Efficacy of Class 1 elastic compression stockings in the early stages of chronic venous disease

A comparative study

J. P. BENIGNI, S. SADOUN, F. A. ALLAERT, F. VIN

France Society of Phlebology, Paris, France

Aim. **The aim of this study was to compare the efficacy of Class 1 (10-15 mmHg at the ankle) compression stockings with that of reference stockings of identical appearance during the early stages of chronic venous disease (CVD).**

Methods. **A prospective multi-center randomized double blind crossover study was conducted on 2 groups of female patients presenting with CVD with a CEAP classification of C1-3SEp As1-5. The efficacy of Class 1 compression stockings was evaluated with respect to global painful discomfort (visual analog scale), each symptom of CVD, the daily behavior of the patient, changes in the volume of the legs, and the functioning of the venous pump (D-PPG). The compliance level of each patient was measured by the number of days that she wore the stockings for at least 6 hours, and tolerance was measured by the reporting of ensuing undesirable events.**

Results. **A total of 125 patients were included in the study and were analyzed for intent to treat. Highly significant differences favoring Class 1 compression stockings were noted with respect to both global painful discomfort and each symptom of CVD with the exception of paresthesia. The relief of symptoms that resulted from the use of the Class 1 compression stockings was twice that which resulted from the use of the reference stockings. Differences that favored the Class 1 compression stockings were also observed with respect to 2 quality-of-life factors (mood and daily work activity). Good compliance in the use of the stockings was reported for 95% of the patients, and tolerance was higher for the Class 1 compression stockings group than for the reference group.**

Conclusion. **The regular wearing of Class 1 graduated elastic compression stockings during a 15-day period results in a significant improvement in the symptomatology of early-stage chronic venous disease, *i.e.*, in the relief of global painful discomfort as well as in quality-of-life criteria. A high level of patient compliance in the wearing of the stockings was achieved in this study.**

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Key words: **Bandages - Vascular diseases - Veins.**

Chronic venous disease (CVD) of the lower limbs is characterized by a combination of clinical signs and symptoms caused by intra-venous hyperpressure that is related to a supposed abnormality in the venous return and stasis of blood in the legs.

From a functional point of view, the disease is manifested by leg pain, heavy legs, restless legs, swelling in the ankles, and even paresthesia. Observable clinical signs include telangiectases, varicose veins, and eventual changes in the skin (pigmentation, venous eczema, dermatitis, lipodermatosclerosis, and healed or open ulcers).

From a therapeutic point of view, ANAES (Agence Nationale d'Accréditation et d'Evaluation en Santé) [1] states that "there is a strong consensus that compression therapy is the basic treatment for chronic venous disease of the lower limbs at any stage". This consensus is based upon irrefutable physiopathological arguments.[2-6]

In daily clinical practice, the efficacy of compression stockings is undermined by a lack of patient compliance when the external pressure applied on the legs is high.[7] Various authors [8-11] recently have called into question the usefulness of applying higher levels of compression as a means to achieving therapeutic effectiveness.[12]

With respect to the treatment of early-stage CVD, patients are often unwilling to endure the discomfort associated with high-pressure compression stockings. Thus, clear proof of the efficacy of a Class 1 (*i.e.*, 10 to 15 mmHg at the ankle) compression stocking would open the door to greater patient compliance when such a product would be prescribed.

Few currently available studies [8-10] have showed the effectiveness of low-pressure compression stockings in the treatment of venous disease.

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Materials and methods

Nature of the study

A prospective multi-center randomized double blind crossover comparative study was conducted on 2 groups.

Objectives of the study

PRINCIPAL OBJECTIVE

To compare the efficacy of Class 1 knee-high compression stockings with that of reference stockings of identical appearance in relieving global painful discomfort during early-stage CVD.

SECONDARY OBJECTIVES

To compare the efficacy of Class 1 knee-high compression stockings with that of reference stockings of identical appearance in:

— each symptom of CVD and the effects of that impairment on the daily behavior of the patient;

— changes in the volume of the legs,

— the impact on the functioning of the venous pump,

— both patient tolerance and patient compliance.

Selection of subjects

INCLUSION CRITERIA

Before being included in the study, each patient was informed by the investigator about the study's objectives and constraints. They then gave their written informed consent according to the terms of the French law of December 20, 1988 that protects individuals participating in biomedical research.

In order to be admitted to the study, each patient had to meet the following criteria:

— age range of 18 to 75 years;

— symptoms of early-stage CVD of the lower extremities: Class C1 to 3-S Ep AS1-5 according to CEAP classification;

— either reticular veins or telangiectases (*i.e.*, clinical classification stage 1), non-saphenous varicose veins <3 mm (*i.e.*, stage 2), or malleolar edema in the afternoon without skin changes (*i.e.*, stage 3);

— symptoms: pain, heavy legs, cramps, paresthesia, or swelling in the ankles;

— global painful discomfort that has lasted more than 8 days and which, on the day that the patient is evaluated, measured 4 out of 10 on the Analog Visual Scale (AVS);

— present the following:

1) competent deep venous trunks, especially the popliteal veins and the medial gastrocnemius veins;

2) competent greater saphenous veins less than or equal to 5 mm in diameter (measured 30 mm below the sapheno-femoral junction) and lesser saphenous veins less than or equal to 4 mm in diameter (measured 30 mm below the saphenopopliteal junction);

3) competent calf perforating veins;

— present, by means of a photoplethysmographic examination, a venous refilling time (T0) of greater than 24 seconds and a venous pump power (V0) that is greater than 3%;

— have an ankle diameter of between 20 and 26 cm and a maximum calf diameter of between 33 and 43 cm.

Exclusion criteria

GENERAL CRITERIA

The study could not include male patients or patients:

— who had not given their written informed consent;

— who were participating or had participated within the last 3 months in another clinical trial;

— for whom evaluation and follow-up of judgment criteria would be difficult;

— who suffered from a severe or long-term disease.

PROTOCOL-RELATED CRITERIA

The study could not include a patient:

— who presented with symptoms and/or signs in their lower limbs of any known and documented evolving pathology of cardiac, renal, hepatic, metabolic, neurological, osteo-articular, or traumatic origin;

— who presented a BMI greater than or equal to 30;

— who presented with a risk factor worsening the CVD: an episode of superficial venous thrombosis (within the past 3 months), a pregnancy, or a childbirth within the 6 months prior to inclusion in the trial;

— who had a past history of deep venous thrombosis;

— who presented with skin changes (*e.g.*, pigmentation, dermatitis, atrophie blanche, open or healed ulcers, or lipodermatosclerosis);

— who presented with peripheral arterial disease in the lower extremities (Stage 2 or higher according to the Leriche classification);

— who presented either with a permanent venous edema that filled the retro-malleolar areas of the ankle, or with lymphedema;

— who presented, by means of a duplex ultrasound examination, with any of the following:

1) a valvular incompetence at the saphenofemoral and/or sapheno-popliteal junctions and/or incompetent perforating veins;

2) an obstacle or a reflux in the deep venous network, especially at the level of the popliteal veins or the medial gastrocnemius veins;

3) a diameter of the greater saphenous vein >5 mm (measured 30 mm below the junction);

4) a diameter of the lesser saphenous vein >4 mm (measured 30 mm below the junction)

— who presented, by means of a photoplethysmographic examination, a T0 of less than 24 seconds and a V0 of less than 3%;

— who was taking calcium channel blockers, anticoagulants, diuretics, anti-inflammatory drugs, or Vitamin C;

— who had received hormonal treatment within the past 6 months;

— who either currently or within the last 15 days received phlebotonic medications;

— who either currently or within the last 48 hours received pain medication;

— who either currently or within the past week had been treated with elastic compression;

— who presented with a venous condition that warranted either sclerotherapy or vascular surgery during the trial.

Criteria for the evaluation of efficacy

Principal criterion

The principal criterion for evaluating the efficacy of the knee-high stockings was the change in global painful discomfort in the legs experienced by the subjects during the course of the study. It was measured with the Analog Visual Scale on days 0 and 14 during the 1st crossover period and on days 21 and 35 during the 2nd crossover period. Between days 14 and 21 there was a washout phase during which the subjects did not wear the stockings.

Secondary criteria

— The intensity of the following symptoms: pain, heavy legs, cramps, paresthesia, and a swelling in the ankles was evaluated on days 0, 14, 21, and 35.

— The effects of CVD on the daily behavior of the patient (mood, ability to walk, daily work activity, interpersonal relationships, sleeping patterns, and a general style for living) were similarly measured with the Analog Visual Scale.

— Leg volume was measured on days 0 and 14 during the 1st crossover period and on days 21 and 35 during the 2nd crossover period. The circumference of the leg was measured at heights of 16 cm, 20 cm, and 25 cm above the floor with the use of a "Leg-O-Meter" device.

— The T0 and the V0 were measured by photoplethysmography on days 0 and 14 during the 1st crossover period and on days 21 and 35 during the 2nd crossover period.

— In addition, each patient kept a journal in which she evaluated herself daily. In this way, it was possible to document the length of time the patient wore the stockings each day as well as any discomfort that she may have felt as a result.

Criteria for evaluation of tolerance and reported side effects on the material

Two factors were considered in the evaluation of patient tolerance of the stockings:

— undesirable or unexpected events either reported spontaneously by patients during the course of the trial or noted by investigators during physical examinations;

— and the level of general comfort or discomfort experienced by the patients during the study. Each major undesirable event was reported on a specific form for reported side effects on the material.

Criteria for evaluation of compliance

Compliance was verified by the investigator who examined the patient's daily journal on days 14 and 28. The minimum period per day that study participants were required to wear the stockings

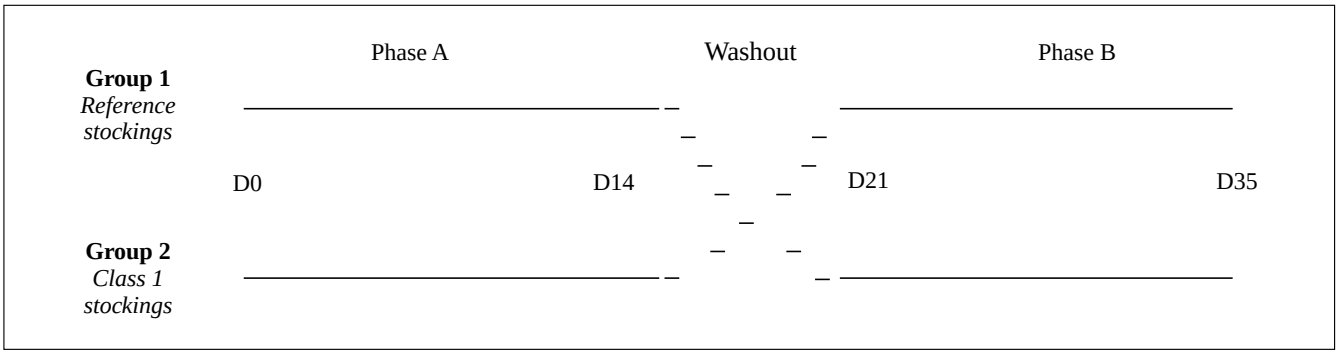

Figure 1.— Course of the study.

was set at 6 hours. A patient's compliance was determined to be satisfactory if the number of days that the stockings were worn for the minimal period (*i.e.*, 6 hours) was equal to or greater than 80% of the time that stockings were worn.

Recruitment of physicians and patients

Each physician enrolled 15 patients in the study after having obtained their written informed consent. In order to avoid selection bias, it was preferable that inclusion in the study be proposed systematically to all patients who were eligible for the study in the order that they arrived for initial consultations.

Treatments

Knee-high ccompression stocking to be studied

A Class 1 knee-high graduated compression stocking (13 to 20 hPa) that meets the criteria of TIPS was used in the study. These criteria include the following: fiber that surpasses 66 dtex and consists of Pa microfibers, Elasthanne, and cotton; Elasthanne 310 yarn, double-covered, Pa22/77/1, with cross-weave reinforced heel and closed toe. The color is black #90.

Control stocking

A regular knee-high stocking that does not meet the TIPS criteria (because of the titer of the yarn that is used) was chosen to be the "standard" reference stocking in this study. Its compression level is less than 10 hPa. The fiber exceeds 66 dtex, and, like the study stocking, the material consists of Pa microfibers, Elasthanne, and cotton. The yarn is Elasthanne 100, double-covered, Pa 44/13/1. Like the study stocking, its color is black #90, and it has a cross-weave reinforced heel and closed toe.

Because they have identical stitching and were woven on the same type of machine, the 2 stockings (active and non-active) used in this study are extremely similar. The decreased elasticity in the non-active stocking (100 dtex as compared to 310 dtex) is compensated by a heavier outside thread (44 dtex as compared to 22 dtex).

Randomization of treatments

The treatments were randomized within balanced groups of 15 patients at each research center. The randomized patient list was provided to each center prior to the start of the study.

The wearing of the stockings

Patients put their stockings on early in the morning immediately after showering and wore them for a minimum of 6 hours per day. Each patient recorded in their daily journal the total time that they had worn the stockings.

Course of the study

The patients were enrolled in the study on day 0. Each patient, according to randomization number, received a set of 2 pairs of stockings as well as a daily journal. A number that corresponded to the set of 2 pairs was recorded on her chart. Each patient then returned for an examination on day 14 in order that the evolution of her venous disease could be followed. On that day, each patient returned to the investigator the 2 pairs of stockings that they had received on day 0 as well as her daily journal.

FROM DAY 14 TO DAY 21, THE PATIENTS WERE TO WEAR THEIR REGULAR SOCKS OR STOCKINGS

Each patient then returned on day 21 for another clinical examination and to receive a 2nd set of 2 pairs of stockings according to her randomization code. A number that corresponded to the 2nd set of 2 pairs was recorded on her chart. Patients who had received 2 pairs of study stockings on day 0 received 2 pairs of reference stockings on day 21, while those 2 had received reference stockings on day 0 received study stockings on day 21. Each patient was then evaluated on day 35 in the same manner as they had been evaluated at the end of the 1st phase of the crossover (Figure 1).

Exiting the study

Patients were free to withdraw from the study at any time without having to provide reasons and without consequences with respect to any future treatment. Nevertheless, when a patient withdrew from the study, the investigator attempted to contact them in order to ascertain the reason for their decision to withdraw and, in particular, to determine whether or not their withdrawal was related to either an inability to tolerate the stockings or a worsening of the venous disease. When possible, the reason for a patient's withdrawal was recorded in their chart.

Statistical analysis

The number of patients to be included in the study was determined prior to the beginning of the study based upon an a risk of 0.05 and a β risk of 0.20. These figures were derived from clinical hypotheses that were based upon the existing literature.[8-11]

The data analysis performed as part of this study was predicated upon the intent to treat, and the data were collected only from those randomized patients who had worn the study stockings at least once and who had been evaluated at least once after having been enrolled. Stocking efficacy data collected during the 1st crossover phase were analyzed alone; in addition, the combined data collected during both crossover phases were analyzed after the washout period had been verified. The data were analyzed in the classic manner, *i.e.*, using mean and standard deviation for the quantitative variables as well as histograms for both the frequencies and percentages of the qualitative variables. Mean comparisons were conducted by analysis of variance, and percentage comparisons were conducted using χ^2 tests. The data analysis was conducted using SAS software Version 8.12 (from the SAS Institute) loaded on Unix equipment and was carried out by the team at the Evaluation Department of the University Regional Hospital Center (Centre Hospitalier Régional Universitaire; CHRU) in Dijon, France. The threshold for significant data in the conducting of these tests was set at an α value of 0.05.

The research protocol was approved by the appropriate human subject protection committee (CCPPRB) of the Dijon University Hospital Center.

Results

Included population

A total of 125 patients was selected and included in the study during the period from September 2000 to June 2002. Sixty patients were included in Group 1 and 65 were included in Group 2. On day 14, at the end of the 1st crossover phase (*i.e.*, Phase A), 117 patients were seen for a 2nd time (55 from Group 1 and 62 from Group 2). Seven patients were definitively lost, and an 8th patient did not return on day 14 for reasons unrelated to her treatment but did participate in Phase B of the study.

After the washout period that ended on day 21, 114 patients (60 in Group 1 and 54 in Group 2) agreed to participate in the 2nd crossover phase (*i.e.*, Phase B). Three patients decided not to continue their participation in the study (after telephone communication with investigators).

On day 35, 111 patients returned for their 2nd Phase-B visit (58 from Group 1 and 53 from Group 2).

A total of 14 patients, thus, were lost between their enrollment and the end of the study.

When the results of Phases A and B were pooled, analyzable data were obtained for 113 patients (55 patients plus 58 patients) treated with the reference stockings and 115 patients (62 patients plus 53 patients) treated with the Class 1 stockings. This reflects a total of 228 patients, each one treated

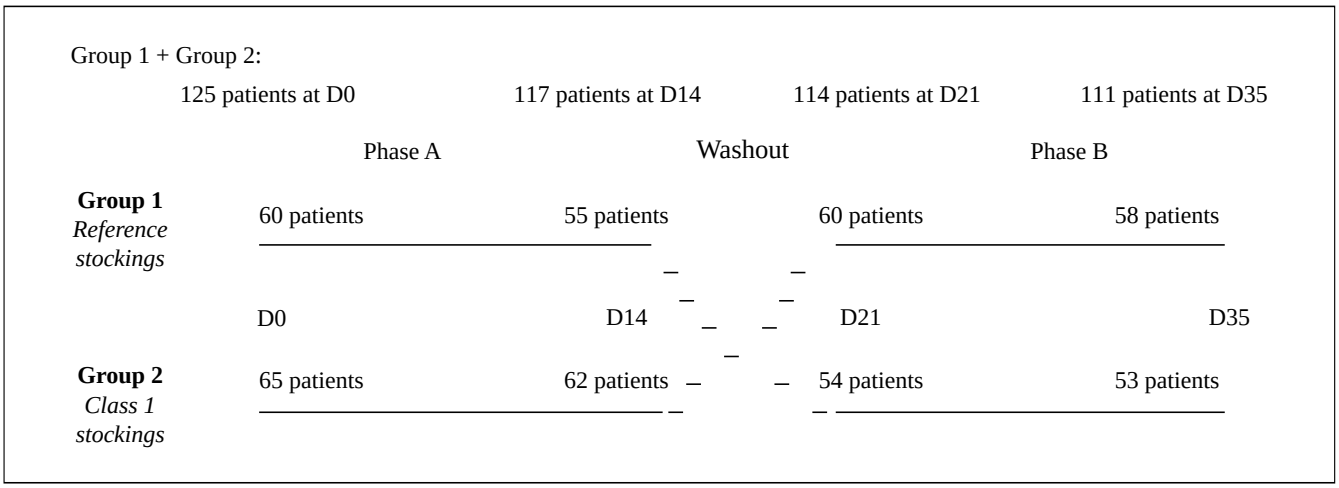

Figure 2.—Evolution of the population.

during a 15-day period either with reference stockings or with Class 1 stockings (Figure 2).

No significant differences between the 2 groups of patients were noted with respect to age, weight, height, professional status, risk factors, or past medical history.

Duplex ultrasound examination revealed that 1 patient in Group 1 had a greater saphenous reflux at the ostium of less than 1 second (but without a reflux at the femoral level) and that 1 patient in Group 2 had a lesser saphenous reflux of less than 1 second. Because these refluxes were not pathological, they were not considered criteria for exclusion from the study even though, in the strictest sense, they constituted a deviation from the protocol.

At the time of patient enrollment, there was no statistically significant difference between the 2 treatment groups with respect to efficacy criteria, the volume of the legs, and the D-PPG measurements (T0 >24 s and V0 >3 s).

Efficacy

Principal criterion of the study

On day 14, at the end of Phase A (Table I), global painful discomfort in the legs at the time of the consultation or during the previous 8 days was significantly less among those wearing the Class 1 graduated compression stocking (Group 2) than among those wearing the reference stocking (Group 1). The decrease of global pain was twice as great among wearers of the Class 1 stocking than among the wearers of the reference stocking.

Secondary criteria of the study

A comparison of the changes in pain, heavy legs, cramps, and swelling in the ankles (Table II) confirms the positive results that were found with respect to the study's principal criterion.

On the other hand, no significant difference between the 2 groups was found with respect to paresthesia.

No significant differences were found with respect to differences in leg volume, changes in T0, or V0 as measured by D-PPG.

In addition, evaluation at day 14 revealed that the Class 1 graduated compression stockings had not significantly changed the impact that chronic venous disease had on the daily behavior of the patients in Group 2 as compared with the effects of the reference stockings in the Group 1 patients.

After having verified the efficacy of the washout period, data from Phases A and B were pooled (Figure 2). Data analysis was performed on a total of 228 treatments (Class 1 graduated compression stockings and reference stockings).

Before treatment began, the 2 groups were comparable with respect to the primary judgment criterion as well as the secondary judgment criteria (pain, heavy legs, cramps, paresthesia, swelling, leg volume, D-PPG examination, and the effects of chronic venous disease on patient behavior).

Decrease in global painful discomfort continued in a manner that paralleled what had been observed on day 14. Similar results were found with respect to pain, heavy legs, cramps, swelling, and paresthesia.

TABLE I.—*Principal criterin of the study. Global painful discomfort in the legs.*

	Before treatment	After treatment	Individual variations
During the 8 days preceding the day-14 consultation (p<0.05)			
Group 1	4.6±1.9	3.1±2.1	-1.4±1.6
Group 2	4.7±1.6	1.8±1.7	-2.9±2.1
At the time of the day-14 consultation (p<0.01)			
Group 1	4.1±2.2	2.9±2.1	-1.2±2.1
Group 2	4.0±1.9	1.4±1.8	-2.6±2.4

TABLE II.—*Secondary criteria of the study.*

	Improvement	No Change	Deterioration
Pain (p=0.0215)			
Group 1	30.2% (n=16)	64.2% (n=34)	5.7% (n=3)
Group 2	55.7% (n=34)	39.3% (n=24)	4.9% (n=3)
Heavy legs (p=0.0025)			
Group 1	35.2% (n=19)	63.0% (n=34)	1.9% (n=1)
Group 2	66.1% (n=39)	30.5% (n=18)	3.4% (n=2)
Cramps (p=0.0379)			
Group 1	2.0% (n=11)	72.7% (n=40)	7.3% (n=4)
Group 2	39.3% (n=24)	59.0% (n=36)	1.6% (n=1)
Swelling in the ankles (p=0.0240)			
Group 1	18.9% (n=10)	75.5% (n=40)	5.7% (n=3)
Group 2	42.6% (n=26)	54.1% (n=33)	3.3% (n=2)

TABLE III.—*Patients' daily behavior.*

	Before treatment	After treatment	Individual variations
Mood * (p<0.01)			
Reference stockings group	1.9±2.3	1.5±1.9	-0.2±1.3
Class 1 stockings group	2.2±2.5	1.1±1.7	-1.0±1.8
Daily work activity * (p<0.05)			
Reference stockings group	2.2±2.3	1.6±1.8	-0.6±1.8
Class 1 stockings group	2.4±2.5	1.1±1.6	-1.4±2.1

* Variations were compared for each individual and within each group.

On the other hand, the pooling of data (Table III) revealed that the wearing of the Class 1 graduated compression stockings had a significant effect on certain aspects of the patients' daily behavior (mood, daily work activity).

Tolerance

Whether "undesirable effects" were defined in this study [8] as all reported effects, missing data, and lost patients, or [2] as only the effects reported by the patients themselves, no significant difference in undesirable effects was found to exist at day 14 between the 2 groups. A significant difference emerged only when the data were pooled. The reference stockings caused more undesirable effects than did the Class 1 stockings (slipping of the stockings down the leg, a warming sensation on the legs, and a feeling of pressure on the legs).

Compliance

Patient compliance was good in that 95% of the study participants wore the stockings for at least 6 hours per day and during at least 80% of the duration of the 2 phases of the study.

At the time of the pooling of data, the difference between patients treated with Class 1 stockings and those treated with reference stockings remained non-significant.

Discussion

The decision to conduct a comparative crossover study, when the protocol was first developed, was made in part because of the relative lack of studies in the literature. Existing studies [8-11] offer a general indication of a decrease in global aching in the legs. In the study by Chauveau *et al.*,[10] the wearing for a 1-day period of graduated compression stockings with a pressure ranging from 7.9 mmHg to 16.7 mmHg at the ankle, when compared to the wearing of regular panty hose with a pressure of 4.5 mmHg at the ankle, resulted in a 40% decrease in pain.

We believed that average clinical period of 15 days for judging the efficacy of compression stockings could more accurately reflect true patient behavior. In our hypothesis, we predicted a clinically significant decrease of 20% in global pain with the study stockings as compared with the reference stockings. The choice of a figure below 20% for our hypothesis still might have been statistically significant, but the demonstrated medical advantages would have been problematic. With the α and β risks set at 0.05 and 0.20, respectively, a total of 125 patients would be sufficient as long as each patient would be able to serve as her own control. This, then, was the reason for the crossover design of the study. Accordingly, because the collected data were pooled, this type of study made it possible to demonstrate significant differences between study and reference stockings with a smaller number of subjects.

Our initial hypothesis turned to be incorrect with respect to the primary judgment criterion (global painful discomfort) and the secondary, *i.e.*, functional criteria, as highly significant differences became apparent as soon as Phase A had been completed; the pooling of data at the end of the study merely confirmed these differences. On the other hand, this particular study design allowed us to establish the fact that, once the Class 1 graduated compression stockings had been worn for 15 days by all of the study participants, the quality-of-life factors (*i.e.*, mood and daily work activity) were found to be significantly improved after data on 228 "pooled patients" had been analyzed.

A longer observation period might have been chosen for the purpose of creating more "sensitive" quality-of-life factors. One earlier study,[13] in which a CIVIQ questionnaire [14] was used after a month of treatment with Class 1 panty hose, showed significantly positive results with this evaluation tool. This longer observation period, however, did not allow researchers to demonstrate significant differences with respect to symptoms. The longer period appears to have increased the lack of precision in the responses of patients who had difficulties recalling problems that were inherently subjective. Memories must be at least somewhat blurred, in fact, over the time span between the disappearance of painful symptoms and the reporting of physical, psychological, or social changes by the patient herself.

The number of patients lost totaled 14 by the end of the study. This figure is not surprising. The pathology of chronic venous disease is indeed debilitating yet benign. Nevertheless, the loss of 11% of the subjects threatened to distort the results. It is for this reason that an analysis based solely on the intent to treat was performed. All patients included in this study were analyzed. We thus aligned ourselves with the most limiting hypothesis possible in order to evaluate treatment efficacy, and we eliminated the biases that would have resulted from a *per protocol* analysis.

Of the patients suffering from early-stage CVD who were selected for participation in the study, 60% complained from the start of a swelling at the ankles. This swelling was decreased significantly by the Class 1 compression stockings. However, no significant changes in leg volume, whether among patients wearing the Class 1 stockings or among those wearing the reference stockings, were observed neither between day 1 and day 14 nor after the pooling of data at the conclusion of the study. Because of this observation, we must question:

— the validity of the method used to calculate leg volume;

— the correlation between a true edema in the ankle and a swelling in the ankles.

The 1st location for measuring the circumference of the leg was at a height of 16 cm from the floor, well above the malleoli. Nevertheless, the method used to measure the volume of the foot and the leg that was used in the study by Vayssairat *et al.*[13] did not permit the demonstration of clear variations. The question remains as to whether patients suffering from early-stage chronic venous disease really present with evening edema or merely experience a simple swelling sensation.

Meanwhile, the efficacy of the Class 1 graduated compression stockings in treating the global pain discomfort and other symptoms discussed above as compared with the lack of improvement of paresthesia in both groups warrants an inquiry into the venous etiology of paresthesia. Can this symptom be related to a different etiology?

The fact that V0 and T0 values were shown by the D-PPG to be normal at the time of enrollment in the study undoubtedly explains the non-significance of the modification of intra-group and inter-group values at the end of the study. The D-PPG is a tool that confirms changes that have occurred in the venous pump once venous disease has reached an advanced stage. Changes revealed by D-PPG during earlier stages of the disease are most likely not significant.

Patient compliance in this study was considered to be good in 95% of the study population. As for tolerance of the stockings, however, the number of negative effects reported was surprising even though their numbers were considerably less among wearers of the Class 1 graduated compression stockings than among wearers of the reference stockings. The explanation for this lies most likely in the very nature of any clinical study in which patients are asked to report the existence or absence of undesirable effects. This type of data collection is never done in everyday medical practice and does not exist in retrospective efficacy studies.

Conclusions

The wearing of Class 1 graduated compression knee-high stockings (10 to 15 mmHg at the ankle) for a 15-day treatment period results in a significant improvement in the symptomatology and in the quality-of-life criteria in patients presenting with early-stage CVD of the lower extremities. The reported good compliance by patients obviously confirms the simplicity of the application of the treatment. This level 1 clinical study thus confirms previously published data [7, 10, 13, 15] on the benefits of low-level compression in the treatment of early-stage forms of chronic venous disease.

Given the publication of this evidence, discussions about future European standardization should be expanded. During a recent consensus conference on elastic compression therapy [16] that took place in Paris in 2002, level-2 evidence was provided on the benefits of low-pressure compression following surgery on the saphenous vein and during airplane flights. These data demonstrate that there is without question a place for Class 1A graduated compression stockings (10 to 15 mmHg pressure at the ankle) thanks to the true medical benefits that they provide.

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[1] Bureau de Normalisation de l'Industrie textile et de l'Habillement, Paris, France.
[2] Société Française de Phlébologie, Paris, France.

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Address reprint requests to: J. P. Benigni, 78 Bd. de la Liberation, 94300 Vincennes, France.