

Compression Bulletin 25

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Clarke-Moloney M, Keane N, O'Connor V, Ryan MA, Meagher H, Grace PA, Kavanagh E, Walsh SR, Burke PE

Randomised controlled trial comparing European standard class 1 to class 2 compression stockings for ulcer recurrence and patient compliance

Int Wound J. 2012 Oct 19. doi: 10.1111/j.1742-481X.2012.01108.x. [Epub ahead of print]

Background

The most effective method of preventing ulcer recurrence is superficial venous surgery. Conservative prevention is based on life-long wearing compression hosiery and educating the patient to comply with this treatment. No clear data are available concerning the optimal compression pressure of stockings to prevent ulcer recurrence.

Aim

of this study was to determine rate of venous ulcer recurrence and level of compliance in patients wearing European class 1 (18-21 mmHg) or class 2 (23-32 mmHg) compression stockings.

Methods

One hundred patients with healed venous leg ulcers were randomised to wear either 18-21 mmHg (n = 50) or 23-32 mmHg (n = 50) compression stockings. Follow-up was at 1 week, 3, 6, 9 and 12 months to monitor ulcer recurrence and compliance assessed by a questionnaire. The source of venous incompetence was investigated by duplex scan.

Results

The ulcer recurrence rate after 12 months was 16.1% (10 patients wearing class 1 and 6 wearing class 2 developed new ulcers, the difference was not significant). Patients with a history of multiple episo-

des of ulceration were more likely to develop a recurrence (P = 0.001). Venous ulcer recurrence rates were lowest in patients who were compliant with hosiery regardless of the level of compression. After 3 months 75% of the patients were fully compliant, after 12 months 65%. 5 patients assigned to class 2 stockings and 6 patients from class 1 were not compliant. Reasons for non-compliance were the inability to apply/remove the stockings (2 patients with class 1, 2 with class 2 stockings), feeling of tightness (2 with class 2 stockings), three times skin sensitivity and unwillingness to wear hosiery (2 with class 1 stockings). Non compliant patients were at a significantly greater risk of recurrence (P ≤ 0.0001). From 13 patients with both superficial and deep incompetence those randomised to class 1 stockings (n = 4) developed ulcer recurrence, while those with class 2 stockings had a lower rate of recurrence.

Conclusion

The higher the compression level the less likely is an ulcer recurrence. Patients wearing compression stockings after ulcer healing are significantly less likely to develop new ulcers than those who do not wear any kind of compression. Patients with both superficial and deep venous incompetence require the greatest level of compression. Patients

should be offered the highest level of compression hosiery they can comply with.

Comment

Although underpowered, this is an excellent study clearly demonstrating the need to continue with compression when the ulcer is healed to prevent recurrence. The Irish authors use the German (RAL) and not the British classification and regret the present confusion of international classification systems. They write: «Compression hosiery in the USA are not identified by compression class and instead are descriptively labelled with the levels of pressure generated, for example, moderate support 20-30 mmHg. Perhaps the compression hosiery industry should consider standardising such a labelling system for British and European hosiery to reduce the risk of inadequate compression being prescribed and inadvertently increasing the risk of ulcer recurrence.» This sounds good, doesn't it?

Efficacy and comfort of medical compression stockings with low and moderate pressure six weeks after vein surgery

Phlebology: Published online before print May 3, 2013, doi: 10.1177/0268355513484142

Background

This prospective, randomized study was conducted to evaluate efficacy, safety, and comfort of thigh-high, round knitted medical compression stockings (MCS) with different pressure six weeks after vein surgery.

Methods

Female patients undergoing vein surgery were randomized for a compression therapy with low (18–21 mmHg, group A) or moderate (23–32 mmHg, group B) pressure MCS. Follow-up was done by a phlebological experienced, blinded physician (in vivo pressure control (Kikuhime), clinical aspect, duplex scan, and questionnaire) one and six weeks after surgery.

Results

88 patients (41 in group A and 47 in group B) were analyzed. One week after surgery, patients of group B had significantly lower edema scores than patients of group A either in the clinical assessment (0.7 vs. 0.3; $p = 0.016$) or in the B-mode scan (0.9 vs. 0.4; $p = 0.013$). Significant less patients of group B had a feeling of «tightness» ($p = 0.01$) and significant more a reduction of discomfort ($p = 0.01$) after week 1 but with no significance in week 6. There was no significant difference according to other clinical and ultrasound findings such as hematoma, infection, hyperpigmentation, cording, or thrombosis after one or six weeks. In week 1 and week 6, more patients suffered from pain in group A (week 1 $p = 0.24$, week 6 $p = 0.063$). Application of the MCSs was easier in group A in week 1 but similar in groups A and B in week 6. Muscle vein thrombosis occurred in one patient of group A.

Conclusion

The authors conclude that compression stockings with a pressure of 23–32 mmHg facilitate a faster resolution of clinical and ultrasound verified edema and the subjective feelings of pain, tightness, and discomfort of the leg in the early period after surgery but have no difference in the longer post-surgical period compared to stockings with a pressure of 18–21 mmHg. They also discuss whether a low compression with a higher stiffness could reach the same results.

Comment

The usefulness of compression treatment after venous procedures was discussed in several recent studies with conflicting results. This prospective randomized study demonstrates a significant benefit of 23–32 mmHg compression stockings to prevent edema and tightness in the early phase after venous surgery compared to lower compression. However the question remains open how long this compression should be applied and if the long term results can be improved. The stiffness of the material may also play an important role in the effectiveness.

Lurie F, Kistner R

Variability of interface pressure produced by ready-to-wear compression stockings

Phlebology 2012 Nov 15. [Epub ahead of print] PubMed PMID: 23155133

Background

Most of the published studies, and all randomized trials have used exclusively provided box labels given by the manufacturers of compression stockings for determining interface pressure.

Aim

to assess the variability of interface pressure and changes in this pressure over one month time interval under ready-to-use compression stockings.

Methods

Fifteen healthy volunteers with a broad range of sizes and shapes of the calves were included. Each volunteer sequentially used six pairs of stockings daily from three different producers for one month each. The six pair set consisted of stockings of three compression classes (class 1: 20-30 mmHg, class 2: 30-40 mmHg and class 3: 40-50 mmHg) made of two materials with different stiffnesses. Interface pressure measurements were performed at B1 point using SIGaT(®) tester (SIGVARIS, St.Gallen, Switzerland) in supine and standing positions, and during performing 10 tiptoes. The difference in pressure between supine and standing positions and between standing and tiptoes was used to calculate in vivo static and dynamic stiffness indices. Pressure measurements were performed twice (in the morning and

after using stockings for eight hours) on the first day of using each pair of stockings, and repeated on the 30th day.

Results

At the time of the first use the interface pressure was within the range specified by the manufacturer for 160 out of 180 individual stockings. Twenty stockings (11.1%) produced interface pressure which was 5 mmHg or more outside the range of specified compression class. In 17.8% of the pairs of stockings the interface pressure produced by each of the two stockings was so different that they can be classified in a different compression class. Changes in pressure sufficient to re-classify stockings to a different compression class were observed in 6.6% of class 1 stockings, 5% of class 2 stockings and 3.3% of class 3 stockings. The difference in pressure between two stockings in the same pair was more than 5 mmHg in 12 pairs (13.3%), and exceeded 10 mmHg in four pairs (4.4%). The pressure under stockings did not change significantly during the day. Static and dynamic stiffness indices were significantly and positively correlated with the interface pressure, but there were no significant differences between the products of the different producers. After one month the interface pressure under the class 1 stockings decreased on average by

1.4 ± 4.3 mmHg (P = 0.013). Class 2 and 3 stockings showed minimal pressure changes which were not statistically significant.

Conclusion

In vivo measurements of interface pressure should be a requirement for clinical studies of compression stockings, and may be reasonable for ensuring appropriate pressure level in clinical practice.

Comment

The authors have measured in vivo pressures at the B1 point, situated about 10 cm above B, which corresponds to the smallest leg circumference above the ankle, and which is taken as the reference point of stocking producers to declare their pressure ranges. The so called residual pressure for B1 related to B is 70-100% which may explain the finding that in vivo pressures are in general smaller than the pressures given by the producers. This publication shows again the confusion between the different national classification systems and underlines the recommendation to use ranges of mmHg instead. Due to the described overlap between compression classes in vivo, pressure measurements are essential in future trials.

Efficacy of gradual pressure-decline compression stockings in Asian patients with lower leg varicose veins: analysis by general measurements and magnetic resonance image

Int Angiol 2012 Dec; 31/6 :534-43

Aim

Up to now, there is no standard establishment of gradual pressure-decline compression stockings (GPDCS) for Asian patients with varicose veins and venous insufficiency.

Methods

57 patients (53 females, 4 males) from Taiwan presenting varicose veins were asked to wear locally produced GPDCS 4 hours per day for 4 weeks. Their legs were measured, they filled out questionnaires and underwent magnetic resonance imaging (MRI) by non-contrast enhanced MRV techniques.

Results

The use of GPDCS provided a mild to moderate improvement of the leg complaints, mainly heaviness, in 40 patients. The main adverse effects were itching («allergy»), slippage and tightness. 36.5% of the patients required a change of the size or pressure in the first 3 days. The MRI examinations concentrating on the popliteal vein in the lying position showed an area reduction, an increase of flow velocity and an increase of the haemoglobin passing the deep veins.

Conclusion

It is hoped that the data collected in this study will help in developing compression stockings standards in Taiwanese and Asian countries, and to establishing criteria for product sizes, compression levels, and related parameters.

Comment

Under discussion the authors state «To the best of our knowledge this study is the first to demonstrate empirical evidence for the effect of GPDCS on varicose veins or deep vein insufficiency with a resulting improvement in deep venous circulation and blood supply.» As a matter of fact, a quick literature search or some reading in the Compression Bulletin would have demonstrated that this is certainly not correct. Just concentrating on MRI and CT investigations examining effects of compression on leg veins results in different body positions had been published (e.g. Downie SP et al., Partsch H et al., Uhl JF, Lurie F et al.). However, it is reassuring to read that also in Taiwan the majority of the patients (40/57) were satisfied with their stockings, even wearing them only for 4 hours per day.

Compression therapy in elderly and overweight patients

VASA 2012; 41: 125-31

Background

Age and weight will have increasing impact on medical therapies. The aim of this analysis was to examine if there are differences in the use of compression therapy depending on age and BMI.

Methods

A questionnaire was given to 200 consecutive phlebological patients (C2 - C6) with a compression therapy time of more than 2 weeks. The 110 returned questionnaires were analysed. A sub-analysis according to age (< 60 years vs. ≥ 60 years) and BMI (< 25 kg/m² vs. ≥ 25 kg/m²) was made.

Results

Patients ≥ 60 years have a leg ulcer significantly more often than patients under 60 (20% vs. 5.9%, $p = 0.03$) and frequently need more help with the compression therapy (70.9% vs. 47.1%, $p = 0.05$). 14.6% of those > 60 years even need the help of another person to apply compression.

Patients ≥ 25 kg/m² have an ulcer stocking significantly more often (15% vs. 4.3%, $p = 0.05$) and need the help of family members to put on the compression therapy (11.7% vs. 2.1%, $p = 0.04$). There is a tendency of patients ≥ 25 kg/m² to complain more often about a constriction of compression therapy (35% vs. 19.2%, $p = 0.06$).

Conclusion

The authors conclude that special aspects have to be regarded for compression therapy in elderly and overweight patients. The data should encourage prescribers, distributors and manufacturers of compression stockings to use compression in a very differentiated way for these patients and to consider: Is the recommended compression therapy right for this patient (pressure, material, type)? What advice and adjuvants do the patients need to get along more easily with the compression therapy? Are there any new materials or adjuvants that allow those increasing groups of people to get along with compression therapy alone?

Comment

We all know that the groups of older patients and also of obese patients with venous diseases are growing according to the demographic evolution. However, our knowledge about the special needs of these groups in compression treatment is very limited. This paper shows important problems in putting compression stockings on as well in the elderly as in the obese population. In addition, venous diseases in these groups tend to be more severe. For a good compliance with compression it seems mandatory to modify compression products according to these needs and to develop and also to prescribe sufficient devices to assist in putting the stockings on.

Ricci S, Moro L, Trillo L, Incalzi RA

Foot-sparing postoperative compression bandage: a possible alternative to the traditional bandage

Phlebology 2013;28:47-50

Background

This study was performed to verify whether a foot-sparing bandage is effective for mobile C2-patients with a sufficient deep venous system who have undergone varicose vein surgery.

Methods

90 consecutive lower legs meeting the inclusion criteria underwent treatment with an inelastic foot-sparing bandage after phlebectomies of C2 varicose veins. Patient's satisfaction, efficacy and local effects were systematically documented.

Results

The bandage was well tolerated and highly effective. Four of the first 20 cases experienced a slight morning edema of the foot, which disappeared during walking. In the remaining cases the foot and distal limb was covered with a custom made short tubular shaped «sock» providing 10 mmHg compression in addition to the bandage. The sock was used only during the first 24 hours after surgery. This measure could prevent any swelling in the remaining 70 cases.

Conclusion

The authors conclude that the foot-sparing inelastic bandage is effective, cheap and tolerated well by well-selected patients who have undergone varicose vein surgery.

Comment

This prospective case-control study shows that in varicose vein patients in the clinical class C2 (CEAP) do not need high pressure foot compression to prevent foot edema after surgery if postoperative compression with a foot sparing bandage is used. A 10 mmHg sock for 24 hours prevented any foot edema. This combination allowed to wear normal footwear and was more comfortable for the patient. It should be considered if compression stockings in C2 patients who wear stockings because of venous symptoms could also be sufficiently treated with a reduced foot pressure to improve compliance.

Prandoni P, Noventa F, Quintavalla R, Bova C, Cosmi B, Siragusa S, Bucherini E, Astorri F, Cuppini S, Dalla Valle F, Lensing AWA, Prins MH, Villalta S on behalf of the Canano Investigators

Thigh-length versus below-knee compression elastic stockings for prevention of the postthrombotic syndrome in patients with proximal-venous thrombosis: a randomized trial

Blood 2012;119:1561-5

Background

Below-knee compression elastic stockings (CES) are effective for the prevention of the postthrombotic syndrome (PTS). Nevertheless, a substantial number of patients with CES still develops PTS.

Methods

In the present open label, randomized clinical trial, thigh-length CES were compared with below-knee CES for the prevention of PTS. A total of 267 patients with the first episode of proximal deep venous thrombosis were randomized to wear either thigh-length or below-knee CES for 2 years. After 3, 6, 12, 18, 24 and 36 months, they were assessed for PTS manifestations according to the Villalta scale.

Results

PTS was developed in 44 (32.6%) of the 135 patients randomized to thigh-length CES and in 47 (35.6%) of the 132 allocated to below-knee CES for an adjusted hazard ratio of 0.93 (95% confidence interval, 0.62–1.41). Severe PTS was developed in 3 patients in each group. CES-related side effects like itching and erythema developed in 55 (40.7%) of the 135 patients allocated to thigh-length CES and in 36 (27.3%) of those randomized to the below-knee group ($p = 0.017$) and led to premature discontinuation of their use in 29 (21.5%) and 18 (13.6%) patients.

Conclusion

The authors conclude that thigh-length CES do not offer a better protection against PTS than below-knee CES and are less well tolerated.

Comment

This study confirms that in most of the cases below-knee CES are sufficient for PTS prevention and show a better compliance compared to thigh-length CES. In individual cases with persisting thigh edema thigh-length CES may still have their benefit.

Mosti G, Iabichella ML, Partsch H

Compression therapy in mixed ulcers increases venous output and arterial perfusion

J Vasc Surg 2012; 55: 122–28

Background

The use of compression therapy in patients with mixed arterial-venous leg ulcers is still a controversial issue.

Objectives

To define bandage pressures that are safe and effective in treating leg ulcers of mixed arterial-venous aetiology.

Methods

In 25 patients with mixed-aetiology leg ulcers inelastic bandages were applied with pressures from 20 to 30, 31 to 40, and 41 to 50 mmHg and the following measurements were performed before and after bandage application to ensure patient safety throughout the investigation: laser Doppler fluxmetry (LDF) close to the ulcer under the bandage and at the great toe, transcutaneous oxygen pressure (TcPO₂) on the dorsum of the foot, and toe pressure. To assess efficacy on venous hemodynamics. Ejection fraction (EF) of the venous calf pump was measured.

Results

LDF values under the bandages increased by 33% (95% confidence interval [CI], 17-48; $P < .01$), 28% (95% CI, 12-45; $P < .05$), and 10% (95% CI, -7 to 28), respectively, under the three pressure ranges applied. At toe level, a significant decrease in flux of -20% (95% CI, -48 to 9; $P < .05$) was seen when bandage pressure exceeded 41 mmHg. Toe pressure values and TcPO₂ showed a moderate increase, excluding a restriction to arterial perfusion induced by the bandages. Inelastic bandages were highly efficient in improving venous pumping function, increasing the reduced ejection fraction by 72% (95% CI, 50%-95%; $P < .001$) under pressure of 21 to 30 mmHg and by 103% (95% CI, 70%-128%; $P < .001$) at 31 to 40 mmHg.

Conclusion

Inelastic compression of up to 40 mmHg does not impede arterial perfusion in patients with mixed ulceration presenting an ankle-brachial pressure index > 0.5 and an absolute ankle pressure of > 60 mmHg. The highly reduced venous pumping function may even be normalized. Such bandages are therefore recommended in combination with walking exercises as the basic conservative management for patients with mixed leg ulcers.

Comment

Future studies are desirable investigating safety and efficacy of elastic compression stockings in this delicate indication of mixed arterial and venous disease.

Carpentier PH, Becker F, Thiney G, Poensin D, Satger B

Acceptability and practicability of elastic compression stockings in the elderly: a randomized controlled evaluation

Phlebology 2011; 26: 107–113

Background

Donning and doffing of compression hosiery may be a problem especially for elderly people limiting the compliance of compression stockings.

Aim

of the study was to evaluate the practical acceptability of compression stockings in elderly patients.

Methods

Twenty women complaining of venous symptoms, presenting with clinical signs CEAP C1-C5, between 68–85 years of age without major disability, were asked to put on, wear for three hours and take off French class II stockings (15-20 mmHg). They assessed difficulties of putting on and off the stockings and the subjective feeling they experienced in comparison with their usual non-compression stockings (controls) by using a visual analogue scale with specific questions.

Results

To put on and off stockings over the heel was significantly more difficult for the compression products than for the usual leg wear. However, a higher level of comfort was reported for the compression stockings when they were worn.

Conclusion

There are significant difficulties regarding putting on and removal of the compression stockings, but these are compensated by a better comfort when they are worn.

Comment

This study shows that light compression stockings are able to increase the leg comfort in general. Probably due to the small number of the tested individuals in each CEAP class this increase of comfort-feeling was not put into relationship with pre-existing various subjective symptoms which are not specified. An interesting observation of the investigators was the fact that doffing was much often more difficult from the right than from the left leg.

Wu SC, Crews RT, Najafi B, Slone-Riviera N, Minder JL, Andersen CA

Safety and efficacy of mild compression (18 – 25 mmHg) therapy in patients with diabetes and lower extremity edema

J Diabetes Sci Technol 2012; 6: 641 – 647

Background

Edema of the foot or in the lower extremity is a frequent finding in patients with diabetes mellitus. To avoid compromising arterial circulation compression treatment is usually not performed in these patients.

Methods

In a pilot-study the authors investigated if diabetic compression stockings with mild compression (18 – 25 mmHg) are able to reduce edema formation in patients with diabetes mellitus without negatively impacting vascularity. The authors investigated 18 diabetic patients (9 males, 9 females) with a mean age of 61 ± 11 years. All patients had lower extremity edema and the ankle brachial index (ABI) was 1.1 ± 0.21 . All participants wore compression stockings with an ankle pressure of 18 - 25 mmHg during the waking hours. Follow-up visits were performed weekly for 4 consecutive weeks. The edema was quantified by circumference measurements at mid-foot, ankle and calf. The vascular status was followed by ABI measurements.

Results

During the study the calf circumference showed a significant decrease of 1.3 ± 0.28 cm ($p < 0.05$) after the first week. Midfoot circumference was significantly reduced after 2 weeks, too (-0.98 ± 0.35 cm). The ankle circumference showed a non-statistically significant trend towards reduction. No adverse events occurred during the study.

Conclusion

The authors concluded that mild compression decreases swelling in diabetic patients with edema formation without compromising vascularity.

Comment

This interesting study shows edema reduction in diabetic patients with edema formation in the foot and calf region. If confirmed in a larger study, diabetic edema could be an interesting indication for compression therapy. However, we must keep in mind that severe arterial occlusive disease or micro-angiopathy with necrotic lesions of the foot are still a contraindication for compression treatment in diabetic patients. In severe diabetic neuropathy with sensory loss there is also a risk for pressure damage of the skin by non-fitting stockings which may not be recognized by the patient early enough.

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