CIRUGÍA ESPAÑOLA

www.elsevier.es/cirugia

Original article

Efficacy, safety and comfort of compression therapy models in the immediate post-operative period after a greater saphenectomy. A prospective randomised study

Eliseo Collazo Chao,[a,*] *María Antonia Luque,*[b] *and Carmen González-Ripoll*[a]

[a]*Unidad de Atención al Pie Diabético e Insuficiencia Venosa Crónica, Hospital Universitario Reina Sofía, Córdoba, Spain*
[b]*Unidad de Cirugía Mayor Ambulatoria, Hospital Universitario Reina Sofía, Córdoba, Spain*

ARTICLE INFORMATION

Article history:
Received December 4, 2009
Accepted May 9, 2010

Keywords:
Compression stockings
Saphenectomy
Safety
Efficacy
Varicose veins
Comfort

A B S T R A C T

Introduction: There is still controversy on the best compression therapy after performing a greater saphenectomy. The purpose of this study is to establish whether the use of a controlled compression stocking has the same level of safety and efficacy as a compression bandage in the immediate post-operative period after a greater saphenectomy.

Material and methods: A prospective, randomised, open-labelled study, comparing three groups: 1) a conventional compression bandage for one week, 2) a conventional compression bandage replaced by a controlled tubular compression stocking at 5 h of its putting in place, 3) immediate direct use of the controlled tubular compression stocking, was conducted on fifty-five consecutive outpatients with a greater saphenectomy in one of their legs, and who fulfilled the inclusion criteria. The working hypothesis was that the controlled tubular compression stocking could replace, in terms of efficacy, safety and comfort, the usual controlled compression in the immediate post-operative period after saphenous vein stripping. The analysis variables were pain, control of bleeding, analgesics in the post-operative period, bruising, incapacity during the first week after the operation and comfort level.

Results: There were no statistically significant differences found between the three types of compressions studied as regards, safety, efficacy, comfort level, pain and analgesic consumption, but there was as regards the level of convenience in favour of the use of the stocking.

Conclusion: The controlled tubular compression stocking can replace the compression bandage with more advantages after greater saphenous vein stripping in outpatients, having the same safety and efficacy.

*Corresponding author.
E-mail address: ecollazo@comcordoba.com (E. Collazo Chao).

0009-739X/$ - see front matter

Efectividad, seguridad y confort de modelos de terapia compresiva en el postoperatorio inmediato de la safenectomía interna. Estudio prospectivo aleatorizado

Palabras clave:
Medias de compresión
Safenectomía
Seguridad
Eficacia
Varices
Bienestar

RESUMEN

Introducción: En la actualidad persiste la controversia sobre la mejor terapia comprensiva tras realizar una safenectomía interna. El objetivo de este artículo es evaluar si el uso de medias de compresión controlada presenta igual grado de seguridad y eficacia que el uso del vendaje compresivo en el postoperatorio inmediato de la safenectomía interna.

Material y métodos: Estudio prospectivo, aleatorizado, no ciego, comparando tres grupos: a) vendaje compresivo convencional durante una semana; b) vendaje compresivo convencional sustituido por una media tubular de compresión controlada a las 5 h de su colocación, y c) colocación directa de la media tubular de compresión controlada, realizado en cincuenta y cinco pacientes ambulatorios consecutivos con indicación de safenectomía en uno de sus miembros inferiores y que cumplan los criterios de inclusión. La hipótesis de trabajo consistió en que la media tubular de compresión controlada puede sustituir, en términos de eficacia, seguridad y comodidad, al vendaje habitual tras stripping de safena en el postoperatorio inmediato. Las variables por analizar fueron dolor, control de la hemorragia, analgésicos en el postoperatorio, secuelas de equimosis, incapacidad durante la primera semana del postoperatorio y grado de confort.

Resultados: No existen diferencias estadísticamente significativas entre los tres tipos de compresión ensayada en cuanto a seguridad, efectividad, grado de confort, dolor y consumo de analgésicos, pero sí en cuanto al grado de comodidad a favor del uso de la media.

Conclusiones: La media tubular de compresión controlada sustituye con gran ventaja al vendaje compresivo tras safenectomía interna en pacientes ambulatorios, presentando la misma efectividad y seguridad.

Introduction

Compression stockings have been known to decrease venous volume and interstitial oedema in patients with chronic venous insufficiency for some time. However, it has recently been calculated more exactly.[1,2] They are also known to effective in preventing recurrence after surgery in patients with chronic venous insufficiency.[3]

Any patient who has undergone an internal saphenectomy has experienced the discomfort of the common postoperative compression bandaging, regardless of the prescribed usage time. This type of compression in the immediate postoperative period has the great advantage that it can adapt to the compression needs of each leg. However, several problems may occur after it has been placed, depending on the skills of the healthcare worker who placed it, i.e. whether it was the surgeon himself or the nursing staff.

Saphenous vein stripping has recently once more proven[4] to be the most cost-effective technique. It is also the most clinically effective in the long term, when prescribed appropriately, compared with sclerotherapy and conservative treatment, which should be reserved for less severe venous diseases. Along with the two-layer pressure bandage, it remains the most used technique in Spanish general surgery for treating venous disease,[5] although endovenous laser treatment is gaining support.[6]

Previous studies[7] have shown good results in patients using graduated compression stockings a week after a total internal saphenectomy in a major outpatient surgery unit, after three days using postoperative dressing.

In one study,[8] which compared saphenous vein stripping with an acorn and by invagination, on the second postoperative day the dressing was changed for a compression stocking to be worn for six weeks.

We found no study where postoperative compression bandaging was replaced by a controlled compression stocking after a few hours on the same day as the intervention. Nor did we find studies where a compression stocking had been placed directly, without the uncomfortable dressing. The safety and efficacy, therefore, of replacing postoperative compression bandaging with a controlled compression stocking, either immediately or within 24 h after saphenous vein stripping, is not known.

The main objective of this study was to determine whether the use of a controlled compression stocking has the same safety and efficacy as using a compression bandage in the immediate postoperative period following an internal saphenectomy. The dressing can be placed in a distal or proximal direction, whereas the stocking necessarily has to start at the foot and go towards the thigh, meaning that it is immediately placed proximally during stripping. The specific objectives were to determine if the stocking could be placed

immediately (proximal stripping) or whether a temporary dressing should be applied (distal stripping) and kept on for a 5 h-period (arbitrarily proposed) before placing the stocking.

If the safety and efficacy of the stocking is the same as that provided by the dressing, in terms of control of bleeding, bruising and disability, the patient would have a more comfortable postoperative period, regarding pain conditions, use of analgesics, ease of maintaining personal hygiene and movement, and fewer complications from the dressing itself.

Materials and methods

The study was conducted in the Major Outpatient Surgery Unit and the Foot Care Unit for Diabetics and Chronic Venous Insufficiency at the Reina Sofía University Hospital in Córdoba, between October 2008 and July 2009.

Design

It was a prospective, randomised, non-blind study, comparing three groups:

1) conventional compression bandage for 1 week,
2) conventional compression bandage replaced by a controlled compression stocking 5 h later,
3) direct placement of a controlled compression stocking.

Patient characteristics

Inclusion criteria

- Saphenous vein inadequacy (C2 to C6 on the CEAP classification).
- Stripping of the internal saphenous vein performed.
- Informed consent.

Exclusion criteria

- Previous thrombophlebitis
- Immunosuppressive treatment
- Rheumatic disease
- Malignancy
- Previous saphenous vein surgery
- Peripheral arterial disease
- Obesity
- Diabetes mellitus treated with insulin
- Uncontrolled hypertension

Techniques

Both total and partial saphenous stripping was accepted, whether performed with the fleboextractor or the classic acorn stripper. Partial stripping was either proximal or distal, depending on the portion affected. For both total and partial proximal stripping procedures, ligature of the arch and its collaterals and crossectomy were performed. The type of anaesthesia (spinal or general) was at the discretion of the anaesthesiologist. All patients received 2500 IU bemiparin subcutaneously 6 h after the spinal anaesthesia, or immediately if a general anaesthesia was used.

Compression therapy procedure

The conventional compression bandage consisted of a protective layer of cotton with a crepe bandage (usually wound twice) up to the groin, and kept on for a week. Two types of full-leg controlled compression tubular stocking were used, which varied depending on the calf diameter (i.e. more or less than 41 cm). Patients were able to take them off after the third day so that they were able to wash themselves and during the night time.

The standard compression bandage consisted of 2 padded cotton units and 2 crepe bandages, costing €1.16. A controlled compression tubular stocking cost €2.50.

Variables analysed

A nurse, who was not involved in the operation or postoperative period, collected the following data by telephone, 48 hours after surgery: pain in the operated limb (scale of 1 to 10), analgesic units administered, presence of bleeding injury and disability (defined as difficulty in performing everyday movements, on a scale of 0 to 4).

Another nurse, also uninvolved in the operation or postoperative period, personally examined the patients on the 8^{th} postoperative day, in terms of: pain in the operated limb (scale of 1 to 10), analgesic units administered the previous day, disability (scale of 0 to 4), total area of ecchymosis (in cm^2) and degree of comfort during the week (scale of 1 to 5).

Statistical analysis

A significance level of 5% and 80% statistical power were assumed. A proportion of 10% of the patients were expected to suffer from bleeding and bruising to the area, meaning that absolute precision was between 7% and 10%, and 95% confidence level. It was therefore estimated that 106 patients were needed (Epidat 3.1), to which 5% was added to cover possible losses. the final sample size was therefore 112 consecutive outpatients, referred to the unit, having been diagnosed with a saphenous vein in one of the lower limbs, and meeting the criteria. Block randomisation was performed using MAS software v.2.1.

The SPSS v.14 statistical package for data analysis was used, performing the chi-square test with Fisher's exact test so that bleeding could be compared in three separate groups of patients to be treated. An analysis of variance was used to compare the groups. Levene tests and Games-Howell and Tukey post hoc tests were performed where necessary.

To compare the variables of pain, disability and comfort level, the Kruskal-Wallis and Mann-Whitney U tests were performed. Data were expressed as mean (SD) or median (interquartile range) for quantitative variables and as an absolute number (%) for qualitative variables. Evaluating the normal distribution of the variables was not necessary, given the size of the sample.

The study was estimated to last approximately twelve months. An interim statistical study was planned when 50% of the sample subjects had been operated upon.

Ethics

The ethical principles established in the Declaration of Helsinki were observed. The patient signed the informed consent form. A favourable report from the Clinical Research Ethics Committee was obtained. All information obtained was subject to the same level of confidentiality as that contained in the medical record (Spanish Law 41/2002, Law 15/1999, Royal Decree 994/99).

Results

The interim statistical study, presented below, was performed after data had been obtained from patient 55. As a consequence of the results, the study was suspended. Eight patients, who ultimately were not able to undergo the saphenectomy, were removed from the study. One patient who underwent the saphenectomy could not be reached before the 8th day after surgery, and was considered lost.

Forty-two women (76%) and 13 men, aged 43 (10) years with a BMI of 28 (4) were recruited consecutively (Figure 1): 31% received a conventional bandage, 34% (19 cases) received the stocking after 5 h with the dressing and 34% received the stocking immediately. Forty of the saphenectomies (73%) were total, with 13 distal and 2 proximal. Local anaesthesia was given to 96%, with the rest under general anaesthesia. Only one patient had slight bleeding in the first 48 hours due to the inguinal incision. No disability at 48 h was reported by 37 patients (69%), with the remaining 17 having slight disability.

Analgesic use is shown in Figure 2 and Figure 3, and the area of ecchymosis on the 8th day is shown in Figure 4. The variables studied are summarised in Table 1.

The area of bruising on the 8th day was higher in patients who underwent total saphenectomy and, interestingly, in those who reported not having any disability at 48 h (126 cm^2 and standard error of 15 in cases without disability, compared to 87cm^2 with a standard error of 12 in those who expressed a slight disability; CI 95%).

There were significant differences in the area of bruising between the total and distal saphenectomy groups (ANOVA of one factor, $P<.05$, CI 95%), but not regarding pain, disability, comfort level nor analgesic intake during the first 48 h and on the 8th day.

There were significant differences in the comfort level during the week depending on the type of compression ($P<.001$). As such, the Mann-Whitney U test was performed between the immediate bandage and after 5 h groups. This was significant ($P<.001$) and in favour of the latter. It was also significant ($P<.001$), in favour of the stocking, when testing between bandage and immediate stocking groups. However, there were no statistical differences between the dressing for 5 h and immediate placement of the stocking.

Discussion

The study demonstrated no statistically significant differences between the three types of compression regarding safety

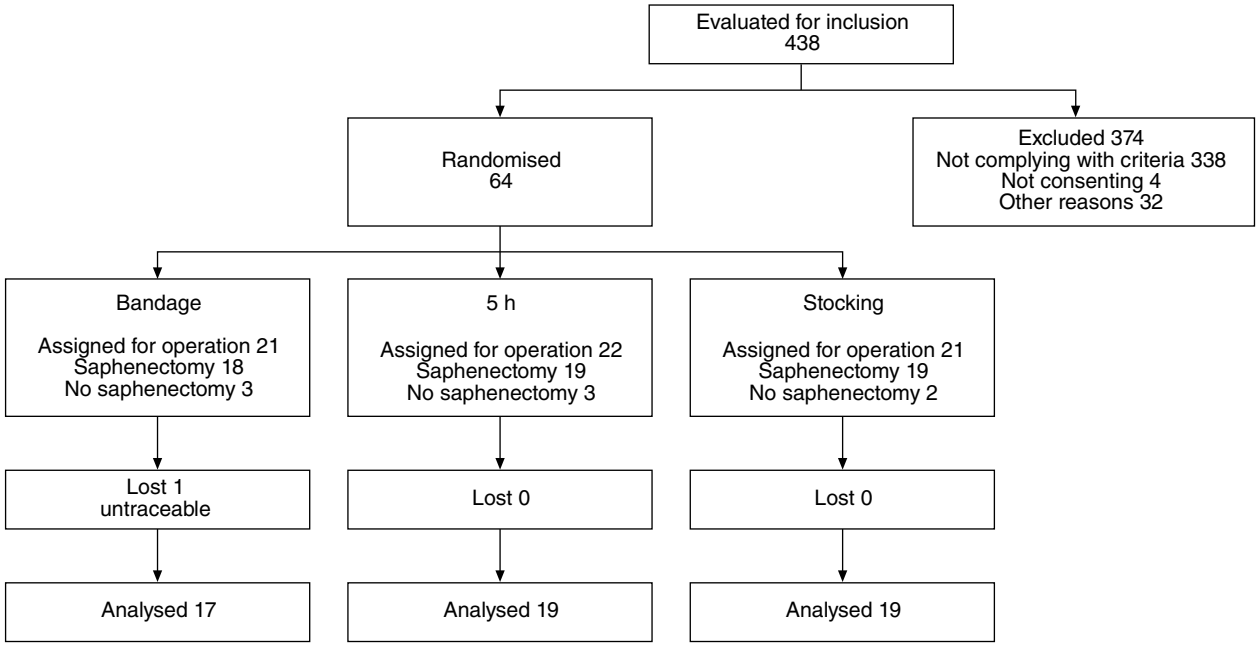

Figure 1 – Flowchart of patients included in the study.

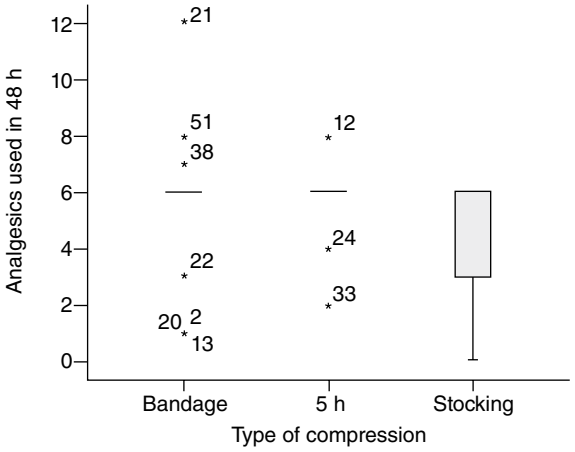

Figure 2 – Analgesics used in the first 48 hours.

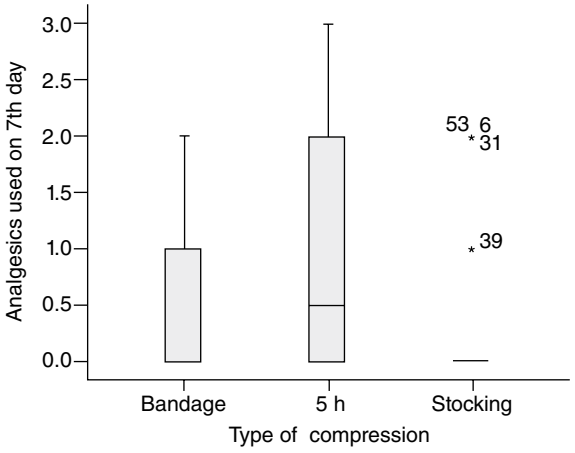

Figure 3 – Analgesics used on the seventh day.

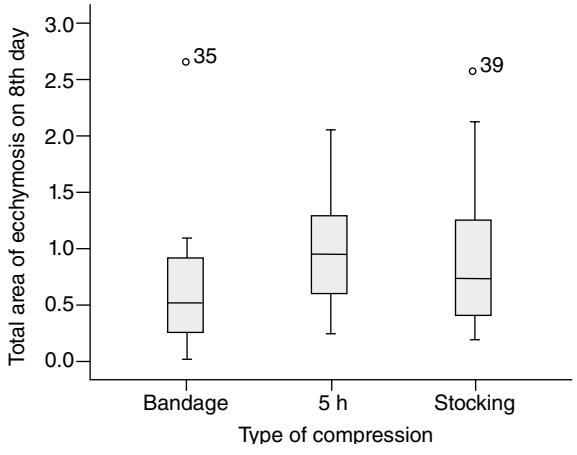

Figure 4 – Area of ecchymosis on the eighth day.

Table 1 – Results of the variables depending on the type of compression used

	Bandage	5 h	Stocking	Sig (CI 95%)
Analgesic used				
At 48 h	5.47	5.78	4.42	P=.161
At 7 days	0.53	0.83	0.37	P =.242
Area of ecchymosis				
8th day	86.41	127.28	125.16	P =.261
Haemorrhage				
At 48 h	1	0	0	P =.33
Disability				
At 48 h	28.53	28	26.11	P =.831
At 7 days	26.41	30.56	25.58	P =.509
Pain				
At 48 h	31.09	28.42	23.42	P =.311
At 7 days	26.76	28.86	26.87	P =.894
Discomfort	39.15	22.08	22.21	P <.001
BMI	28.55	28.06	27.12	P =.787
Proportion of saphenectomy				
Total	11	15	14	P =.715
Distal	5	3	5	
Proximal	1	1	0	

5 h indicates conventional bandage placed immediately after surgery replaced after 5 h with a controlled compression stocking; bandage, conventional bandage maintained for one week; BMI, body mass index; CI, confidence interval; stocking, controlled compression stocking was directly placed.

(bleeding due to incision) and efficacy (area of ecchymosis and disability). There were also no differences in comfort, regarding pain and analgesic use. However, there was a difference between the comfort level achieved with the compression therapy and immediate stocking placement. Moreover, the disadvantages of the usual compression bandage disappear with the immediate placement of the controlled compression tubular stocking, meaning that the patient is able to leave the hospital the same day of surgery.

Potential confusion between the difference of the sections of the saphenectomy performed is discarded, because there were no statistically significant differences between the degree of pain, disability and comfort in relation to the proportion of the saphenectomy, although there were in relation to the area of ecchymosis.

This study could not have been blind, except for the nurse examining patients after 48 hours, given the evidence of bandage or stocking use. Selection bias was avoided by including consecutive patients referred to the unit for an internal saphenectomy. Therefore, all the existing population, until a given number, was entered into the study, as the unit used was the one to which all patients in the province are referred. Follow-up period after completing the treatment and evaluation were not considered necessary.

The very small number of patients with proximal saphenectomy means that the findings in relation to it cannot be extrapolated for this type of study.

REFERENCES

1. Müller-Bühl U, Heim B, Fischbach U, Windeler J, Finkenstädt TH, Schläfer M. Effect of compression stockings on leg volume in patients with varicose veins. Phlebology. 1998;13:102-6.
2. Cooke EA, Benkö T, O'Connell BM, McNally MA, Mollan RAB. The effect of graduated compression stockings on lower limb venous haemodynamics. Phlebology. 1996;11:141-5.
3. Dorobisz AT, Rybak Z, Hepp W, Szyber P. A value of compression therapy prophylaxis following surgery in patients suffering from chronic venous insufficiency. Pol Merkur Lekarski. 2002;12:36-8.
4. Michaels JA, Campbell WB, Brazier JE, Macintyre JB, Palfreyman SJ, Ratcliffe J, et al. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). Health Technol Assess. 2006;10:1-196. iii-iv.
5. Morales-Cuenca G, Moreno-Egea A, Aguayo-Albasini JL. Los cirujanos generales frente a la cirugía de las varices. Cir Esp. 2009;85:205-13.
6. Leopardi D, Hoggan BL, Fitridge RA, Woodruff PW, Maddern GJ. Systematic review of treatments for varicose veins. Ann Vasc Surg. 2009;23:264-76.
7. Biswas S, Clark A, Shields DA. Randomised clinical trial of the duration of compression therapy after varicose vein surgery. Eur J Vasc Endovasc Surg. 2007;33:631-7.
8. Scheltinga MR, Wijburg ER, Keulers BJ, Kroon KE. Conventional versus invaginated stripping of the great saphenous vein: a randomized, double-blind, controlled clinical trial. World J Surg. 2007;31:2236-42.