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Hydrotherapy for Varicose Veins: A Randomized, Controlled Trial

E. Ernst, T. Saradeth and K. L. Resch

University of Vienna Medical School, Department of Physical Medicine and Rehabilitation, Währinger Gürtel 18–20, 1090 Vienna, Austria

ABSTRACT

Objective: To assess the effectiveness of regular hydrotherapy in primary varicose veins.
Design: Randomized, single blind, prospective, controlled trial.
Setting: Social security system related rehabilitation center for employees (nationwide assignment of inpatients).
Patients: 122 patients with primary varicose veins.
Interventions: Group A (n=60) received daily treatments during 24 days that consisted of external application of alternating cold and warm water to both lower extremities. Group B (n=62) served as controls and was not treated with hydrotherapy. Both groups were comparable in terms of concomitant diseases and treatments.
Main outcome measures: Foot volume, ankle circumference and venous re-fill time, using light reflex rheography, served as objective variables, while a number of typical symptoms were recorded as subjective parameters.
Results: A more pronounced improvement in all objective signs in group A compared to B was observed. Four out of seven subjective symptoms improved more frequently in group A than in B.
Conclusions: Hydrotherapy is effective in treating primary varicose veins. It can be considered as an adjunct measure to compression therapy and other conservative treatments.

Correspondence and offprint requests to: Dr. E. Ernst, University of Vienna Medical School, Department of Physical Medicine and Rehabilitation, Währinger Gürtel 18–20, 1090 Vienna, Austria.

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Introduction

Varicosity is both frequent and potentially harmful. Its prevalence in the female population is reported to be as much as 68% [1]. It causes considerable suffering and is associated with serious sequelae such as ulcers, gangrene or venous thromboembolism. Furthermore, it causes considerable direct and indirect costs [2]. Compression stockings provide the conservative treatment of choice [3]. In addition, several adjunctive measures may be considered; in particular, a number of drugs have been shown to reduce symptoms [4], yet most doctors are not convinced that these offer relevant benefit.

Hydrotherapy has a long tradition in Europe. One of its domains is the treatment of varicose veins [5]; yet the notion that it is effective in this condition is based almost purely on empiricism. The present study was designed to scientifically test its clinical effectiveness by a controlled trial.

Materials and Methods

Patients

One hundred and twenty-two patients gave informed consent to participate in the trial. They were outpatients, admitted to a rehabilitation unit for reasons

Table 1. Demographic data on patient groups A and B

Demographic data	Group A (n=60)	Group B (n=62)
Age (years)	60.6 (1.1)	60.6 (1.2)
Body weight (kg)	74.9 (1.5)	74.4 (1.5)
Sex (females)	81.7%	66.1%
Arterial hypertension	25	23
Obesity (BMI>28.0 kg/m^2)	20	20
Symptomatic coronary heart disease	9	7
Chronic back pain	32	30
Hyperlipoproteinaemia	11	11
Gout	4	2
Subclinical diabetes	1	2
Diabetes IIb	4	1
Arthrosis	25	25
History of vein surgery (≤5 years)	2	2
History of vein surgery (>5 years)	5	6
History of sclerotherapy (≤5 years)	1	0
History of sclerotherapy (>5 years)	9	8

Data are expressed as means (SEM) where applicable.

other than venous disease. Table 1 gives detailed demographic data of the study groups.

Inclusion criteria were primary varicose veins of at least one leg as diagnosed by the patients' history, symptoms, physical examination and light reflex rheography (LRR) [6]. Patients were always examined by the same experienced doctor (S.T.), who was blinded to the patients' treatment. Exclusion criteria were venous insufficiency not due to primary varicosity, venous thrombosis, thrombophlebitis, lymphoedemas, congenital angiodysplasias, venous valve agenesia, venous compression syndromes, congestive heart failure, liver or kidney diseases, malignancies, acute inflammatory processes, haematological disorders and symptomatic peripheral arterial occlusive disease.

Study Design

On admission patients were randomized into groups A and B. Group A was treated with hydrotherapy, group B was not. As there is no placebo or sham treatment for hydrotherapy, the most rigorous design was a randomized, controlled, single-blind trial. All concomitant therapy was left constant during the study period. Patients who had compression stockings kept them and patients who had none at entry were not prescribed any during the trial period. Table 2 lists other concomitant treatments for both groups.

Intervention

Hydrotherapy consisted of daily treatments with alternating warm and cold water [5,7,8]. Treatments were administered to both legs at 7 a.m. 5 days per week. On Saturdays and Sundays patients were instructed to treat themselves. Two out of four different hydrotherapeutic measures (Table 3) were chosen intermittently.

Table 2. Concomitant therapy in groups A and B

Concomitant treatments	Group A (n=60)	Group B (n=62)
Medication for varicose veins	35	38
Compression stockings	16	14
Fibrates	9	8
Nitrates	8	10
Allopurinol	3	5
Calcium-channel blockers	10	8
Diuretics	6	8
L-thyroxin	4	6

Table 3. Daily treatments with water during the study

Hydrotherapy	Temperature (°C)	Duration
Showering the legs (according to Kneipp [8], two alternations or more, always finishing with the cold treatment)	35–38 12–16	1–2 min 20 s
Continuous cold water treatment (according to Kneipp [8])	12	40–80 s
Feet baths (two alternations or more, always finishing with the cold treatment)	35–38 12–16	5 min 15 s
Walking in cold water (water level to the calf, leg out of the water during each step)	10–18	15–50 s

Before treatment, both legs had to be agreeably warm.

Measurements

The following variables were quantified at entry and after 12 and 24 days of therapy, always at the same time of day and by the same, blinded investigator (S.T.):

1. Foot volume by water plethysmography [9]
2. Minimal leg circumference at the ankle
3. Venous refill time by LRR [6] – short times indicate venous insufficiency
4. Subjective symptoms were quantified by the patient marking visual analogue scales between two extremes (none to unbearable). Seven symptoms were thus recorded: frequency of cramps, stabbing pain in the calf, itching, paraesthesias, heaviness of legs, leg pain during standing or sitting, and need to elevate legs during the days

If both legs were affected by varicose veins, they were both evaluated. Care was taken that at least 3 h had elapsed between the last treatment and the above measurements.

Statistics

The data were evaluated as a cross-sectional comparison between A and B and expressed as means and SEM. For each group, the absolute changes relative to the respective baseline values were analysed statistically. After confirming normal distribution, the *t*-test was used for objective variables and the χ^2-test used for subjective symptoms (after dichotomizing into 'improvement' and 'no improvement' according to the direction of each change on the visual analogue scales). The null-hypothesis (no difference between A and B) was rejected when p was less than 0.05.

Results

At baseline none of the variables tested yielded significant differences between groups A and B. There were no drop-outs during the trial and no adverse effects were reported.

Table 4 summarizes the course of the objective parameters. At days 12 and 24 the average foot volume decreased significantly more in group A than in group B. Similarly the circumference at the ankle decreased significantly more in group A at the end of the study. Venous refill time increased significantly more in group A compared with B after both 12 and 24 days of treatment.

Table 4. Objective variables in groups A and B

Parameter (units)	Group	Baseline values	Day 12 values	Day 24 values
Foot volume (ml)	A	3154 (35)	3104 (34)*	3110 (35)*
	B	3081 (32)	3059 (32)	3081 (33)
Minimal circumference (cm)	A	22.09 (0.17)	21.96 (0.16)	21.90 (0.16)*
	B	21.85 (0.13)	21.82 (0.13)	21.91 (0.13)
Venous refill time (s)	A	27.1 (1.8)	32.2 (2.0)*	31.0 (2.1)*
	B	27.6 (1.7)	25.2 (1.6)	28.2 (1.8)

Data are expressed as means (SEM).
* Significant intergroup difference of absolute changes ($p<0.05$).

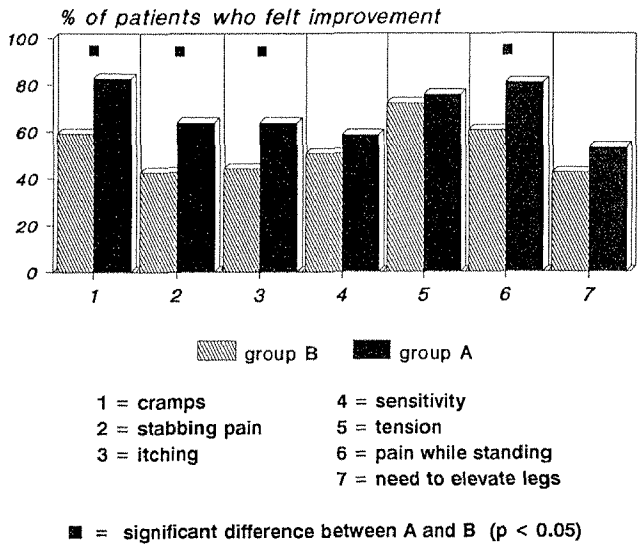

Fig. 1. Subjective symptoms in groups A and B at the end of the study.

The evaluation of the subjective symptoms is depicted in Fig. 1. Even though group A improved numerically for all seven symptoms, the intergroup differences reached a level of significance for only four symptoms: cramps, stabbing pains, itching, and pain during standing or sitting.

Discussion

The present results imply that hydrotherapy is effective in alleviating objective and subjective signs of primary varicose veins. Considering that this form of treatment is advocated in most textbooks of physical medicine and rehabilitation [5,10–12], it seems surprising that no controlled study, other than a pilot project of our own group [9], has so far been published.

Owing to the nature of the present trial, placebo effects must be considered. These can be most impressive, particular when evaluating subjective criteria [13]. Since placebo effects are less likely to occur with objectively measureable variables, we believe that the present results are (at least in part) true effects of the hydrotherapeutic interventions, unrelated to placebo.

The changes in objective parameters may well be considered as small, particularly those of foot volume and circumference (Table 4). Nevertheless, they are statistically significant. This indicates that they are highly uniform. The modification of LRR refill time, however, is more impressive. This parameter can be considered as one of the most relevant objective endpoints for evaluating primary varicosity non-invasively [6]. It must be stated that no other conservative treatment of varicose veins (other than compression) is known to lead to changes that are more pronounced than the ones observed in this trial.

Our study was designed primarily from a practical point of view, and thus cannot answer the question as to what mechanism is responsible for the clinical effects. Several hypotheses might be considered: reduction in venous capacity [14], venoconstriction [15], intravascular fluid shifts [16], increased diuresis [17] and elevated glucocorticoid levels [15] have all been reported after treatment with cold water. They might therefore have a role in producing the findings described above. Future experiments should be directed towards clarifying precisely why hydrotherapy benefits these patients.

The observed effects are not acute effects of hydrotherapy, yet we do not know how long they persist when hydrotherapy is discontinued. Similarly one cannot speculate whether the clinical benefit would wear off during long-term use. These issues are worth addressing in future studies.

Even though the present data imply that hydrotherapy can improve symptoms and signs of primary

varicose veins, we do not advocate it as a first-line or sole treatment. Compression is clearly the conservative treatment of choice and surgery should be performed whenever indicated [3]. Nevertheless, hydrotherapy can be used *in addition* to other conservative measures. It is inexpensive, can be performed by the patient at home, has no harmful side-effects and (most importantly) reduces symptoms.

In conclusion, hydrotherapy can be considered as an adjunct to compression therapy when conservative treatments are indicated for primary varicose veins.

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