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Compression stockings for the treatment of venous leg ulcers

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Key words: Compression stockings – bandages – venous ulcer.

Summary: The aim of the study was to compare the effectiveness of medical compression stockings, which require no special fitting technique, with that of low-elasticity bandages, in patients with venous leg ulcers.

Study design and patients: A prospective study with a total of 50 ambulant patients with leg ulcers, who were randomly divided into two treatment-groups: 25 patients were treated with strong compression bandages made from short-stretch material (Rosidal-K) and 25 patients were treated with medical compression stockings (SIGVARIS® Thrombo and, over these, Sigvaris-503® calf stocking). In view of the statistically significant lower mean age and the significantly longer duration of the ulcers in the Sigvaris group, the two groups were comparable with one another only with certain limitations. Local treatment of the ulcers consisted of non-adherent, absorbent dressings (Vliwin®), over which a foam-rubber pad, individually modeled to size, was placed. Complete healing of the ulcer within 3 months was set as the end-point of the study.

Methods: The following parameters were measured: area of the ulcer, compression pressure, transcutaneous oxygen pressure and laser Doppler flux at the margin of the ulcer before and after 3 minutes of arterial blockade, venous volume and venous filling index by means of air-plethysmography (APG) without and with compression.

Results: After 3 months 21 patients (84%) in the Sigvaris group and 13 (52%) in the Rosidal group were cured. This statistically significant difference can be partly explained by the better baseline conditions in the group that wore stockings. An important advantage of the stockings, compared with the short-stretch bandages, is the maintenance of adequate compression throughout the day.

Conclusion: In patients who are both willing and able to be cooperative, the treatment of venous ulcers with medical compression stockings can be an effective measure.

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According to traditional medical instruction, the use of medical compression stockings is indicated only after the leg ulcers have healed, but not while they are in the florid stage. Even the manufacturers of medical compression stockings state in their product information that compression stockings are contraindicated in the presence of leg ulcers. On the other hand, Cornu-Thénard et al. (5) and American authors (10, 13) report very satisfactory cure rates for ulcers under compression-stocking therapy. For a great number of patients this type of therapy would represent a considerably simplified form of treatment.

An important problem in the treatment of venous leg ulcers from which, according to epidemiological studies, about 1% of the adult population suffers (12) is that although the majority of these ulcers can be cured with good compression therapy, the treatment as usually carried out by the patient himself is often completely inadequate. A well-fitted medical compression stocking, on the other hand, would guarantee the patient a consistent quality of compression and would make him independent of his variable degree of skill in putting on a compression bandage himself.

The aim of the present study was to investigate the efficacy of treatment with medical compression stockings in patients with venous leg ulcers and to compare the results with those of a conventional compression method.

Patients

Fifty-nine patients with venous ulcers who were attending our Out-Patient Department were included in the study, with their agreement.

A condition for inclusion in the study was the presence of venous refluxes, detected by means of directional Doppler ultrasound probe through superficial and/or deep veins of the leg. An ankle-arm pressure index (Doppler ultrasound) below 0.8 was a criterion for exclusion from the study.

Healing of the ulcer within a 3-month period of observation was established as the decisive end-point of the study.

The randomization of the patients into 2 treatment-groups was made according to the first letter of the last name:

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Patients with the first letters from A to M were allocated to the «Rosidal group» and those with the first letters N to Z to the «Sigvaris group». In the Rosidal group 3 patients who refused the repeated measurements dropped out of the study, and in the Sigvaris group there were 6 drop-outs due to their inability to put on their stockings. Thus in each group there remained 25 patients, who were examined at weekly intervals for 12 weeks.

The decisive parameters in the two groups of patients are presented in Table I.

Due to the statistically significant differences in the parameters marked with an asterisk (*) in Table I (Chi-square analysis), the randomization has to be considered unsatisfactory.

Methods

1. Bandage and compression

The ulcers were cleaned with a physiological saline solution and covered with a non-adherent, absorbent wound-bandage (Vliwin®, Rauscher). Irrespective of the extent and the appearance of the ulcers, any different local therapy was deliberately avoided.

This bandage was covered with a foam-rubber pad (Kompres®, Lohmann). To fix this local bandage, an anti-thrombosis prophylactic stocking (Thrombo of Ganzoni) was used in the Sigvaris group and a thin roll of synthetic expanded plastic (Haftan, Rauscher) in the Rosidal group.

The patients in the Sigvaris group were given an adapted Sigvaris-503 calf stocking A-D (Ganzoni) and were instructed to pull this over the thrombosis stocking every morning. In the evening the Sigvaris-503 stocking was taken off by the patient, whereas the local ulcer bandage and the anti-thrombosis stocking remained on the leg day and night. In the case of heavy secretion the bandage was changed in the Out-Patient Department.

In the Rosidal group a Rosidal-K bandage (Lohmann, short-stretch bandage, 10 cm wide and 2.5 m long) was put on by an experienced nurse. Here, too, in the case of heavy secretion from the ulcer, the patient was offered a change of bandage in the Out-Patient Department.

In both groups an obligatory change of bandage was carried out at weekly intervals in the Out-Patient Department.

2. Measurement of compression pressure

The compression of the stockings and the bandages was measured at a point in the middle of the calf by means of an air-filled pressure probe (Talley Instruments, Great Britain). In several cases this probe was left on the leg for a few days.

3. Air plethysmography (APG)

Using an air-plethysmograph (ACI Medical, USA) (3), changes in the blood volume in the lower leg were

measured in the standing position, with and without compression.

In this study the «venous volume» (VV) and the venous filling index (VFI) were evaluated. VV is defined as the increase in volume of the lower leg that occurs on standing up after the veins have been completely emptied by lying down with the legs held in vertical position. The venous filling index means the increase in volume over time. In comparison to healthy subjects, the index is raised in the presence of venous refluxes due to the rapid retrograde venous filling on standup.

Table I: Comparison between Sigvaris and Rosidal groups (median values, minimum to maximum values).

	Sigvaris (n = 25)	Rosidal (n = 25)
Age (years)*	54 (36-81)	70 (34-93)
Sex (m/f)	12/13	15/10
Left/right leg	14/11	15/10
Area (cm ²)	3.2 (0.8-10.4)	6.0 (0.8-26)
>1 ulcer	6	10
Medial localization	20	19
First appearance/relapse	4/21	4/21
First appearance (years ago)	5 (1.5-40)	15 (2-38)
Duration of ulcer (months)*	2 (0.25-36)	5 (0.25-36)
History of thrombosis	10	10
Varicose veins		
Duration (years)	30 (2-51)	30 (2-73)
Long saphenous	12	8
Short saphenous	3	3
Magna + parva	6	8
Isolated perforantes	4	5
Earlier varicose-vein therapy (yes/no)	15/10	8/17
Refluxes (Doppler):		
superficial/deep	11/17	14/15
Stemmer's sign*		
neg/pos	17/8	8/17

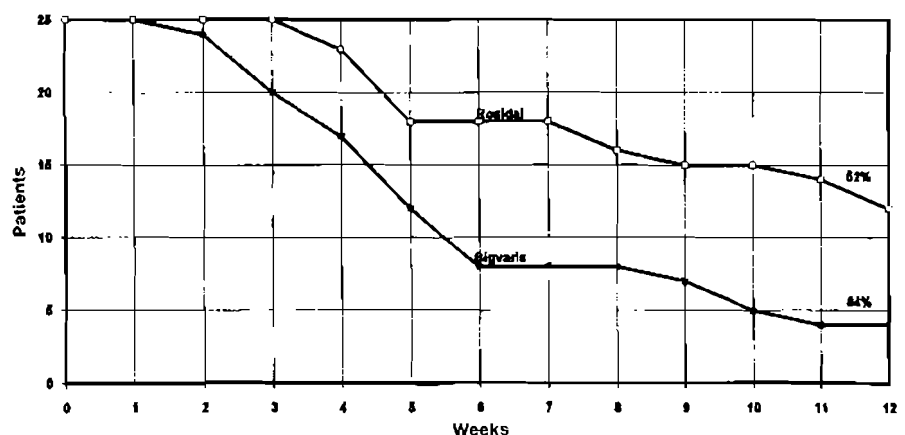


Figure 1: Ulcers that were not healed in the two treatment-groups, in relation to the duration of the treatment. After 12 weeks, 13/25 patients with Rosidal and 21/25 patients with Sigvaris were cured.

4. Transcutaneous oxygen measurement (TCpO₂)

A measuring probe (Radiometer, Copenhagen) was fixed on the proximal margin of the ulcer and heated up to 44°C. Continuous measurements of the transcutaneous partial oxygen pressure were carried out in the resting supine position and after 3 minutes of arterial blockade on the distal thigh.

5. Laser-Doppler fluxmetry (LDF)

By means of a bipolar probe (Moore Instruments, Great Britain) the laser-Doppler flux was measured continuously on the proximal margin of the ulcer and simultaneously on the back of the foot with the patient in the supine position and after 3 minutes of arterial blockade.

Through the arterial occlusion a correction was made for the «biological zero». The quotient of maximum reactive hyperemia and resting flux was given as the reactive hyperemia index (RHI).

6. Area of the ulcer

At weekly intervals the area of the largest ulcer present was traced on to a transparent sheet of paper, from which it was planimetrically measured.

Results

1. Healing of the ulcers

After 3 months, 21 patients (84%) in the Sigvaris group and 13 patients (52%) in the Rosidal group were cured. The difference is statistically significant ($p < 0.05$, log-rank test). As shown in Figure 1, after 6 weeks more than 50% of the patients in the Sigvaris group were cured, while in the Rosidal group 12 weeks were needed in order to obtain the same result.

2. Compression pressure

The results of an earlier study, according to which compression pressure of 2 compression stockings worn one over the other is cumulative (8), are confirmed by the present study.

The compression values measured in the supine, sitting and standing positions, immediately after the stocking has been put on, are presented in Table II. With comparable mean values in the standing position, it can be seen that in the lying position the Rosidal short-stretch bandage, which is well tolerated by the patient even at night, exerts

clearly less pressure than the elastic Sigvaris stocking. The considerably broader scatter of the values in the Rosidal group shows that even experienced nursing staff put the bandages on differently.

While with the Sigvaris stockings the compression values fell only slightly after 1 week, the Rosidal group already showed a considerable, significant decrease in the compression after 24 hours (Figures 2 and 3).

3. Volume reduction

As Table III indicates, short-stretch bandages of the Rosidal type reduce both the venous volume and the venous filling index, with comparable compression, to a considerably more pronounced extent than the elastic material of the Sigvaris stocking. In Figure 4 the effect of different types of material on the venous volume are presented for one individual patient, whereby 2 short-stretch bandages of

Table II: Compression values (mm Hg) after application of stocking/bandage ($\bar{x} \pm SD$)

Thrombo + Sigvaris 503 n = 16	Lying	Sitting	Standing
	31.1 ± 4.15	35.0 ± 6.7	39.1 ± 3.7
after 1 week	28.2 ± 5.3 (-9.3%)	28.9 ± 8.0 (-17.4%)	33.2 ± 5.9 (-15.8%)
Rosidal n = 21	Lying	Sitting	Standing
	27.4 ± 8.7	33.8 ± 13.1	38.0 ± 9.3
after 24 hours	15.6 ± 4.4 (-43.8%)*	21.3 ± 5.6 (-36.4%)*	24.4 ± 6.6 (-35.8%)*

* Student test $p < 0.05$

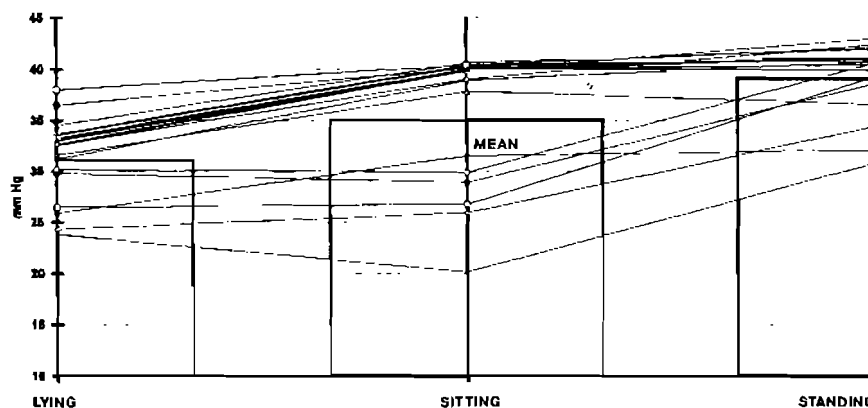


Figure 2a: Pressure values for Thrombo stocking and Sigvaris 503 calf stocking, worn one over the other.

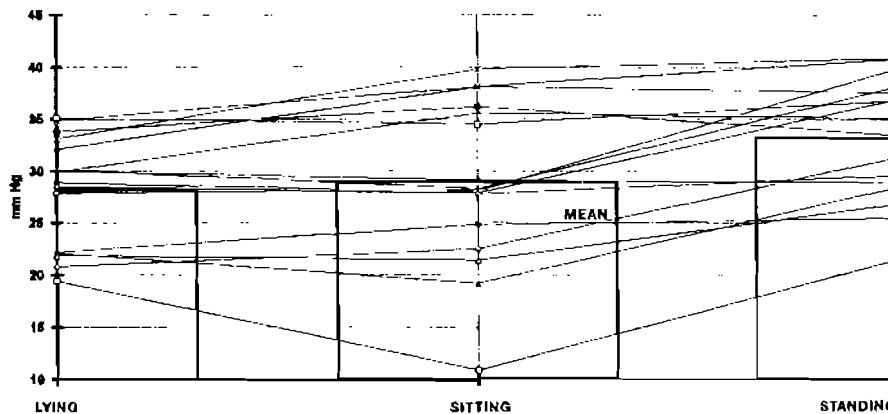


Figure 2b: Compression pressure values after 1 week.

Figure 2: Compression pressure Thrombo and Sigvaris 503 calf stocking (n = 16): Individual and mean values (mm Hg) of compression pressure measured in the lying, sitting and standing positions.

the Rosidal type and 2 Sigvaris stockings were worn one over the other as a model for long-stretch material.

4. Transcutaneous oxygen pressure

As shown in Table II, after compression therapy there is a moderate, not statistically significant increase of the transcutaneous oxygen pressure

values, which is more pronounced in the Rosidal group than in the Sigvaris group.

5. Laser-Doppler flux

The flux values in the vicinity of the ulcers were considerably increased, both in comparison with the flux values in the foot and with the values in

healthy subjects as already observed in an earlier study (7). The quotient of maximum peak flux and resting flux (RHI) was accepted as a parameter for the «micro-circulatory blood-flow reserve». The decisive results in the two treatment-groups, for the cured patients and for those who were not cured, are presented in Table V. Although the increase of RHI in the group which we cured is greater than in those patients who were not cured (58.9 and 28.5%, compared with 17 and -4.3%), the difference is not statistically significant. The level of the baseline RHI values does not allow any conclusion to be drawn as to whether the ulcers will or will not heal.

Discussion

In spite of the poor comparability of the two treatment-groups, the Sigvaris group having better chances of healing at the start of the study (Table I), our investigation led to a surprising result:

Through a special treatment regime with medical compression stockings in patients with venous ulcers, cure rates were achieved comparable with the best in literature (1, 6).

Out of 25 patients, 21 (84%) were cured after 12 weeks.

In an earlier study it was observed by R. Stemmer that age and the period of duration of the ulcer have no influence on the cure rate, so that in the present study the unequal distribution of these two factors in the two treatment-groups should not have been of any consequence (11). On the other hand, it is evident and also proven in different studies that on average large ulcers take longer to heal than smaller ulcers.

Even though in our two groups the area of the ulcers was not statistically significantly different, the Sigvaris group does show considerably smaller baseline area values than the Rosidal group.

It still has to be emphasized that, contrary to traditional medical instruction, medical compression stockings represent a very good therapeutic possibility, at least in the treatment of small ulcers and in patients who are capable of putting the stockings on by themselves.

The cure rate of 52% after 12 weeks in the Rosidal group is comparable to the results reported by other authors (2, 9). It has to be stressed, however, that the use of a single Rosidal short-stretch bandage alone is not a recommendable

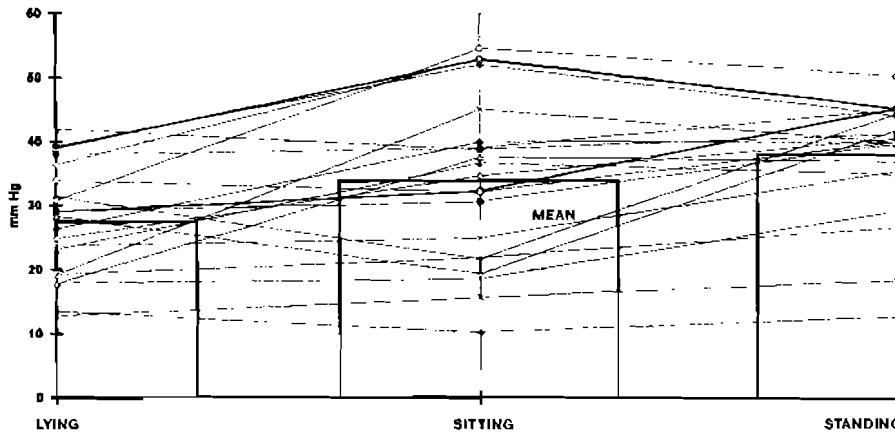


Figure 3a: Immediately after application of the bandage.

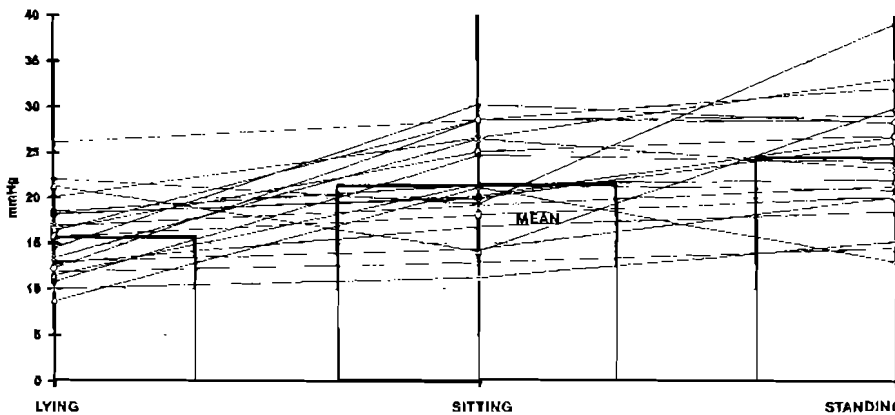


Figure 3b: Pressure values after 24 hours.

Figure 3: Compression pressure Rosidal (n = 21): Individual and mean values (mm Hg) of compression pressure measured in the lying, sitting and standing positions.

Table III: Venous volume (VV, ml) and venous filling index (VFI, ml/sec), measured by means of APG before and after compression.

	VV before	VV after	Diff. %	VFI before	VFI after	Diff. %
Thrombo + Sigvaris 503	169.8 ±59.3	118.8 ±43.5	-30%	8.0 ±3.1	5.3 ±2.7	-33.8%
Rosidal	183.9 ±70.0	81.9 ±30.5	-55.5%*	10.6 ±5.6	4.0 ±1.8	-62.3%*

* Student test p < 0.05

Table IV: Mean values ± standard deviation of TCpO₂ (mm Hg) before and after treatment (44°C) n. s.

	n (Sig/Ros)	Sigvaris	Rosidal
Before treatment	25/25	33.5 ± 22.6	24.2 ± 20.1
After 9 weeks	7/15	33.4 ± 22.1	42.7 ± 24.0
After 12 weeks	4/12	34.8 ± 16.9	33.8 ± 28.3

form of therapy. We usually treat venous ulcers with Fischer bandages, whereby a 10 m long zinc-oxide bandage is applied, accurately modeled to the shape of the leg, and over this a 2.5 m long Rosidal-K bandage is wrapped.

As shown by the results obtained by means of APG, the relatively unyielding material of a short-stretch bandage causes a significantly more pronounced reduction of the blood volume of the leg, in comparison with the elastic, yielding material of the stocking.

With the same compression, after the application of a Rosidal short-stretch bandage there is a significantly greater reduction of the blood volume in comparison with the more yielding Sigvaris stocking (-62% compared with -35%). If a second stocking, a Sigvaris-503 calf stocking, is pulled over the first, compression is practically doubled and the volume reduced by 64% compared with the baseline value (Figure 4).

However, when a second Rosidal bandage is wrapped over the first, thus doubling compression, there is only a slight additional reduction of the volume. This indicates that a minimal limit-value of the blood volume is reached.

The venous filling index (Table III) is a quantitative measure for venous refluxes. It has to be emphasized that short-stretch bandages with comparable compression cause an average reduction of 62% in reflux, while with elastic compression stockings the average reduction is only 34%. The more pronounced effect on the reduction of the venous volume and on the venous refluxes with unyielding material can be explained mainly by the fact that not only the superficial veins but also the deep veins are narrowed. This is an important reason why we prefer short-stretch bandages for active decongestant therapy.

The chosen mode of application for the short-stretch bandages in the present study, however, showed two decisive disadvantages:

1. The compression measurements prove that even when experienced persons apply the bandages, compression achieved fluctuates over a very broad range of values.
2. With a single Rosidal bandage there is already a considerable loss of pressure after 24 hours, so that adequate compression can no longer be guaranteed.

Table V: Reactive Hyperemia Index (RHIVirtual units) in healed and not-healed ulcers (\bar{x} bar \pm SD).

Healed	n	before treatment	after treatment in 4 weeks
Sigvaris	13	1.93 \pm 1.04	2.48 \pm 1.56
Rosidal	5	1.58 \pm 0.80	2.51 \pm 1.76

Not healed	n	before treatment	not healed after 12 weeks
Sigvaris	4	1.86 \pm 1.11	1.78 \pm 0.56
Rosidal	12	2.16 \pm 0.82	2.53 \pm 2.22

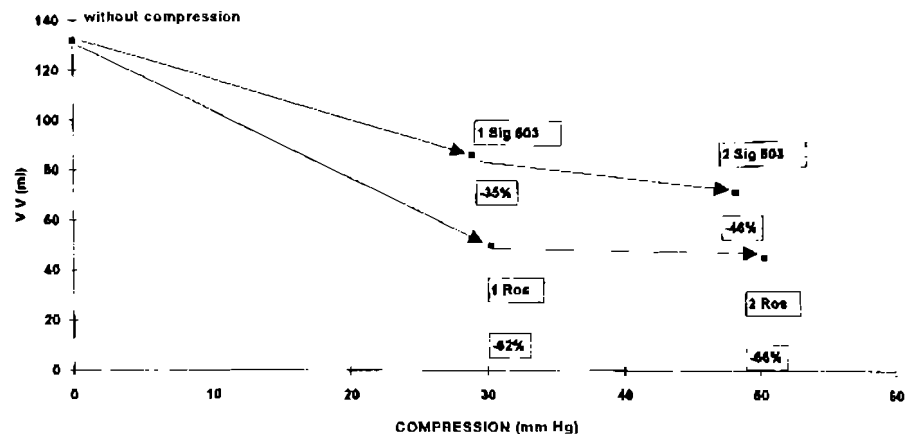


Figure 4: Relation between compression pressure (horizontal axis) and venous volume measured by means of APG (vertical axis) in one patient. By using a Sigvaris 503 calf stocking the venous volume of the lower leg in the standing position is reduced by 35%. By using a second stocking the compression pressure is almost doubled and the volume is reduced by 46%. In contrast to the yielding stocking material, a Rosidal short-stretch bandage, which was wrapped around the leg with practically the same pressure as the Sigvaris stocking, reduces the volume by 62%. Although a second bandage wrapped over the first increases the compression considerably, it does not lead to any significant additional reduction of volume.

In contrast, the pressures in the resting position obtained with the Sigvaris stockings are in a narrower range of values and are also only slightly reduced after 1 week. The decrease in pressure, as observed with both types of material, is primarily due to the reduction in volume of the leg and not to any weakness of the material. This reduction of edema, which is a desirable effect from a therapeutic point of view, is achieved more rapidly and more effectively with short-stretch bandages than with compression stockings. With the use of short-stretch material, however, it is important that when the bandage becomes slack due to a reduction in swelling of the leg, the compression bandage is immediately re-wrapped or at least wrapped over, which was not the case in the present study.

The measurements of transcutaneous oxygen pressure and of laser Doppler flux revealed no difference in the effi-

cacy of the two types of compression used. The tendency towards increases in the RHI and TCpO₂ was not statistically significant, due to the small number of cases studied.

Conclusion

On the basis of the results of this study, compression stockings can be recommended as primary treatment for cooperative patients with venous leg ulcers that are not too extensive. The advantages of this type of treatment for both doctor and patient are obvious.

In the case of severe secretion, the dressing can be changed at any time and the patient may shower and actively participate in his treatment.

It must be stressed that no specific local therapy should be used and that the ulcer should be covered only with absorbant, non-adherent dressings.

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