Randomised Clinical Trial of the Duration of Compression Therapy after Varicose Vein Surgery

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Objective. To determine whether a period of one or three weeks of compression following varicose vein surgery influenced the outcome.

Design. Randomised controlled trial.

Method. 300 patients aged between 18–80 years underwent unilateral varicose vein surgery in a Day Procedure Unit. Compression bandaging was applied post-operatively for three days. Patients then wore graduated elastic compression stockings randomised to a period of either one or three weeks. Patients were assessed by questionnaire on pain scores at rest and during mobilisation for up to six weeks, total analgesic consumption, duration of time off work, any complications, and patient perception of cosmetic results at various periods up to 12 weeks following surgery.

Results. The mean pain score reported by patients over 6 weeks was similar in the two groups (1 week group: mean 2.18, three week group: mean 1.87). The 95% confidence interval (CI) for the mean difference in pain was (−0.05–0.66). Analysis of the pain curves at 1 week, 4 weeks and 6 weeks, showed equivalence at 4 and 6 weeks, but not for 1 week, with the group wearing stockings for only one week complaining of more pain for this period. A significant increase in the total number of analgesia tablets consumed was also found in the group wearing stockings for only one week. No significant differences were found in the other secondary endpoints — return to work (categorised as <2 weeks, 2–6 weeks or 6–12 weeks), patient satisfaction or post-operative complications.

Conclusion. We found no benefit in wearing compression stockings for more than one week following uncomplicated high saphenous ligation with stripping of the great saphenous vein with respect to post-operative pain, number of complications, time to return to work, or patient satisfaction for up to 12 weeks following surgery.

Keywords: Varicose veins; Surgery; Great saphenous vein; Compression; Duration; Randomised controlled trial.

Introduction

Standard surgical treatment for primary varicose veins of the great saphenous system in the UK is high saphenous flush ligation, usually with stripping of the great saphenous vein. Although various newer treatments such as foam sclerotherapy are currently being investigated, primary varicose vein surgery remains one of the most commonly performed operations in the UK.

Whilst varicose vein surgery is regarded as a safe and minor procedure, it is associated with a significant surgical morbidity and patient dissatisfaction. Patients should therefore be made aware of the potential outcome prior to surgery. Postoperative limb compression is widely used after surgery to reduce haemorrhage, oedema, haematoma and pain. Despite this, we could find only very limited work on the optimum duration of compression therapy after varicose vein surgery. Most surgeons utilise some form of compression bandaging and/or stockings for a variable duration (Table 1), but the reason for such variation is not clear and seems to be based on individual surgeon’s practice or prejudice rather than objective evidence.

We decided to investigate the duration of postoperative compression on pain scores, post-operative complications, time off work, and patient satisfaction with the cosmetic outcome. Long periods of stocking wear appeared unnecessary (since demonstrated by others), so we looked at two short post-operative compression regimes. Both utilised a short period (three days) of Velband/Coban bandaging in the immediate post-operative period (as such bandages have been shown to be superior to crepe bandages...
in preventing subcutaneous haematoma formation following stripping of the great saphenous vein\textsuperscript{6}). Patients were then randomised to one or three weeks of TED stockings\textsuperscript{TM} (as low compression stockings have been shown to be more comfortable and equally effective following varicose vein surgery,\textsuperscript{7} and are widely used for this purpose).

### Patients and Methods

Ethics committee approval was obtained. All patients between the ages of 18–80 years, listed for primary varicose vein surgery to the great saphenous system in the Day Procedure Unit at the Norfolk & Norwich University Hospital, were invited to participate in the study. We aimed to recruit 300 patients with the expectation of a 70% response rate; assuming 150 patients in each group, it was calculated that we would have 89% power to demonstrate equivalence of within one unit, assuming a significance level of 5% and a common standard deviation of 3 units. All patients enrolled were randomised using sealed envelopes which allowed equal recruitment to wearing standard full length TED stockings for either one or three weeks continuously.

Eligible participants were included if they satisfied inclusion and exclusion criteria (Table 2). All patients meeting the entry criteria were invited to participate in the study. The primary end points measured were pain scores at week 1, 4, and 6 and average pain score; secondary end points were analgesic consumption, complications and return to full activity after surgery, to determine whether wearing stockings for 1 or 3 weeks altered the outcome of these parameters.

Questionnaires containing 12 questions were used (Appendix 1). Pain scores were measured as pre-op pain, during the first 24 hours after surgery, and at 1, 4 and 6 weeks after operation using a numerical rating scale (NRS) of 0 (no pain) – 10 (worst possible pain). Amount of analgesic consumption (number of pain relief tablets taken — each patient was supplied with Co-dydramol tablets as take-home medication — and/or need for any other help for pain relief), any untoward effects following surgery, duration of time off work and patient perception of cosmetic results were also recorded.

Operative technique was standardised to saphenofemoral junction flush ligation with ligation and division of all tributaries. The GSV was stripped to the level of the knee using a PIN stripper\textsuperscript{8} and multiple phlebectomies of the remaining varicosities were performed using Oesch hooks. All groin wounds were infiltrated with 10 ml. 0.5% bupivacaine hydrochloride with adrenaline (Marcaine\textsuperscript{®} with adrenaline, AstraZeneca, Horizon Place, Luton, LU1 3LU) to improve pain relief as a previous study had shown poor post-operative pain control despite analgesic medications.\textsuperscript{9} At the end of the operation all patients were placed in Velband\textsuperscript{®} (Johnson & Johnson Ltd, Maidenhead, SL6 3UG) followed by Coban\textsuperscript{®} (3M Healthcare Ltd, Loughborough, LE11 1EP) bandages, to be changed on day 3 (by the GP Practice Nurse) for the standardised full length TED stockings (Kendall T.E.D. Anti-Embolism Stockings, Tyco Healthcare,

### Table 1. Survey of type and duration of post-operative compression therapy

<table>
<thead>
<tr>
<th>Ref</th>
<th>Compression</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Compression bandaging replaced after 1–2 days with class 2 thigh length compression stockings</td>
<td>Not given</td>
</tr>
<tr>
<td>13</td>
<td>Cohesive elastic bandage using figure-of-eight technique over a layer of orthopaedic wool</td>
<td>Not given</td>
</tr>
<tr>
<td>14</td>
<td>No comment</td>
<td>Not given</td>
</tr>
<tr>
<td>15</td>
<td>No good evidence that any one bandaging system is superior... The bandage can be removed after 24–48 hours and replaced with a full-length stocking worn continuously for 1 week</td>
<td>1 week</td>
</tr>
<tr>
<td>16</td>
<td>No comment</td>
<td>Not given</td>
</tr>
<tr>
<td>17</td>
<td>Gamgee pads and crepe bandages; rebandage after removal of Gamgee pads before discharge; remove on day 7</td>
<td>A firm tubular bandage support for further 4 weeks</td>
</tr>
<tr>
<td>18</td>
<td>No comment</td>
<td>Not given</td>
</tr>
<tr>
<td>19</td>
<td>Additional compression bandages over bandages put on in the theatre</td>
<td>Not given</td>
</tr>
<tr>
<td>20</td>
<td>“Leg bandaged”</td>
<td>Not given</td>
</tr>
</tbody>
</table>

### Table 2. Inclusion and exclusion criteria

#### Inclusion criteria

- Age 18–80 years
- Primary varicose vein surgery for SFJ/GSV reflux
- Previous sclerotherapy
- No contraindication to day case surgery

#### Exclusion criteria

- Age <18 or >80
- Previous varicose vein surgery
- Varicose veins arising from SSV reflux
- Patients with active ulceration
- Refused consent
- Not suitable for day case surgery
Hants PO13 0AS) provided before discharge, and provided with take home analgesic of Co-dydramol (non-proprietary dihydrocodeine tartrate 10 mg, paracetamol 500 mg).

Each surgeon filled in a form indicating the severity of disease according to the clinical classification of the CEAP system (Table 3). The revised CEAP classification described here was not published until data collection was complete so no distinction was made in our study between C4a and C4b patients who comprised a small proportion of all patients. The surgeon recorded how many phlebectomy incisions were required and any per-operative complications encountered.

**Statistical analysis**

The data were analysed by constructing 95% confidence intervals for the differences between groups. In line with standard practice of equivalence trials the two treatments were concluded to be equivalent if the confidence intervals excluded any clinically important differences. In this paper we define a clinically important difference as one unit of pain in our pain scale which has a range of 0–10. All computations were done using the statistical package Stata (Stata/SE 9.1 for Windows, Texas, USA).

**Results**

220 participants returned questionnaires, a response of 74%, 110 in the one-week group and 110 in the three-week group. The groups were similar in terms of baseline measures — age, gender, pre- and post-operative pain, and severity of disease (Table 4), hence no adjustment for baseline imbalances was required.

The primary endpoint was pain experienced over the six weeks. As some respondents did not complete the whole questionnaire, a few responses were missing each week. To compensate for this we calculated the average pain score for each patient using all the available pain measures for that patient. Although the pain scores were not normally distributed, due to the large sample size in each group, the assumptions of the t-test and its associated confidence intervals were met. The average pain score in the 3 week group was 2.18 compared to the 1 week group figure of 1.87. The 95% confidence interval for the mean difference in average pain is (0.05, 0.66) hence we conclude that the two groups are equivalent within the previously defined limit of equivalence (i.e. within 1 unit of the pain scale).

The mean pain during the first week after surgery was significantly higher in the week 1 group (mean difference 0.65, 95% CI 0.14–1.16); during the 4th and 6th weeks the mean pain was not statistically different and was clinically equivalent (mean difference 0.21, 95% CI −0.23–0.65 4th week, mean difference 0.01, 95% CI −0.31–0.34 6th week). The results for the primary endpoints are given in Table 5.

An analysis of the secondary endpoints (Table 6) showed one significant difference between the groups. In terms of return to work there was no significant difference between either group at any of the time points measured (less than 2 weeks, 2–6
weeks 6–12 weeks). Analgesia consumption was measured by the number of tablets of Co-Dydramol taken, classified as 5–10; 10–20; 20–30; 30–40; 40+.

There was a significant difference between the two groups \( p\)-value \(= 0.05 \), Chi-squared test for trend), with the 3-week group more likely to use less tablets than the one week group. However, patient satisfaction and post-operative complications were similar. One third of all patients complained of some complication, although bruising was by far the commonest complaint (29 patients). Twelve patients complained of either areas of numbness or pins and needles, and 13 patients had possible wound infections. However, there was no difference between the two groups in the number of complications.

**Discussion**

There is very little clear guidance on the duration of compression after varicose vein surgery in standard text-books or literature. The lack of any evidence as to how long such support was required encouraged us to set up the trial reported here.

For the surgeon, the main reason for post-operative compression would appear to be to reduce haematoma formation and allow healing with the best functional result, i.e. to prevent recanalisation of veins either damaged surgically or filled with thrombus caused by disconnection elsewhere. For the patient, stockings are conceivably worn to improve post-operative comfort and, perhaps, to improve the cosmetic result. For these reasons we looked at pain scores, post-operative complications, analgesia consumption, time off work, and patient satisfaction with the cosmetic outcome.

**Pain.** We demonstrated equivalence between the two groups in terms of average pain experienced over the six weeks, also with pain scores during the fourth and sixth week, but the results show non-equivalence at one week in favour of the group wearing stockings for three weeks. However, it is our belief that the two groups should be considered as equivalent with regard to pain. Although there was a significant difference in pain scores at the end of the first week, at this point both groups had undergone identical treatment. There was equivalence in overall pain scores over the duration of the trial, but analgesia consumption was actually greater in the one-week group. The need for medical referral were equivalent in the two groups. It may be that the group who knew they were about to remove their stockings at one week were more apprehensive in anticipation of removing the stockings than the group who knew they were going to continue to wear stocking for a further two weeks, and this knowledge influenced their perception of pain. Patients were encouraged to complete the questionnaire contemporaneously, but it may also be that, if it was completed at the end of the six-week period, the one-week point registered as "more significant" in some way to the group who were then about to discontinue stocking wear. No differences were found when the data was analysed for gender, clinical classification, or disease severity as recorded by number of stab avulsions.

**Post-operative complications.** There is no evidence from this study that bruising or haematoma formation are reduced by wearing a stocking for longer than one week. It is also of interest that patients see bruising as a post-operative complication — better information supplied to the patient before surgery might reduce the number of "complications" as some bruising is inevitable.

**Analgesia consumption.** There was a significant difference between the two groups, with the three-week group more likely to use fewer tablets compared to the one-week group.

**Time taken to return to work.** There was no difference between the two groups for the percentage of people returning to work at any time period. Therefore, it appears that there is no benefit in
wearing stockings in an attempt to improve such an outcome.

Patient satisfaction. There was no significant difference in the percentage of patients being satisfied between the two groups, so no advantage in wearing stockings for more than one week on this outcome.

Our study has a number of potential drawbacks. First, we only have a 74% response rate that might imply some form of responder bias. Our study was also unblinded so that the patients knew which treatment they were receiving and this might have biased the results. However, an equal response rate in both groups goes against any responder bias in the comparison of the treatments; also it would have been impossible to run the trial blinded. A further drawback is that we collected the data retrospectively so it is possible that our study has recall bias. However, if this were the case we would not expect to see decline in pain scores over time, thus we think it is unlikely to have affected our study. The study also has a number of advantages, namely that we did not restrict the number of analgesic tablets the patients could receive, nor did we in any way encourage either group as to when they could return to work. This adds to our study since we have not deviated from how the stockings would be used in practice.

Another proviso to this study may be that there is some evidence that long-term wearing of stockings after such surgery decreases the recurrence rate (although the term recurrence requires careful analysis – it is undoubtedly true that many patients develop further varicosities, which often involve other anatomical areas). However, to prevent such recurrence seems to involve wearing of stockings for months or years and may well not be acceptable to patients.

Conclusion

We have demonstrated that post-operative compression for 1 week or 3 weeks following varicose veins surgery are equivalent in terms of average pain over the six weeks of the trial, and that there was a significant difference in the number of analgesic tablets consumed, with the 3-week group consuming less. We did not find any significant differences in time taken to return to work, patient satisfaction or post-operative complications.

In view of these findings, we have altered our practice to recommend wearing TED stockings for only one week following surgery.

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Appendix 1.

QUESTIONNAIRE

The following questions on pain refer to pain that you feel may be related to your operation for varicose vein only:

1. Using the scale below, please circle a number that you feel corresponds with the level of pain, if any, BEFORE you had your varicose vein surgery:
   
   
   0       1       2       3       4       5       6       7       8       9       10
   no pain                                      moderate pain                                               worst pain possible

2. Using the scale below, please circle a number that you feel corresponds with the level of your pain in the first 24 hours After your operation:
   
   
   0       1       2       3       4       5       6       7       8       9       10
   no pain                                      moderate pain                                               worst pain possible

3. Using the scale below, please circle a number that you feel corresponds with the level of pain in the first week After your operation:
   
   
   0       1       2       3       4       5       6       7       8       9       10
   no pain                                      moderate pain                                               worst pain possible

4. Using the scale below please circle a number that you feel corresponds with the level of your pain in the 4th week After your operation:
   
   
   0       1       2       3       4       5       6       7       8       9       10
   no pain                                      moderate pain                                               worst pain possible

5. Using the scale below please circle a number that you feel corresponds with the level of pain After 6 weeks of your operation:
   
   
   0       1       2       3       4       5       6       7       8       9       10
   no pain                                      moderate pain                                               worst pain possible

6. Have you had any untoward effects after your operation other than bruising? Please specify:
   (Please note some amount of bruising of the leg is a common problem after this operation)

7. How long did you have off work after the operation? Please tick one:
   
   Not employed / Retired prior to operation
   Less than 2 weeks
   2 to 6 weeks
   6 to 12 weeks

8. What is the nature of your occupation?

9. Are you employed or self-employed?

10. Have you sought any help other than the prescribed medication for the pain? Please tick more than one if applicable.
    
    General practitioner
    Surgeon
    Others (please specify)

11. Please indicate the total number of pain relief tablets you took after your operation:
    
    5-10
    10-20
    20-30
    30-40
    More than 40

12. Are you satisfied with the overall appearance following your surgery?
    
    Yes / No.

Signature……………………………. Date……………..

Thank you for your help. Please return this questionnaire and the consent form in the envelope provided to:

Mr. S. Biswas, Department of Surgery, Norfolk and Norwich Hospital, Brunswick Road, Norwich, NR1 3SR
References


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