, in which the behavior of the patient regarding lifestyle and compliance to treatments has to be improved, and advanced chronic venous insufficiency obviously fulfills these two conditions.[8]

Spa treatment is a popular way to administer physical therapy for chronic venous disorders (CVD) in France, with more than 60,000 patients treated annually. Typically, it is delivered as a three week treatment course in a spa resort specialized in the treatment of CVD patients, and combines the effects of active and intensive balneotherapy using mineral waters with a patient education program dedicated to CVD. It is partly reimbursed by the French

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Competition of interest: none.

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National Health Services (NHS) as a customary treatment, although its efficacy has never been assessed in a scientific way.[9]

The aim of this study was to evaluate, in a pragmatic approach, the efficacy of spa treatment as it is performed in the resort of La Léchère (balneotherapy with patient education), in patients with advanced chronic venous insufficiency (ie, in patients with skin changes of the lower leg of venous origin [CEAP clinical classes C4/C5]), in addition to their usual treatments.

METHODS

Study design and organization. This study was organized as a single blind randomized controlled trial with two parallel groups, the spa treatment being administered on the top of the usual medical care. The tested hypothesis was that patients with advanced chronic venous insufficiency (CVD with CEAP C classes C4-C5) would have a long-standing (remaining significant at month 12) improvement of their signs, symptoms, and quality of life after a three weeks spa treatment course in La Léchère as it is customarily performed in this spa resort, compared with a randomized controlled group with no spa treatment.

Subjects. Inclusion criteria were primary or post-thrombotic CVD (Ep or Es) with skin changes but no active ulcer (C4 or C5), and the evidence of a venous incompetence demonstrated by Ultrasound Duplex examination with at least a significant reflux (more than one second duration in standing position) in the superficial, deep, and/or perforator veins (Pr). Patients had to be at least 18 years old, living in Grenoble area, and willing to participate (written informed consent) in the study (ie, to perform a three weeks course of spa treatment of in La Léchère resort and a follow-up of 15 months duration including a weekly self-administered questionnaire and a medical examination every three months). Patients were not included if they already had any prior spa treatment course, if a surgical or endovascular treatment of the venous disease was planned for the study time course or had been performed less than six months prior to the inclusion visit. Patients with contra-indication of spa treatment (life-threatening disease, cardiac or renal failure, immunodeficiency, psychiatric disorders, strong limitation of ambulation) were also excluded, as well as those with edema of non-venous origin (clinical lymphedema, cardiac failure, hypoalbuminemia), symptomatic neurological diseases of the lower limbs (neurogenic pain or abnormal neurological examination of the lower limbs), or significant peripheral arterial disease (ankle-brachial index [ABI] <0.90). The study protocol was approved by the Grenoble Medical Research Review Board (Comité de Protection des Personnes) on July 12, 2000.

Randomization. A centralized randomization was performed after the inclusion visit, and its result kept hidden from the investigators. The treatment was then organized and carried out in La Léchère (100 km from Grenoble), similarly to the customary procedure applied for any patients undergoing the spa treatment for chronic venous disorders, and the follow-up performed in Grenoble University Hospital, by a blind investigator.

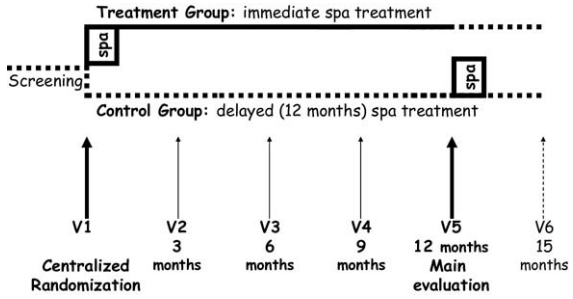


Fig 1. Pseudo cross-over design of the study: the comparison addresses the first year (ie, the year after treatment for the treatment group), vs. the year before treatment for the control group.

Intervention. The patients of the treatment group underwent a three week spa treatment course in La Léchère soon after randomization. The control group also had a spa treatment, but after the comparison time course (ie, starting soon after day 365 [Fig 1]).

The spa treatment course was performed according to the rules of the French NHS and the study patient was taken care of as any other CVD patient in the spa resort, with his participation to the study being kept hidden. The treatment regimen consisted of four balneotherapy sessions per day, six days a week during three weeks, and two to three educational workshops during the stay. The types of balneotherapy sessions were chosen by the spa physician for each patient according to his or her needs and capabilities when he/she arrived at the spa resort. These choices were subjected to adjustment on the occasion of the two follow-up medical visits systematically performed during the spa treatment course. Proposed care sessions were:

- A 15 minute joint mobilization session in a deep (150 cm) and warm (34 °C) pool under the supervision of a physiotherapist (improvement of the ankle, but also knee and hip joints' mobility for a better ambulation and muscle-pump functioning);
- A 15 minute walking session in a specially designed pool with foot paths in a semi-deep (80 cm) and cool (28 °C) water (training of the muscle pump function under water compression);
- A 20 minute whirlpool bath session with automatic air and water massages cycles (aiming at relaxation and mobilization of the superficial skin volume flow[7]);
- A 10 minute under affusion massage session of the leg and ankle skin areas by a physiotherapist (mobilization and softening of the sclerotic subcutaneous tissues);
- A 10 minute bath session with customized underwater strong massaging shower (same target).

All these spa sessions used the mineral waters of La Léchère, emerging at 58 °C, but cooled down to 26 °C to 36 °C for therapeutic use. The mineralization of these waters is mainly made of calcium and magnesium sulfates.

During the stay, the patient also participated in two to three 90 minute educational workshops performed according to a previously published method.[8] These workshops were interactive and involved small groups of patients (up to eight persons), who shared knowledge, experience, and skills through games and group activities under the supervision of a teaching nurse. The workshops were aiming at increasing the understanding of venous pathophysiology and the targets of venous treatments, but also the awareness of the patient about the importance of his behavior regarding exercise, weight and diet control, and an adequate use of compression stockings. Through this improvement of the patient's knowledge, skills, and awareness, the workshops were thus aimed at increasing his motivation and compliance with the treatments, and especially with the compression stockings and the behavioral changes that were needed in his or her everyday life. Due to organizational limitations, the patient was able to participate in two to three among five workshops addressing the following issues:

- What is the venous system? How does it work? What can improve and what can hamper it?
- What kinds of dysfunctions do occur during chronic venous disorders? How to control their consequences?
- Venous treatments: objectives and techniques.
- How to use and enjoy your compression therapy in everyday life.

Concomitant treatments. During the whole study time course, patients of both groups remained attended by their usual physicians, who provided them with any care they thought useful for their patients, according to the regulations of the French National Health Service. No standardized basal treatment or counseling was provided by the investigators.

Main outcome measurements. The follow-up examinations were performed at the Grenoble University Hospital by the same investigator (BS) every three months during the year of study course, and a final visit was performed at month 15.

The primary outcome criterion was the severity of the skin changes, evaluated as the intensity of the skin pigmentation assessed by skin chromametry at the level of the medial malleolar region. The chromameter is a small handheld device that is applied on the surface of the object to be evaluated, in order to analyze the reflected light through different kinds of filters after calibrated illumination with a xenon flash. A calculator allows the online extraction of three parameters that characterize the object's color: parameters "a" for the green-red axis, "b" for the blue-yellow axis, and "L" for the darkness of the object. In clinical medicine, chromametry has been mainly used for the quantification of the erythema (parameter "a") as a marker of vasodilatation or inflammation in vasomotor and cosmetic studies;[10,11] however, pigmentation ("brownish pigmentary darkening of the skin in the ankle region"[1]), one of the cardinal manifestations of skin disease in chronic venous disorders, can also be assessed by chromametry.[12] In a previous study about chromametry in patients with CVD, we found that the darkness parameter measured at the ankle was linearly related to the severity of the venous disease, as classified according to the CEAP "C" classes; in the same study, we showed that the repeatability, intra-, and inter-observer reproducibility of the measurement were respectively 15%, 18%, and 21% of the mean deviation, quite adequate for clinical research studies.[12] In the present study, all measurements were carried out by the same investigator. They were performed after a 10 minute rest, the patient in supine position, with the Minolta CR-200 chromameter (Minolta France SA, Colombes, France) placed orthogonally to the skin surface, in contact with the medial malleola; the median value of three successive measurements was recorded in order to decrease the variability of the measurement. For a more simple expression of the results, we derived the darkness parameter in a pigmentation index: PI = 90 – L. These conditions were those validated in our previous study.[12] The chromametry measurements were performed in both legs for each subject, but only data regarding the most affected one were taken into account in the statistical analysis.

Several additional variables were measured as secondary outcome criteria:

- The "a" chromametry parameter (green-red axis), as an index of skin erythema and dermatitis (erythema index), was measured simultaneously with the pigmentation index.
- Quality of life was measured every three months by the Chronic Venous Insufficiency Questionnaire 2 (CIVIQ2) self-administered questionnaire, a disease specific quality of life instrument dedicated to chronic venous disorders and validated in this condition.[13] In addition to the global CIVIQ2 scale, its four dimensions (pain, physical, psychological, and social components) were separately analyzed.
- Self-evaluation of the intensity of leg symptoms was performed each week by the patient him- or herself and reported on a diary using two 10 cm height visual analog scales (VAS). The symptoms' intensity was rated separately for each leg, from "no discomfort" at the bottom end (measured 0.0), to "unbearable" at the top (measured 10.0), according to a method previously described and discussed in detail.[14] For the analysis, only the VAS of the most affected leg was taken into account.
- The occurrence of leg ulcers was also recorded.
- Data regarding direct cost of medical and nursing cares were recorded for subsequent medico-economic analysis, but are not analyzed in this paper.

At each visit, any adverse events were recorded, as well as any change in the treatment of the patient.

Data management and statistical analysis. Data management was performed blindly, including a final blind review regarding protocol deviations and missing data.

The main outcome analysis was conducted on an intention to treat approach. Only the data of the first study year were used for the inter-groups comparisons, the primary and main secondary outcome criteria being assessed at 12

months. The final examination performed at month 15 was mandatory on a legal point of view as an end of study visit, but was only analyzed as a supplementary evaluation of the early effects of the spa treatment in the control group.

The statistical analyses were performed with SPSS software (version 14.0 for Windows; SPSS, Inc., Chicago, Ill). A variance analysis had been planned, with a *P* value below .05 considered as significant. However, due to the non-Gaussian distribution of some parameters, the Mann-Whitney test was preferred. A Fisher exact test was performed for categorical data. We also calculated Cohen's "d" effect size parameter as the δ/σ ratio (ie, the standardized difference between the two groups); according to Cohen, the effect size can be classified as "small, d = .2," "medium, d = .5," or "large, d = .8".[15]

As we expected a large effect size, we calculated the number of patients required as 20 in each group (using a bilateral test, with $\alpha = .05$, $\beta = .15$, and $\delta/\sigma = 1$). However, this hypothesis was based on poorly documented potential outcomes (worsening by 15% of the pigmentation in the control group vs 5% in the treated group, with a 10% standard deviation) and we decided to include 60 patients in order to accommodate potential problems of underestimation of variability and possible drop outs.

Table. Description of patients groups at study onset (no statistically significant difference)

Variables	*Treated (n = 29)*	*Controls (n = 30)*
Gender (F:M)	20:9	20:10
Age: mean (sd)	59.3 (10.6)	62.5 (10.9)
History of DVT	13 (45%)	17 (57%)
Venous Incompetence (Ultrasound Duplex)		
Superficial	27 (93%)	28 (93%)
Perforator	17 (59%)	18 (60%)
Deep	10 (35%)	14 (47%)
CEAP "C" Class		
4a	21	15
4b	8	5
5	3	10
Early withdrawal	1*	3*
Other drop out	0	0
Pigmentation index: mean (sd)	4.4 (5.5)	5.9 (3.6)
Erythema index: mean (sd)	3.3 (2.1)	3.3 (1.4)
CIVIQ2 QoL scale: mean (sd)	52.8 (12.6)	52.2 (13.4)
Symptoms VAS: mean (sd)	4.1 (1.9)	3.9 (2.6)

CIVIQ2, Chronic Venous Insufficiency Questionnaire 2; *DVT,* deep vein thrombosis; *F,* female; *M,* male; *QoL,* quality of life; *VAS,* visual analog scale.
*not included in the analysis.

RESULTS

Description of the subjects and interventions. Sixty-three patients validating the inclusion criteria agreed to participate, but four withdrew soon after randomization and refused the follow-up. One late refusal was from a woman from the treatment group because of personal difficulties in the organization of her stay in the spa resort. The three others came from subjects from the control group: one for an unexplained personal reason; a second one because of the onset of family problems; and the last one because he expected an immediate spa treatment and did not accept the result of the randomization. Therefore, 59 subjects were followed-up in the study (29 in the treated group and 30 in the control group). No additional drop-out occurred during the study time course, and, as no other major protocol deviation was found, intent to treat and per protocol analysis were identical. Less than 2% missing data were found in the data base, mainly due to gaps in the weekly VAS evaluations, and replaced for the purpose of the analysis using a classical carry over procedure.

As shown in the Table, no statistically significant difference between the two groups was found at study onset regarding age, sex, etiology, CEAP "C" class, and outcome variables.

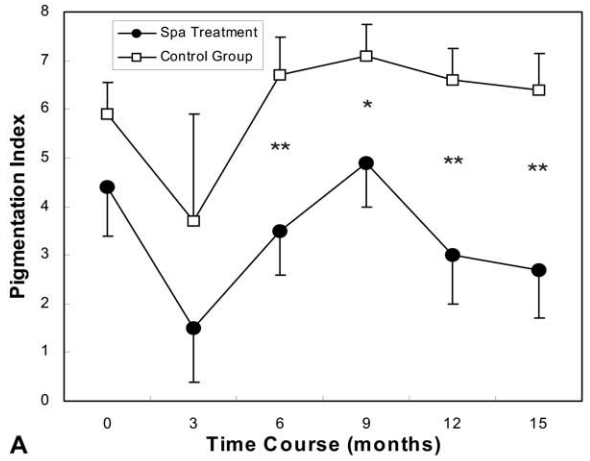
Regarding the balneotherapy sessions, all 29 patients of the treated group had the under affusion massages and the whirlpool sessions; twenty-six patients had the walking pool session, and the three others who could not walk had sessions of immerged pedaling in sitting position; nine patients needed the mobilization pool sessions, and the others had sessions of customized underwater massaging showers. Four patients who did not want to participate in the interactive workshops of therapeutic education were proposed to attend a cycle of three educative conferences on venous diseases and treatment.

Chromametry showed seasonal similar variations of the skin pigmentation in both groups, which account for the sinusoidal shape of the curves in Fig 2, *A*; this is explained by the actinic pigmentation related to sun exposure. However, a significant difference in the pigmentation index was found between the two groups, at months six ($P < .01$) and nine ($P < .05$). Furthermore, 12 months after the spa treatment, and consequently adjusting for seasonal variations, the pigmentation index was reduced in the treatment group, whereas it was increased in the controls, showing a significant difference ($P < .01$), with a size effect as high as 0.77.

Regarding the erythema index (Fig 2, *B*), the difference was already found significant at month 3, and remained significant during the whole study time course ($P < .01$), with a size effect of 0.72 at month 12.

Quality of life, as expressed by the CIVIQ2 scale, also improved significantly ($P < .01$) for the whole year of the study course and remained significantly improved at month 12 with a size effect of 0.82 (Fig 3). The analysis of the four components of this scale showed that all of them were significantly improved, although the psychological dimension had a smaller magnitude than the three other ones (Fig 4).

Leg symptoms, as assessed by the weekly self-evaluation of VAS by the patient were also very much improved ($P < .001$).The weekly evaluation allowed a more precise analysis of the time course effect of the treatment. Fig 5 shows that, as a mean value, the improvement started very early during the spa treatment, became maximal during the first 15 weeks after treatment, and decreased very slowly along



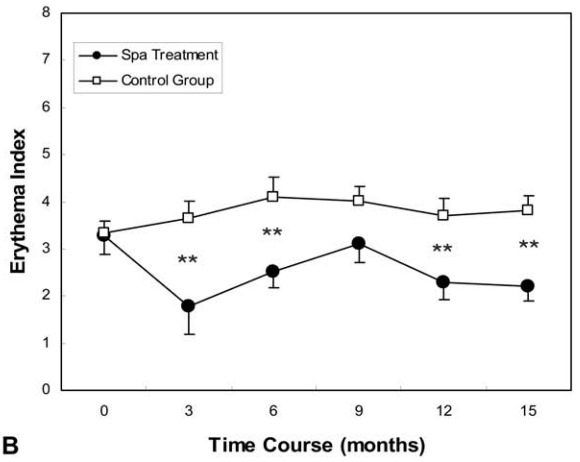


Fig 2. Evolution of the chromametry parameters during the study. **(A)** Pigmentation index (darkness parameter): Cohen's D effect size parameter at 12 months = 0.77. **(B)** Erythema index (redness parameter): Cohen's D effect size parameter at 12 months = 0.72. (**P* = .05; ***P* < .01).

with time during the study year, but remained significant at week 52, and even with a large effect magnitude (size effect 0.84).

Incidence of leg ulcers. Only 6 ulcers occurred in this small series of 59 patients during the study year**; o**ne in the treated group and five in three patients from the control group (Fisher exact test: *P* = ns).

The control group responded similarly to the treated group after its own spa treatment (day 450), with the same magnitude of improvement as in the treatment group regarding symptoms and quality of life (Figs 2-5). The three months follow-up after treatment in this group did not allow the detection of post-treatment changes in the chromametry parameters.

Tolerance. Twenty-seven patients reported adverse events in the treated group, and twenty-six in the control group. All but one were unrelated to the spa treatment.

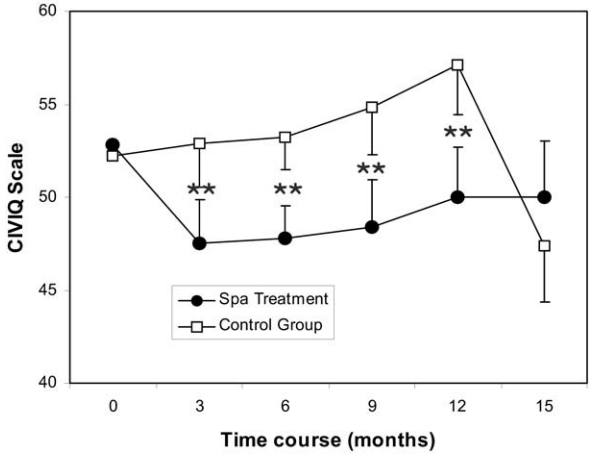


Fig 3. Evolution of CIVIQ2 quality of life instrument during the study. Cohen's D effect size parameter at 12 months = 0.82 (***P* < .01).

Seven of these events required the hospitalization of the patient; four in the treated group (newly diagnosed breast cancer; scaphoid surgery; cholecystectomy; unexplained thoracic pain) and three in the control group (prostate surgery; giant cell arteritis; unexplained thoracic pain). The only adverse event related to the spa therapy occurred in a 70-year-old woman from the control group, who experienced a sensation of weakness and palpitations during a bath session on the sixth day of her spa treatment (ie, after the study comparison time course), with negative cardiac explorations and no complications.

DISCUSSION

This study is the first randomized controlled trial evaluating the efficacy of spa therapy as an adjunct treatment to the usual medical care in patients with severe CVD. A significant improvement was shown on the CVD related signs (pigmentation, erythema), symptoms (VAS), and quality of life (CIVIQ2 scale). It is of large magnitude (effect sizes .72 to .84) and long duration (at least one year).

This trial was not carried out in a double-blind fashion. This could have been possible for a comparison of the effects of two different mineral waters or for the selection of the best level of some technical parameters for a balneology technique, but obviously, it was not possible for the evaluation of the global effect of the spa treatment course, which was our aim. However, we made all possible efforts to avoid any evaluation bias:

- The treatment was administered 100 km from the follow-up examination site, and the investigator was kept blind about the treatment group of the patient as much as possible.
- The primary outcome criterion was chosen as an operator-independent one, and the data management including the statistical analysis was performed blindly until the final between groups comparison.

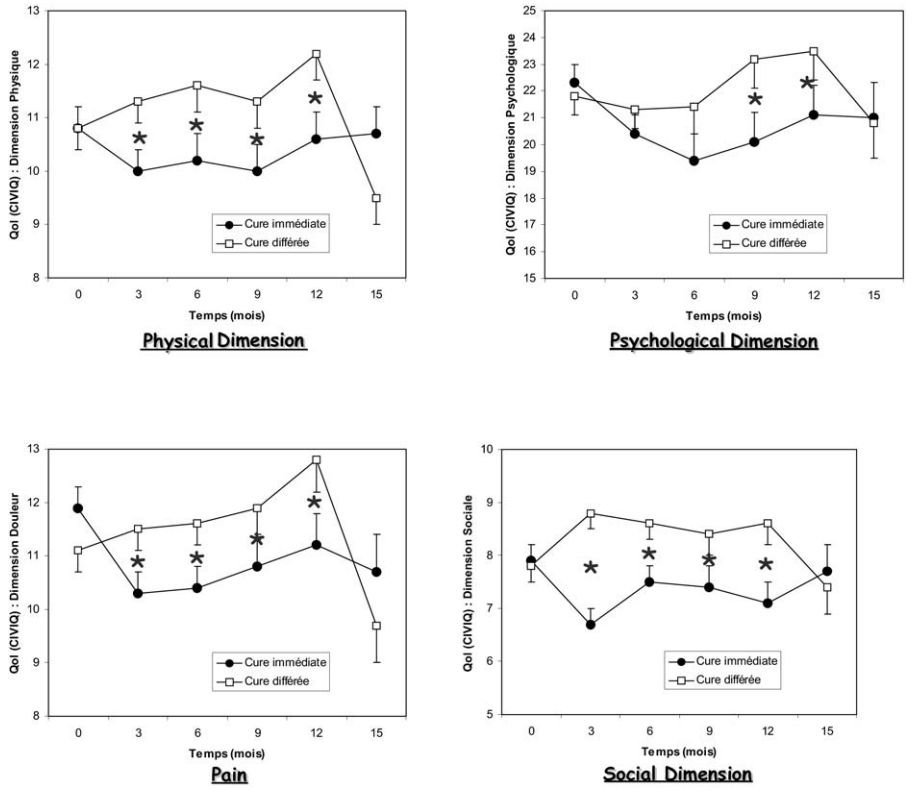


Fig 4. Evolution of the four dimensions of the CIVIQ2 instrument during the study. (*$P < .05$).

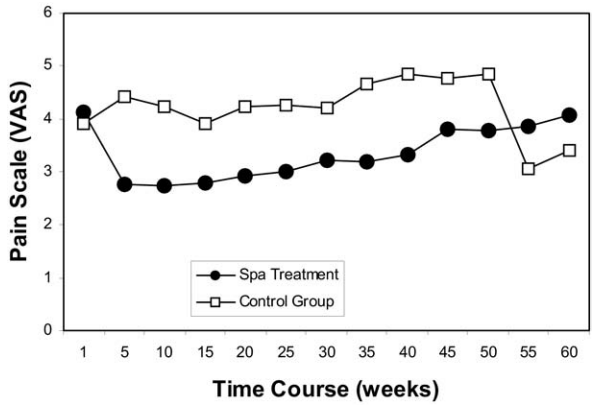


Fig 5. Evolution of the pain scale (Visual Analogic Scale) during the study. Cohen's D effect size parameter at 12 months = 0.84. ($P < .001$ from week 4 to week 52).

- As the subjects could not be blinded, we decided not to qualify the quality of life as the primary outcome criterion. This would have been relevant, as quality of life is closely related to the therapeutic objectives in such patients with a non-life threatening but painful and disabling condition. However, the possibility that the judgment of the patient might be influenced by the subjective satisfaction to be actively treated in a pleasant environment could not be ruled out when preparing the study (indeed, the analysis showed afterward that CIVIQ2 quality of life auto-questionnaire was more improved in the physical dimensions than in the psychological one). Therefore, we preferred a measurement independent from patient judgment, such as the skin pigmentation index, as the primary outcome criterion.

Hence, it is a strength of this study to rely on a physical sign as the primary endpoint, and chromametry is confirming here its ability to be used in clinical research studies, as a reliable and sensitive to change quantitative marker of the severity of skin changes in venous disease. By itself, pigmentation remains a surrogate criterion for skin disease severity in patients with CVD; however, the magnitude of the effect shown and its consistency with an associated substantial improvement of symptoms and quality of life are impressive and convincing.

The unusual design of the study (Fig 1), with a spa treatment performed at the end of the study time course in the control group, was adapted from previous studies by the Nancy group regarding the efficacy of spa therapy in severe low back pain.[16] We chose this design in order to avoid dropouts in the control group, and also to allow the detection of a potential negative placebo effect in this group: subjects of the control group could have felt frustrated not to have the immediate spa treatment, and this

negative feeling might have influenced the measurement of their quality of life and symptoms. In this study, such a significant influence of negative feelings in the control group can reasonably be ruled out, since no significant worsening of the VAS and CIVIQ2 was shown immediately after randomization nor during the last weeks of the comparison period (ie, the weeks prior to their spa treatment) in the control group, and also because the magnitude of the effect of the spa treatment in this group, as shown in the 12 to 15 month follow-up of the study, was similar to what had been previously seen in the treatment group. In any case, our primary endpoint, the pigmentation index, could not have been influenced by such psychological factors.

The treatment tested in this work was the spa therapy as a whole, as it is experienced by 7,000 patients in La Léchère each year, with a three week stay far enough from home to withdraw the patients from his usual environment, an intensive balneotherapy of 72 sessions using the local mineral water under the supervision of a physician specialized in spa medicine, and the patient education program specifically developed for these patients. It was important that the validation was made in this way because these are the conditions of the reimbursement of the spa treatment by the National Health Services in France. Therefore, the positive results found include the effects of every component and their potential synergy. This study does not allow us to differentiate between the effects of each component, including the possible effects of the mineral water[17] and the impact of the psycho-sociological influence of a health-centered stay of three weeks 100 km from home. However, the association of intensive active balneotherapy and patient education is the central core of the treatment, and we feel that it accounts for the main part of effects on physical signs of such large magnitude and long duration.

Few data can be found in the literature regarding the effects of balneotherapy in patients with chronic venous disorders. Ernst and Saradeth[18] showed in a randomized study that the Kneipp technique (alternate warm and cold water showers) was able to improve venous function as evaluated by photoplethysmography, and edema measured by volumetry in the short term. A similar study by Mancini et al,[19] performed in a spa resort with a follow-up of six months in a small number of patients, also showed an improvement of the venous function. Supervised exercise without balneotherapy was also shown to improve calf muscle pump function in the short term[20,21] and after a six month training.[7] Although this was not directly measured in our study, a remarkable increase in the ability to walk, both qualitatively and quantitatively, is usually observed during such an intensive spa treatment, and the level of improvement could be as high as to allow changes in behavior able to have strong and long lasting effects.

On the other hand, advanced chronic venous insufficiency fulfills the criteria for a beneficial effect of therapeutic education, as it is a chronic, disabling condition, requiring from the patients changes in their lifestyle (exercising, diet control) and the use of treatments such as compression stockings, requiring some skills and a high motivation in order to achieve a good therapeutic compliance. However, this approach has been scarcely developed up to now, except in the spa resorts. The program developed in La Léchère showed a positive impact on patient knowledge and understanding of the venous disease on the short term in an observational study,[8] and a positive influence on the patients' compliance to compression stockings in an other mid-term (six month) survey [unpublished data]. However, no controlled evaluation of this educational program has been performed up to now.

We hypothesize that active balneotherapy and therapeutic education have synergistic effects and that their combination makes a very powerful tool able to obtain long-lasting changes in the behavior of the patient regarding physical activity, diet control, and compliance to compression therapy: During the active and intensive balneotherapy (72 sessions in three weeks), the patients experience the strong influence of physical factors on their body, thus demonstrating practically what they understand theoretically during the educational workshops. And during the workshops, they learn how to adapt some of the behaviors and exercises they have observed as beneficial during the balneotherapy sessions to their everyday life. For example, the edema reduction they observe after the bath helps them to realize how important is the beneficial effect of the external pressure produced by the compression stockings; they also understand the link between the improvement in their walking technique, the improvement of ankle joint mobility they experience during the stay, and the improvement of their symptoms. These personal experiences give the patients a high motivation for the behavioral changes they need to implement in their everyday life when returning home. In other words, the magnitude and more over the duration of the effects shown in this study cannot be explained unless deep changes were obtained in the behavior of the patient, which, unfortunately, were not directly evaluated in this study; we believe that these effects result from the combination of both active balneotherapy and therapeutic education.

The results demonstrated here strictly apply only to the spa treatment in the very same conditions as it is performed in La Léchère. However, they strongly support the use of intensive active balneotherapy associated with therapeutic education as a powerful complement of the usual medical care (mainly compression therapy) applied in patients with advanced venous insufficiency, at least for those patients for whom no definite benefit can be expected from the surgical or endovascular treatment of superficial venous incompetence. To a larger extent, they also confirm the interest of physical therapy in this condition, as already shown in previous studies.[7,20,21] The magnitude and duration of the results obtained in a disabling, widespread, and difficult to treat condition such as severe chronic venous disorders speaks in favor of further evaluations of this therapeutic regimen, looking for the most important components for an efficient treatment course, and evaluating to what extent they can be transposed to other medical settings.

In fact, as its tolerance is usually very good in the absence of the above mentioned contraindications,[22] we think that this spa treatment course could be proposed to all patients with advanced chronic venous insufficiency who can invest three full weeks in an intensive health stay, whenever a satisfactory hemodynamic restoration of the venous function is out of range, especially in the post-thrombotic syndrome.

CONCLUSION

This study shows that spa therapy, as performed in La Léchère, with a combination of active balneotherapy and patient education, is able to improve significantly the skin trophic changes and the CVD related quality of life and symptoms in the severe CVD patients when used as an adjunct to the usual medical care. The effect is of large magnitude and remains significant one year after the spa treatment, justifying its use in patients with advanced chronic venous insufficiency and no possible surgical or endovascular correction of the venous function. The exportability of such results to other medical settings remains to be investigated.

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AUTHOR CONTRIBUTIONS

Conception and design: PC
Analysis and interpretation: PC, BS
Data collection: BS
Writing the article: PC
Critical revision of the article: PC, BS
Final approval of the article: PC, BS
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