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Complementary treatment of varicose veins – a randomized, placebo-controlled, double-blind trial

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Summary The aim of this study was to test the effectiveness of a combined homeopathic medication in primary varicosity. A well-defined population of 61 patients was randomized into active medication (Poikiven®) or placebo. Both were given for 24 d. At the start of the trial, after 12 d medication and at the end of the study, objective and subjective parameters were recorded: venous filling time, leg volume, calf circumference, haemorheological measurements and patients' symptoms such as cramps, itching, leg heaviness, pain during standing and the need to elevate the legs. The results show that venous filling time is changed by 44% towards normal in the actively-treated group. The average leg volume fell significantly more in this group, but calf circumferences did not change significantly and blood rheology was not altered in any relevant way. None of the patients reported side-effects. Subjective complaints were relieved significantly more by Poikiven than by placebo. These results suggest that the oral treatment of primary varicosity using Poikiven is feasable.

Keywords: homeopathy, varicose veins, placebo-controlled double-blind trial

Introduction

Primary varicosity is frequent; in West Germany an estimated 5.3 million individuals are affected.[1] The average prevalence of significant varicose veins, based on all published population based studies, is 15%.[2] Much of this high prevalence qualifies as disease as opposed to a mere cosmetic problem.[2] However, conservative treatment options are limited[3] and research into improved forms of treatment is not as innovative as one would wish.

Complementary medicine, particularly homoeopathy, is looked upon as a form of placebo treatment by many. Recent reports,[4–7] however, have shown that it can be clinically effective. Some doubt has therefore been cast on the attitude of orthodox medicine towards alternative treatments.[8] In view of this, we have performed a placebo-controlled, double-blind trial using a homeopathic combined preparation in a well-defined population of patients with primary varicose veins. Our working hypothesis was that the drug would ameliorate subjective and objective signs of primary varicosity. This had previously been our clinical impression when using the drug on an empirical basis.

Materials and methods

A total of 61 consecutive patients (16 males, 45 females, aged 58.1 ± 7.4) gave their informed written consent for inclusion in the trial. They had all been admitted to our rehabilitation clinic for at least 4 weeks. Concomitant diagnoses are listed in Table 1, concomitant treatments (which were kept unchanged during the trial) in Table 2. Primary varicose veins were diagnosed clinically (always by the same investigator) using established clinical tests Trendelenburg, Perthes etc.) and other physical signs (like ankle swelling, trophic changes). Present symptoms (see below) and past history (see exclusion criteria) were also noted. Light reflection rheography, a new photoplethysmographic technique,[9,10] was used to confirm the clinical diagnosis. No compression stockings were prescribed during the trial; patients already wearing such stockings continued to do so. Exclusion criteria were post-traumatic or post-thrombotic chronic venous insufficiency, lymphoedema hereditary vascular abnormalities, venous compression syndromes, congestive heart disease, liver and kidney disorders, malignancy, inflammatory disease, haematological abnormalities and peripheral

Table 1 Concomitant diagnoses.

	Placebo $n = 30$	*Verum* $n = 31$
Arterial hypertension (WHO)	$n = 11$	$n = 16$
Obesity (BMI more than 20%)	$n = 12$	$n = 18$
Symptomatic coronary heart disease	$n = 2$	$n = 6$
Back pain	$n = 17$	$n = 16$
Hyperlipoproteinaemia	$n = 7$	$n = 9$
Gout	$n = 3$	$n = 3$
Subclinical diabetes	$n = 1$	$n = 2$
Diabetes II b	$n = 3$	$n = 2$
Gonarthrosis	$n = 6$	$n = 6$
Coxarthrosis	$n = 2$	$n = 2$
Polyarthrosis	$n = 4$	$n = 2$

Table 2 Concomitant treatments.

	Placebo $n = 30$	*Verum* $n = 31$
Ginkgo biloba extract	$n = 3$	$n = 6$
Fibrates	$n = 4$	$n = 6$
Nitrates	$n = 4$	$n = 2$
Allopurinol	$n = 3$	$n = 2$
Ca-channel blockers	$n = 2$	$n = 3$
Diuretics	$n = 5$	$n = 3$
L-thyroxin	$n = 1$	$n = 3$
Hydrotherapy (according to Kneipp)	$n = 15$	$n = 15$
Compression stockings	$n = 8$	$n = 8$

arterial occlusive disease. All patients benefitted from the general effects of rehabilitation (being looked after professionally, away from home, regular exercise etc).

On admission patients were randomized to receive either placebo ($n = 30$) or active agent ($n = 31$). The latter consisted of 20 drops t.i.d. of Poikiven® (100 ml contain: Meliotus offic. D1 20ml, Aesculus D1 20ml, Hamamelis D1 20ml, Carduus marianus D1 10ml, Arnica ϕ 5ml, Lycopodium D4 10ml, Lachesis D4 10ml, Rutin D1 5ml). This medication was continued for 24 d. All patients were tested immediately before the first dose, after 12 d and on day 24.

The following variables were quantified: Venous filling time (VFT) by light reflex rheography.[9,10] Abnormally short VFT indicates venous insufficiency. Foot volume was measured using a 'home built' 'water plethysmograph'[11] which was temperature controlled and designed to weigh the water that was displaced from a tank by the leg and foot (Fig. 1). This apparatus had a coefficient of variation of 0.4% when repeatedly (15 times) measuring an identical healthy leg and a coefficient of variation of 0.06% when an 'artificial leg' with constant volume was used. Furthermore, the maximal circumference of both calves was recorded. Each patient was tested at the same time of the day after sitting quietly for 15 min. Room temperature was kept constant. The above three tests were done for both legs separately and data were then pooled for analysis (thus giving 60/62 legs in each group).

As primary varicosity is associated with abnormal blood rheology,[12] the following haemorheological measurements were performed: haematocrit,[13] plasma viscosity at 37°C[14] and blood viscosity at normal and 45% haematocrit[15,16] using a rotational viscometer (37°C) at controlled shear rates and controlling the shear history of the blood sample.[17]

Subjective improvement was monitored by asking the patient to score his/her complaints on a scale between 1–82 (Table 3). Scores were taken at baseline and 24 d after starting the treatment.

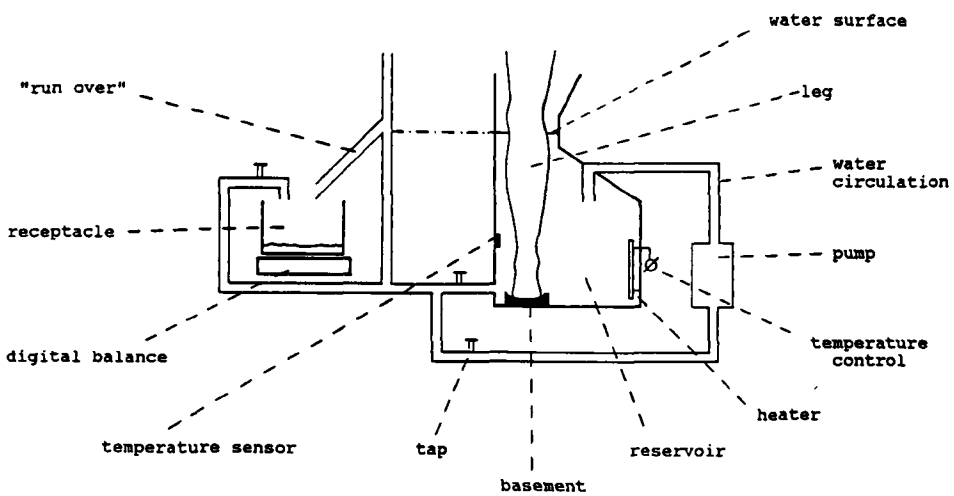

Figure 1 Water plethysmograph (for measurements of leg volume).

Table 3 Symptoms which each patients scored on a scale between 1–82.

1	Cramps in the calf
2	Itching in the legs
3	Heaviness of the legs
4	Pain during prolonged standing
5	Need to rest legs in elevated positions

The results were tested for normal distribution and then submitted to Student's *t*-test. The longitudinal analyses was done using the test for paired data, the cross-sectional ones using the test for unpaired data. The null-hypothesis was rejected when P was less than 0.05 at two-sided testing.

Results

The placebo-group baseline VFT was significantly longer than that of the experimental one; this difference was reversed following treatment. The VFT fell gradually in the placebo group, reaching the level of significance at the end of the trial. In the active-agent group opposite changes were observed, leading to a significant (44%) increase, indicating improved venous competence. The absolute changes of both groups were significantly different (Table 4).

Plethysmographic leg volume fell significantly at 12 and 24 d in the active-agent group, while this was true only at day 12 in the placebo-treated patients. The absolute changes were significantly greater in the experimental group at day 12 (Table 5).

Changes in calf circumference showed no significant cross-sectional difference, with the exception of a significant (but small) decline in the placebo group at the

Table 4 Venous filling time (s) in placebo and experimental group (means ± s.e.m., values in brackets describe % change compared to baseline).

	D	*Placebo (60 legs)*	*Verum (62 legs)*	*S*
baseline	†	31.9 ± 2.6	23.9 ± 1.9	
day 12	n.s.	28.7 ± 2.5 n.s. (−10.0%)	29.2 ± 2.5*** (+22.2%)	°°°
day 24	†	26.1 ± 2.2*** (−18.4%)	34.4 ± 3.0*** (+44.2%)	°°°

the shorter the filling time the more pathological

*** $P \leq 0.001$ significant absolute changes compared to baseline in each group (longitudinal differences)

† $P \leq 0.05$ significant differences (D) of values in one group *vs.* the ones in the other group (cross-sectional differences)

°°° $P \leq 0.001$ significant differences (S) of absolute changes in one group *vs* the ones in the other group (cross-sectional differences)

Table 5 Leg volumes (ml) in placebo and experimental group (means ± s.e.m. values in brackets describe % change compared to baseline).

	D	*Placebo (60 legs)*	*Verum (62 legs)*	*S*
baseline	n.s.	3127 ± 49.6	3137 ± 47.9	
day 12	n.s.	3104 ± 48.7** (−0.75%)	3085.3 ± 44.0*** (−1.67%)	°
day 24	n.s.	3104.1 ± 47.6 n.s. (−0.75%)	3113.2 ± 48.0* (−0.78%)	n.s.

Symbols and abbreviations as in Table 4: 1 symbol: $P \leq 0.05$, 2 symbols: $P \leq 0.01$, 3 symbols: $P \leq 0.0001$.

Table 6 Calf circumference (cm) in placebo and experimental group (means ± s.e.m. values in brackets describe % change compared to baseline).

	D	*Placebo (60 legs)*	*Verum (62 legs)*	*S*
baseline	n.s.	36.8 ± 0.4	36.7 ± 0.3	
day 12	n.s.	36.9 ± 0.4 n.s. (+0.32%)	36.5 ± 0.3 n.s. (−0.67%)	°
day 24	n.s.	36.6 ± 0.4* (−0.40%)	36.6 ± 0.3 n.s. (−0.27%)	n.s.

Symbols and abbreviations as in Table 4.

end of the trial and a significant absolute decrease in the active-agent group at day 12 (Table 6).

There were no intra-group changes or inter-group differences in haematocrit. There was a small significant drop in plasma viscosity in the placebo group at day 12 (from 1.241 ± 0.011 to 1.224 ± 0.009 mPa s) and one in the treatment group at day 24 (from 1.243 ± 0.012 to 1.235 ± 0.015 mPa s). There are no inter-group differences in this variable at any point. Likewise native blood viscosity at shear rate 0.7 s^{-1} shows no significant longitudinal or cross-sectional differences. The same applies for blood viscosity at 45% haematocrit with the exception of a significant absolute increase at day 24 (by 1.5 ± 0.7 mPa s) in the placebo group.

Patients' subjective symptoms demonstrate that at the end of the trial significantly more patients on active treatment experience improvement in subjective symptoms as follows: amelioration of cramps (71.0 *vs.* 43.3%, $P \leq 0.05$, chi^2-test); itching was improved in 67.7% of active-agent and 43.3% of placebo patients; 'leg heaviness' was significantly reduced in both groups (83.9% active treatment, 66.7% placebo). Pain on prolonged standing was reduced in 83.9% of the active-agent group (significant) and in 66.7% of the placebo group (not significant). Furthermore, 80.6% of the patients on active treatment described a reduced need for leg elevation compared to only 50.0% in the placebo group (significant difference).

Discussion

Standard textbooks only list surgery, sclerotherapy and external compression as the treatments of primary varicose veins.[18] The former two methods are not without risk[19] and external compression is often associated with poor compliance. Several drug treatments have been advocated, dihydroergotamine,[20] rutosides,[21] flavonoides,[22] calcium dobesilate,[23] and horse chestnut extracts,[24] to name just a few. In practice, however, these have not proved convincingly successful.[18]

The results of this study suggest that an oral homoeopathic combination is effective in respect to both objective and subjective variables. Other controlled trials (4–7) have demonstrated the effectiveness of homoeopathy for several diseases. There has been criticism of the lack of standardization of the medications used.[25] Poikiven® is a commercial product which is above criticism in this respect (Lomapharm, Emmertal, FRG). The obvious advantage of homeopathic drugs is in the absence of side-effects; none were reported by our patients.

It is clearly not possible to speculate on the active compound(s) in the drug used in the present study. Further experimental work is required to clarify this point and to attempt to elucidate its mode of action.

In conclusion, our results suggest that this randomized, double-blind, controlled trial demonstrates that a combined homoeopathic medication is effective in treating the symptoms and signs of primary varicose veins.

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