

Compression Bulletin 31

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Booster study: Comparative evaluation of a new concept of elastic stockings in mild venous insufficiency

Couzan et al could demonstrate in their first study that progressive compression stockings (PCS) were as efficient in the investigated patient population as degressive compression stockings. Patients assessed wearing comfort and ease of donning better in the PCS group.

A randomized double-blind trial of upward progressive versus degressive compressive stockings in patients with moderate to severe chronic venous insufficiency

The second study of Couzan in patients with moderate to severe chronic venous insufficiency (CVI) showed a better efficiency in the improvement of leg pain and symptoms after 3 months of treatment in the PCS group, but not at 1 and 6 months. Wearing comfort was rated similar in both groups, but PCS were felt to be easier to apply.

Compression stockings with a negative pressure gradient have a more pronounced effect on venous pumping function than graduated elastic compression stockings

In this study it could be demonstrated, that progressive elastic compression stockings (PECS), with a higher pressure at the calf, led to a significantly better improvement of the venous pumping function as conventional graduated elastic compression stockings (GECS) with a lower pressure at the calf.

Interface pressure and venous drainage of two compression stocking types in healthy volunteers and in patients with hemodynamic disturbances of the legs

GECS and PECS have similarly improved the hemodynamic parameters in healthy volunteers and patients. PECS were easier to apply but tended to slip towards the foot more often.

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Graduated or progressive elastic compression stockings – an overview of the current discussion

Introduction:

In the last few years there was an ongoing scientific discussion about the necessary pressure gradient in medical compression stockings (MCS). Traditionally MCS are graduated with the highest pressure in the ankle region and a decreasing pressure along the leg due to the physiological fact that the intravenous pressure is highest in the ankle depending on the height of the blood column to the heart. These MKS are also named Graduated Elastic Compression Stockings (GECS). The high pressure in the ankle region is one of the reasons why it may be complicated for the patient to don (put on) the stockings. In the meantime several studies have been performed using below knee MCS with a reversed pressure gradient and an increasing pressure from the ankle to the calf. These stockings are known as Progressive Elastic Compression Stockings (PECS).

The effectivity of MCS can be due to an improvement of venous haemodynamics (pumping function, ejection fraction) or by a permanent or massaging pressure effect on the skin and the fatty tissue. Studies have demonstrated that a significant improvement of the venous function can only be achieved by either high pressure below the compression garment or by a high static stiffness index of the material used (1-3). The same authors and others could also demonstrate that an improvement of venous symptoms and oedema can already be achieved by low compression pressure of 10-15 mmHg (4-9). The most important outcome of compression for the patient are clinical parameters like oedema reduction, ulcer healing and improvement of symptoms.

There are different theoretical reasons why PECS could be favoured in comparison to GECS:

1. A higher pressure in the calf (measuring point C) can better improve venous haemodynamics. Using PECS the higher calf pressure can be achieved without increasing the ankle pressure (measuring point B). This effect could principally also be reached with a higher compression class in conventional GECS.
2. A lower pressure in the ankle region improves the ability to don the MCS and thus also the compliance with compression treatment.

PECS may have the same ankle pressure but a higher calf pressure compared to GECS or PECS may have a lower ankle pressure but a similar calf pressure compared to GECS.

The questions arising from these reasons are:

- Would a higher calf pressure improve venous haemodynamics better?
- Would a reduction in ankle pressure improve patient's comfort and compliance?
- Would a reduction in ankle pressure lead to more foot oedema?
- Do we need higher calf pressure to sufficiently treat our patients and do we really need high ankle pressure for the same reason?

Some of these questions have been investigated in comparative studies.

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Couzan S, Assante C, Laporte S, Mismetti P, Pouget J-F

Booster study: Comparative evaluation of a new concept of elastic stockings in mild venous insufficiency

Presse Med. 2009;38:355-361

Aim

The aim of this randomized, double blinded study was to evaluate a new progressive concept of compression stockings (PCS) in comparison with degressive compression stockings (DCS) in patients with mild venous insufficiency and without permanent oedema.

Methods

Patients with mild venous insufficiency and without permanent oedema (Class 1 according to Porter's classification or C0s-C1s-C2s according CEAP classification), were randomly assigned to one of the following two treatment groups:

Patients in the PCS group received knee-high stockings with an average ankle pressure of 7 mmHg and an average pressure of 20 mmHg at the calf.

Patients in the DCS group received knee-high stockings with an average ankle pressure of 20 mmHg and an average pressure of 14 mmHg at the calf.

Both stockings were identical in appearance and produced by Lempy Médical according to the NF G30 102 norms agreed by the French institute for textiles and garments. The use of venotonic and analgesic products were prohibited during study participation.

At two weeks patients underwent a medical visit where they had to complete a questionnaire that assessed leg tiredness, wearing comfort of the stockings and compliance to compression treatment by means of a visual analogue scale.

The primary outcome was change in leg heaviness after 2 weeks of treatment. Secondary endpoints were wearing comfort and compliance to compression treatment.

Results

Of the 130 patients randomised to treatment, 66 were assigned to the DCS treatment group and 64 to the PCS group. Baseline criteria were comparable in both treatment groups, with an average patient age of 42 years and 68% women included in the study.

40/66 patients in the DCS group (60.6%) vs 46/64 patients in the PCS group (71.9%) reported an improvement or even complete disappearance of heavy leg symptoms after 2 weeks of treatment.

The upper limit of confidence interval was inferior to the margin of non-inferiority defined in the study protocol, therefore confirming non-inferiority of the progressive compression stockings versus the degressive compression stockings in regard to the alleviation of heavy leg symptoms.

Compliance with compression treatment assessed by an visual analogue scale, was significantly better in the PCS group (score of 9) versus the DCS group (score of 8), where score of 10 meant that compression was wore on all study days.

Patients treated with PCS reported more often (95.2%) that they could don the stockings very easy or easily as compared to patients in the DCS group (56.2%).

More patients in the PCS group (93.6%) felt no or only little discomfort while wearing the stocking as compared to the DCS group (59.4%).

Conclusion

This randomised, double blinded trial is the first evaluation of a new compression concept in mild venous insufficiency. Progressive compression stockings were as efficient as degressive compression stockings in the alleviation of heavy leg symptoms in this patient population. Hence, the PCS demonstrated to be more comfortable and easier to don and patients in the PCS group had a better compliance to compression treatment.

The authors concluded, that this promising new concept of compression stockings deserves to be evaluated in other settings.

Comment of the Editors

The comment of the editor for the booster study will be provided together with the editor's comment of the second Couzan study.

Couzan S, Leizorovicz A, Laporte S, Mismetti P, Pouget JF, Chapelle C, Quere I.

A randomized double-blind trial of upward progressive versus degressive compressive stockings in patients with moderate to severe chronic venous insufficiency

J Vasc Surg 2012;56(5):1344-1350

Aim

This study aimed to assess the efficacy of progressive compression stockings compared to degressive compression stockings graded 30 mmHg in the improvement of lower leg symptoms of chronic venous insufficiency (CVI) in ambulatory patients with moderate to severe chronic venous disease as defined by CEAP classification.

Methods

Patients presenting with pain/heavy legs due to moderate CVI (CEAP C2b to C5), and eligible for 30 mmHg compression therapy, were enrolled in the double-blind, randomized controlled trial. Exclusion criteria included: recommended bandage therapy, current use of compression stocking >30 mmHg, active ulcer, deep vein thrombosis or pulmonary embolism in the past 3 months, arterial disease of a lower limb, non-venous oedema and inflammatory, dermatologic or traumatic disorder of a lower limb.

Eligible patients were randomized to receive either knee-length upward progressive stockings (10 mmHg at the ankle, 23 mmHg at the upper calf) or degressive stockings (30 mmHg at the ankle, 21 mmHg at the upper calf). Stockings were to be worn every day from morning to bedtime for 6 months. A follow-up visit was scheduled at

3 months, with phone call at months 1 and 6. The primary outcome, improvement of pain or heavy legs without onset of either ulcer, deep or superficial vein thrombosis of the lower limb or pulmonary embolism, was assessed at 3 months. Secondary outcomes included the primary outcome assessed at months 1 and 6, ease of application of the stocking as reported by the patient, and compliance.

Results

401 patients were enrolled in centers across France between June 2007 and March 2008; 199 in the progressive stocking group and 202 in the degressive group. Data for 381 patients was available for analysis of the primary outcome. Two-thirds of patients had C3-grade venous insufficiency and the majority had numerous or extended varicose veins. The median venous clinical severity score (VCSS) was 5, and 61.2% of patients had prior varicose vein treatment.

Primary outcome

At 3 months the rate of success was significantly higher for the progressive stocking group than the degressive group (70% vs 59.6%, $P = 0.03$), mainly due to a higher rate of symptom improvement in the progressive group.

Secondary outcomes

No significant difference between treatment groups was reported in success rate at months 1 and 6. During the study period, five patients experienced thromboembolic events in the progressive stocking group and six in the degressive group. Compliance to stocking use was similar, at 3 months 72.2% of the progressive group and 71.1% of the degressive group used their treatment all day.

The main reason for study discontinuation was discomfort or difficulty in applying stocking, and similar between groups. However, 86.2% of patients in the progressive stocking group vs 57.1% in the degressive group considered the stockings easy to apply ($P < 0.0001$) at 6 months, a difference which was also significant at months 1 and 3. Discomfort was similar between groups. Of 15 serious adverse events reported, 1 was considered possibly related to treatment (uncomplicated varicose vein surgery in the progressive stocking group at 6 months).

Conclusions

This study demonstrated the greater efficacy of progressive compression stockings in improving pain and lower leg symptoms in patients with CVI compared to traditional degressive stockings at 3 months. There were

no safety concerns with progressive stockings and patients considered them to be easier to apply. Further studies are needed to assess the maintenance of improvements in venous insufficiency symptoms and longer term effects of progressive compression stockings on complications such as ulcers and deep vein thrombosis.

Comments from the Editors

Couzan study 1: Patients with mild CVI

The first Couzan study (Booster study) did not demonstrate superiority of the PCS in the primary endpoint «leg heaviness» in patients with mild CVI, even despite the fact that the PCS had a higher calf pressure of 20 mmHg as compared to the DCS with a calf pressure of 14 mmHg. It has not been discussed why the authors have chosen DCS with a calf pressure of 14 mmHg although they have mentioned that a pressure of at least 20 mmHg at the calf is needed for an efficient improvement of the venous pump function.

The very good compliance of > 80% for both compression stocking systems over the study duration of two weeks has to be noted. PCS had a slightly higher compliance rate with an average of 90%. It would have been interesting to see if a longer treatment time would have led to a clearer difference in compliance rates between the two treatment groups.

Patients had to indicate if they felt a discomfort while wearing the compression stockings – unfortunately the authors did not describe the type of «discomfort». Patients in the DCS group reported

more often a strong feeling of «discomfort», without prescribing the feelings more in detail.

It is interesting that the pressure gradient of the two compression stocking systems is reflected in the locations where the patients assigned their feeling of «discomfort»: Patients of the PCS group felt «discomfort» more often in the leg area (71.4%) than patients of the DCS group (40.5%). On the other hand, «discomfort» in the ankle and foot area was reported more often by patients of the DCS group.

Couzan study 2: Patients with moderate or severe CVI

With a comparable calf pressure of 23 mmHg (PCS) versus 21 mmHg (DCS), there was only a significant difference between the two compression stocking systems in the primary endpoint after 3 months of treatment ($p = 0.03$), but not after 1 and 6 months. After 1 and 6 month of treatment there was no difference in regard to a alleviation of leg symptoms (leg heaviness or leg pain).

The authors discussed that the primary endpoint at 3 months of treatment was chosen because they thought that a clinical improvement should be seen in a short period of time, hence they did not discuss why the efficacy of the DCS, expressed as % success outcome, decreased from a higher percentage at 1 month to a lower percentage at 3 months visit and then increase again at 6 months of treatment. Interestingly the patients in the DCS group showed a clear trend to a decrease over time in the percentage of patients that had no

improvement in leg symptoms, whereas the numbers in the PCS rather seemed to stagnate.

As for the first Couzan study, the very high compliance in both treatment groups should be noted. Over 70% of the patients had indicated at every visit, that they wore the compression stockings from morning to bed time. Aside of the significant difference in the primary endpoint after 3 month of treatment, only easiness of application was reported to be significantly better in the PCS group at all visits.

Although both compression stocking systems had a comparable calf pressure, no difference in wearing comfort or compliance could be found between the two treatment groups. In view of the results of the booster study one would have expected that at least the wearing comfort of a compression stocking with an ankle pressure of 30 mmHg should have led to more discomfort.

The authors have shortly noted that patients in the PCS group took more analgesics and NSAID's during the study. It is unclear why the authors allowed the intake of analgesics and NSAID's in a study with a primary endpoint that looked at «leg pain and leg heaviness» and how the difference in medication intake might have influenced the study results.

The studies of Couzan et al have clearly demonstrated that both compression stocking systems do improve clinical symptoms in patients with mild venous disorders (C1s-C2s) (1), and also in more severe stages (C2s-C5s) (2).

Serge Couzan's concept of non-graduated, progressive compression stockings is theoretically very convincing. Due to the fact that the main part of the venous reservoir constituting the chamber of the venous pump is located at mid-calf level this region should be rather the target of compression therapy than the ankle region. Actually a more pronounced improvement of venous pumping function by using such stockings could be demonstrated in comparison with conventional graduated compression stockings in patients with severe venous incompetence (3).

Even a stronger effect on venous pumping function can be achieved when strong inelastic bandages are used with higher interface pressure over the calf compared to the ankle (4).

Improving the calf pump is obviously also a target when sport socks are used, which can be achieved by applying Velcro wraps at midcalf level over the stocking (5).

Using different methodology of measuring the ejection fraction of the calf pump by placing the strain gauge transducer to the foot Riebe et al found an improvement both with DCS and PCS, however, DCS seemed to be more effective. (6)

There is still some discussion ongoing concerning the risk of producing distal swelling due to a kind of potential tourniquet effect in immobile patients for whom an improvement of venous pumping is less relevant. Using water displacement foot volumetry Mosti et al found a better edema-preventing effect of PCS compared to DCS in individuals with occupational edema(7), but a decrease of total leg volume does not completely rule out a potential shift of edema towards less compressed distal regions.

Both studies of Couzan et al have clearly demonstrated that the highest advantage of the PCS lies in the better applicability. The easier donning and doffing might effecting a higher degree of compliance in patients wearing the PCS, although the compliance in both studies was very high and comparable for both compression systems.

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Compression stockings with a negative pressure gradient have a more pronounced effect on venous pumping function than graduated elastic compression stockings

*Eur J Vasc Endovasc Surg*2011;42:261-266

Aim

The study aimed to assess the effect of progressive elastic compression stockings (PECS) on venous pumping function in patients with advanced venous insufficiency, compared with conventional graduated elastic stockings (GECS).

Methods

Chronic venous insufficiency patients assessed as C2 to C5 by CEAP classification and presenting with significant reflux (> 1s) in the great saphenous vein (GSV) were recruited. Patients were also required to have sufficient mobility to complete the assessment exercises.

Interface pressure of the stockings was measured continuously using Picopress at level B1 (12 cm proximal to inner ankle) and level C (maximal calf circumference). Strain gauge plethysmography was used to measure ejection fraction (EF) of the venous calf pump.

Measurements were taken on the same day; without compression followed by the two stockings in a randomized sequence with 15 minutes between measurements. The stockings were applied with the patient in a supine position 5 mins before the experiment.

Results

30 patients with CVI were recruited to the study. Ejection fraction was significantly improved with compression stocking use, with a greater increase from baseline seen with PECS (+75 %, $P < 0.001$) than GECS (+32.7 %, $P < 0.001$).

The interface pressure measurements showed that GECS exerted a median pressure of 22 mmHg at B1 with a decrease of 14% to the pressure at the calf (level C). As expected, PECS showed the reverse pressure gradient, with a median pressure of 18.5 mmHg at B1 and an increase of 57% to the pressure at level C. These pressures only increased slightly when the patient was standing or during exercise. Ejection fraction was found to correlate significantly with standing pressure ($r = 0.43$, $P < 0.001$) and the maximal pressure during exercise ($r = 0.406$, $P < 0.01$) at level C but not B1.

Conclusions

These results show that the higher pressures achieved over the calf with PECS are significantly more effective at improving venous pumping function than lower pressures. The effect of these stockings on thromboprophylaxis, chronic oedema or lymphoedema reduction and deep venous thrombosis requires further study.

Comments of the Editors

In this prospective study the ejection fraction (EF) of the legs of 30 patients with severe venous disease were compared when two different MCS were worn. The conventional graduated below knee stocking (GECS) showed a mean ankle pressure (B1) of 22 mmHg and a calf (C) pressure of approximately 18.9 mmHg in the supine position. In contrary the MCS with a progressive pressure gradient (PECS) showed a similar ankle pressure of 18.5 mmHg but a significantly higher calf pressure of approximately 29 mmHg. The EF was measured 5 cm distally from the patella and proximally to the elastic stockings. The EF increased significantly by 32.7% (95% CI: 16.8-48.6) with GECS and by 75% (95% CI: 48.6-101.3) with PECS. No clinical outcome parameters are reported.

This study shows that a higher calf pressure leads to a more pronounced improvement of the EF under compression when measured proximally to the stocking. It remains unclear if this improvement is related only to the higher calf pressure or also to the pressure profile in the MCS.

Riebe H, Korschake W, Haase H and Junger M.

Interface pressure and venous drainage of two compression stocking types in healthy volunteers and in patients with hemodynamic disturbances of the legs

Clin Hemorheol Microcirc 2015;61:175-183

Aim

The aim of this study was to examine the hemodynamic effects of standard-of-care, graduated elastic compression stockings (GECS) and inverse or progressive graduated elastic compression stockings (PECS) in healthy volunteers and patients with chronic venous insufficiency (CVI). Impact on comfort and compliance was also assessed.

Methods

Patients with CVI and CEAP classification C3-C5 were recruited. A significant insufficiency of the great and small saphenous vein had to be documented with duplex ultrasound and a pathological venous reflux time of >1s had to be present. Good mobility for performing the assessment exercises was also required. Exclusion criteria included systemic diseases such as diabetes mellitus and uncompensated heart failure. The presence of peripheral arterial occlusion disease was also excluded.

Allocation of the first stocking was randomized and double-blinded. Patients and healthy subjects were required to wear the stocking for a period of 7 days, with a week break before wearing the second stocking type. Interface pressure achieved by the stockings was measured at level B1 (12 cm proximal to inner ankle) and level C (maximal calf circumference) during a standardized exercise program. Venous drainage was determined by strain gauge plethysmography in the foot region.

A questionnaire was developed to assess comfort and was completed directly after the wearing period of each stocking.

Results

32 healthy subjects and 32 patients were included in the study. Interface pressure measurements were as expected: mean pressures for GECS were 27.3 mmHg (B1) and 19.6 mmHg (C); for PECS 17.8 mmHg (B1) and 24.7 mmHg (C).

Ejection fraction was significantly improved with stocking use in both healthy volunteers and patients, however, GECS was associated with a significantly greater improvement than PECS ($p = 0.02$ (healthy volunteers $p = 0.07$; patients $p = 0.01$). The change in venous filling index was reduced with both stockings, with no significant difference between them (GECS: -0.05 ml/100 ml/s vs PECS -0.03 ml/100ml/s). The difference between patients and healthy volunteers, however was significant.

Results from the questionnaire showed that PECS was considered to cause significantly less strangling and tightness of the leg, and was easier to don than GECS, however, PECS slipped towards the foot more often than GECS.

Conclusions

This study shows that pressure therapy with conventional graduated stockings or progressive stockings is effective in improving the venous pump function, but that the greater comfort associated with PECS may lead to greater compliance.

Comments of the Editors

In this well performed study GECS and PECS were compared in venous patients and healthy controls. The ejection fraction (EF) and the venous filling index (VFI) were measured at the forefoot. It is remarkable that the mean pressure at

B1 level was 27.3 mmHg for GECS but only 17.8 mmHg for PECS resulting in a difference of almost 10 mmHg. In contrary the pressure difference at C level was smaller with 19.6 mmHg (GECS) and 24.7 mmHg (PECS).

As a result the EF measured below the ankle level was improved with both stockings but significantly more with GECS. Haemodynamic measurements at different levels of the leg, foot or calf level, may not represent the same results but it is remarkable that a significant improvement could be achieved with both products.

Despite a tendency to slip down more often, no negative side effects of PECS were reported and the results of the comfort questionnaire demonstrate that PECS are easier to don and show less strangling and tightness of the leg compared to GECS. The authors conclude that «coupled with the good results in the effectiveness of venous drainage, the better wearing comfort of the PECS could be a great advantage in terms of the expected patient compliance».

Graduated or progressive elastic compression stockings – an overview of the current discussion

Summary:

Graduated elastic compression stockings (GECS) and progressive elastic compression stockings (PECS) with very different pressure profiles were used to investigate the clinical and haemodynamic effects in the present studies (Tab. 1).

Study	B1-level (Pressure mmHg)		C-level (Pressure mmHg)	
	GECS	PECS	GECS	PECS
Couzan 1	20	7	14	20
Couzan 2	30	10	21	23
Mosti	22	18.5	18.9	29
Riebe	27.3	17.8	19.6	24.7

It remains unclear how the pressure was measured in the Couzan studies or if the numbers provided are just the manufacturers figures. Mosti and Riebe measured the pressure in vivo and under the compression stocking. Mosti used compression stockings with a comparable pressure at the B1 level, in the Couzan 2 study they used stockings with a comparable pressure at the C-level. The ejection fraction (EF) was only measured by Mosti and Riebe, but they used different techniques and measured at different locations of the foot and below the knee. Clinical outcome and comfort were assessed in the studies of Couzan and Riebe only. In consequence the comparability of the study results is limited.

All compression stockings used in the studies improved venous function significantly. It seems, as expected, that a higher pressure at the B1- or C-level is associated with a better improvement of the haemodynamic parameters. There is no proof that this improvement is associated to either the progressive or degressive pressure profile of the stockings.

Both GECS and PECS improved clinical parameters significantly. There was a significant better outcome after 3 months of treatment in the PECS group observed in the Couzan 2 study and a significant better improvement in the ejection fraction in patients of the GECS group in the Riebe study.

The most important result may be that the pressure at the B1-level can be reduced without negative effects on the functionality of the compression stocking or the clinical outcome. The pressure reduction at the B1-level makes the compression stocking more comfortable for the patients, easier to don and with less feeling of strangling and tightness as reported in the studies of Riebe and Couzan. This effect might be important for the compliance of our patients that undergo compression therapy with elastic compression stockings.

