A Systematic Review of Postprocedural Compression Following Treatment of Superficial Venous Incompetence

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Abstract

Objective

To investigate the evidence regarding the optimal type and duration of compression following treatment of symptomatic superficial venous incompetence (SVI).

Methods

The National Institute for Health and Care Excellence's (NICE) Healthcare Databases Advanced Search (HDAS) engine was used to identify all English language randomised controlled trials (RCT) investigating compression strategies following treatment for SVI. Outcomes of interest included postprocedural pain, venous thromboembolism (VTE), Health Related Quality of Life (HRQoL) and anatomical occlusion.

Results

In total, 18 studies were included comprising some 2550 treated limbs. Compression was compared with no compression in 4 studies, 9 studies compared different durations of compression and a further 5 compared different types of compression. A 1-2 week period of compression was associated with a mean reduction of 11 points (8– 13); $p<0.001$ in pain on a 100mm Visual Analogue Scale compared with shorter duration of compression. This was associated with improved HRQoL and patient satisfaction. Longer durations of compression did not add further benefit. There was low quality evidence suggesting that 35mmHg compression with eccentric thigh compression achieved lower pain scores when compared with lower interface pressures. There were no differences in VTE or technical success in any group including no compression.

Conclusion

Postprocedural compression of 1-2 weeks following SVI treatment is associated with reduced pain when compared with shorter duration. Further research is required to identify the optimal interface pressure and type of compression and to understand the impact of compression on VTE.

Introduction

Lower limb superficial venous incompetence (SVI) is a common disease among adults worldwide. Prevalence varies from 30-50% with varicose veins being the commonest manifestation of the disease[1-3]. Early symptoms include aching, leg heaviness and itching, and disease progression may lead to skin changes and ulceration. Symptoms are associated with a significant impairment in patient health related quality of life (HRQoL) at all stages of the disease[2-7].

Interventional treatment of SVI aims to abolish reflux and can be achieved by occluding incompetent veins using endovenous thermal ablation (EVTA), ultrasound guided foam sclerotherapy (UGFS), one of the newer non thermal non tumescent methods (NTN); or by surgically removing them. All are effective and offer patients significant improvement in HRQoL[8-15]. Though rare, the most common major complication of SVI intervention is venous thromboembolism (VTE). More frequently, patients report postprocedural pain, which is associated with a HRQoL reduction lasting up to two weeks[16]. Following SVI treatment, patients typically undergo a short period of postprocedural compression, which is hypothesised to limit bruising and swelling thereby reducing postprocedural discomfort in addition to reducing the risk of VTE and increasing anatomical occlusion success rates. Compression is however unpopular with patients and thus compliance rates can vary[17,18].

Previous surveys and reviews found that nearly all clinicians utilise postprocedural compression but with different devices, interface pressures and durations[19-21]. National and international guidelines also support the use of compression but acknowledge weakness in the evidence base for this recommendation[22-24]. However, several randomised studies have been published on postprocedural compression subsequent to these guidelines and a fresh look at the evidence is therefore merited. This updated systematic review aims to integrate and summarise randomised controlled trials evidence of postprocedural compression following treatment of SVI.

Methods

A review was carried out in accordance with the Preferred Reporting Instrument for Systematic reviews and Meta-Analysis (PRISMA) guidelines[25], and the protocol was prospectively registered on PROSPERO CRD42020209918.

Inclusion criteria

English language reported randomised clinical trials (RCTs) of adult patients were eligible for inclusion if they involved a comparison of compression regimes against one another or against no compression following treatment for symptomatic SVI of Clinical aEtiological Anatomical Pathophysiological (CEAP) class 2-5 patients involving the great saphenous vein, small saphenous vein, anterior accessory saphenous vein, or any combination of these.

Search strategy & study selection

A combined search of EMBASE and Medline was performed using the National Institute for Health and Care Excellence's (NICE) Healthcare Databases Advanced Search (HDAS) engine on 28/08/2020, this was then repeated on 18/05/2021. Appendix 1 outlines the search strategies used. Titles and abstracts of the results of the search strategy were compiled into a single file and duplicated articles were electronically removed by the HDAS engine.

Two reviewers (AHM; ST) independently assessed abstracts of all studies identified by the search and excluded any not meeting inclusion criteria. Full manuscripts of potentially eligible studies were then assessed independently against the inclusion criteria. Disagreements about inclusion were resolved by consensus, and if this failed, by the arbitration of a third review author (DC).

Data & Outcomes

Three reviewers (AHM; SHM; ST) independently extracted data from included study manuscripts using standardised data extraction tables. Data extracted included the number of patients and limbs, demographics, disease severity, follow up duration, type of interventions, description of the compression strategy, and compliance with compression. Clinical outcomes used for comparison included patient-reported pain score, anatomical occlusion, VTE, generic and disease specific HRQoL, disease recurrence and patient satisfaction.

Study authors were contacted to obtain further information, where required. Raw data was extracted for outcomes of interest; distribution, mean and standard deviation for continuous outcomes, number of events for dichotomous outcomes, and where applicable, hazard ratio and 95% confidence intervals for time-to-event data from the published reports. Risk of bias in included studies was assessed using the Cochrane risk of bias in randomised trials tool[26].

Analysis was performed using Review Manager (version 5.4, The Cochrane Collaboration, 2020) with statistical heterogeneity being assessed using I^2 test and a fixed effects model being used where heterogeneity was deemed low[27]. Continuous outcomes were analysed using mean difference (MD) and 95% confidence intervals (CI), or standardised mean difference and 95% CI where studies measured the same outcome using different scales. Categorical outcomes were analysed using risk ratios with 95% CI and a narrative summary was undertaken for data that could not be analysed by meta-analysis.

Results

Search results

Titles and abstracts of 812 original articles were screened of which 23 were selected for full text review. Of those, 18 met the selection criteria and were included in the review (Figure1, Table 1) and five were excluded (Appendix 2). A total 2584 limbs were treated in the included studies using EVTA in seven studies[28-34], open surgery in six[35-40], UGFS in four[41-44], and one study combined EVTA and surgery[45]. Nine studies compared different durations of compression[30-37,39,43,45], five compared different types of compression whilst controlling for duration[29,38,40,42,44] and four studies compared compression to no compression post SVI treatment[28,32,41](Table 2). The cumulative median (IQR) duration of compression used in the 18 studies was 7 (3-14) days.

Bias risk assessment

Most studies described satisfactory methods of random sequence generation and allocation concealment meaning that selection bias risk was low in all but five studies (Figure 2). Most authors reported adequate steps to minimise performance bias risk apart from one study (Bond et al)[40]. Detection bias risk was deemed low in most studies as outcome assessment was often blinded and where this was not possible most authors used validated patient reported outcomes with the exception of six studies (Campos Gomes et al; Cavezzi et al; Krasznai et al; Mariani et al; Rodrigus et al; Travers et al)[34,36-38,42,43]; where some outcomes were assessed using non validated tools or non-standardised methods (Figure 2). Reporting bias risk was deemed high in two studies (Bakker et al; Lugli et al)[29,30].

Bias risk due to incomplete outcome data was high in several studies due to high loss to follow up rates in six studies (Bakker et al; Bootun et al; Campos Gomes et al; Elderman et al; Krasznai et al; Travers et al)[30,31,33,34,37,43], whereas five studies failed to report this data altogether (Biswas et al; Bond et al; Hamel-Desnos et al; Mariani et al; Rodrigus et al)[35,36,38,40,41]. Another sources of bias was assessment of compliance to compression, which was not reported in nine studies (Biswas et al; Bond et al; Campos Gomes et al; Elderman et al; Houtermans-Auckel et al; Lugli et al; Onwudike et al; O'Hare et al; Rodrigus et al)[30,32,36,39,40,44]. Device manufacturers funded three studies (Cavezzi et al; Mariani et al; Hamel-Desnos et al), and another four did not declare information on conflict of interest or funding sources (Bond et al; Lugli et al; Rodrigus et al; Travers et al).

Comparison of compression vs no compression

Four studies compared the use of compression post SVI treatment to no compression (Campos - Gomes et al, Hamel- Desnos et al; Onwudike et al; Pihlaja et al); (table 2). Postprocedural pain was formally assessed in only one study (Pihlaja et al), which reported very low pain scores in both groups. There was a small difference in favour of 1 week of compression, however this failed to reach the threshold of statistical significance (Figure 3). Disease specific HRQoL significantly improved in all patients, and at three and six months, there was no statistical or clinically meaningful difference when comparing compression to no compression (Figure 4). At three and six months follow up, no significant difference was detected in occlusion rates between groups (Figure 5). Rates of VTE were significantly higher than in the literature (1.5% overall, range 0.6-3.3%), however the absolute numbers were low and did not differ statistically between the postprocedural compression group and those with no compression (Figure 6)[28,32,41,43].

Comparison of durations of compression

Nine studies compared the use of different durations of compression (Bakker et al; Biswas et al; Bootun et al; Elderman et al; Houtermans-Auckel et al; Krasznai et al; Rodrigus et al; Travers et al; Ye et al); (Table 2). To facilitate comparisons, compression durations were divided into four groups: ultrashort durations of less than a day, short durations of 1-day to 1-week, medium durations of 1-2 weeks and longer durations of more than two weeks.

One study compared compression duration of 4 hours versus 3 days (Krasznai et al) and reported no significant difference between groups in postprocedural pain measured on a 100mm Visual Analogue Scale (VAS), [20 (0-40) vs 10 (0-40) respectively; p=0.730][34]. Likewise, no statistically significant difference was detected between groups in terms of VTE and recovery time to full activity.

Four studies compared a compression duration of 1-3 days versus 1-2 weeks (Bakker et al; Bootun et al; Elderman et al; Ye et al) (Table 2). In all four studies, mean postprocedural pain measured at 1-2 weeks post-procedure on a 100mm VAS was significantly lower when compression was applied for 1-2 weeks compared to 1-3 days. Suitable metanalysis data was obtained for three studies and showed a mean reduction in pain of 11 (8 – 13); *p<0.001* when using 1-2 weeks of compression; (Figure 7). Generic HRQoL was reported in two studies (Bakker et al; Bootun et al) but using different instruments. At one week follow up and using the Short Form-36 tool, Bakker et al demonstrated a significant difference in vitality and physical function in favour of 1 week of compression compared to two days; (Figures 8-9)[30,46,47]. Whereas Bootun et al reported no significant difference in HRQoL using the Euro-Qol-5D tool measured at two week follow up when comparing 1 day versus 1 week of compression [0.76 (0.7–1.0) vs 0.76 (0.7–1.0)]; p=0.914[31,48]. Patient satisfaction was assessed in one study (Elderman et al) at six weeks and demonstrated higher patient satisfaction on a 50mm VAS scale in those treated with 2 weeks compared to one day of compression; (Figure 10). Out to six months of follow up, anatomical occlusion and disease specific HRQoL were not significantly different when comparing 1-2 weeks versus 1-3 days of compression (Figures 11-12). Regardless of whether compression was worn for 1-3 days or 1-2 weeks, VTE incidence was extremely rare with only one calf vein thrombosis detected among the 752 patients included in this analysis (0.1%).

Four studies compared compression for 1-14 days versus durations longer than 14 days (Biswas et al; Houtermans-Auckel et al, Rodrigus et al; Travers et al). Clinical heterogeneity in timing and method of pain outcome measurement prevented meta-analysis. Postprocedural pain comparisons were reported in three studies and did not show a significant difference in pain scores when comparing one week to three weeks (Biwas et al), three days to four weeks of compression (Houtermans-Auckel et al), one week to three and six weeks (Rodrigus et al)[35,36,39]. There were no VTE events detected in all four studies, whereas HRQoL and anatomical occlusion were not reported outcomes in any of these studies. SVI recurrence was assessed in one study (Travers et al) at one year follow up. Per protocol analysis showed a lower incidence of recurrence using one year of compression compared with two weeks. Of 36 limbs randomised to compression, recurrence was reported in (2/18) 12% of patients that adhered to compression for one year, compared with (21/35) 60% in those receiving compression for two weeks only[37].

Comparing types of compression

Five studies compared the use of different types of compression post SVI treatment (Bond et al; Cavezzi et al; Lugli et al; Mariani et al; O'Hare et al)[29,38,40,42,44]. Clinical heterogeneity in the types of devices and how they were applied precluded meta-analysis. Cavezzi et al compared 23mmHg stockings versus 35mmHg stockings. Postprocedural pain on 100mm VAS at 1 week was very low in both groups but statistically lower in the 35mmHg group (4±7 vs 15±19 p=0.010). There were no

reported VTE events in either group[42]. Lugli et al looked at the use of 35mmHg compression with the addition of eccentric thigh compression versus 35mmHg compression only. The main outcomes were postprocedural pain and complications, the addition of eccentric compression was associated with lower postprocedural pain at 1 week follow up compared to stockings alone (14±16 vs 49±16 respectively; $p<0.001$)[29]. There were no reported VTE events in the study.

Comparisons of stockings versus bandages were carried out in three studies (Bond et al; Mariani et al; O'Hare et al). All three studies reported no VTE events. Bond et al compared the use of compression bandaging to two kinds of stockings, each were worn for a week following open surgery. At one week follow up, there were no significant difference in postprocedural pain between all three options[40]. O'Hare et al combined bandaging and stockings for a total period of fourteen days post UGFS. In one group bandaging was applied for one day followed by stockings for the remainder, whereas the comparison group wore bandaging for five days followed by stockings. There was no significant difference between groups in postprocedural pain, HRQoL and occlusion rates at six weeks follow up[44]. Lastly, Mariani et al compared two weeks of bandaging to stockings following open surgery and found no significant difference between groups in terms of postprocedural pain and patient satisfaction at two weeks.

Discussion

Summary of results

The main finding is the association of reduced postprocedural pain with compression duration and interface pressure. When comparing 1-2 weeks of compression to shorter intervals, four studies reported a significant reduction in patient reported pain and meta-analysis of three of these studies revealed a mean reduction in pain of 11 (8 – 13); *p<0.001* on 100mmVAS. This reduction in postprocedural pain is corroborated by improvements in HRQoL and patient satisfaction using 1-2 weeks of compression compared to shorter intervals[30,33]. A similar pattern was seen comparing 1 week of compression with no compression, though this comparison was likely not sufficiently powered to reach statistical significance. In terms of the method of compression, there was some supportive evidence for a reduction in pain with higher degrees of pressure (35mmHg or the addition of eccentric compression) [29,42]. Out to six months of follow up, dispensing with compression did not adversely affect anatomical occlusion. Likewise VTE rates were not affected by presence or type of postprocedural compression, however the studies included were not appropriately powered to detect a difference in such a rare complication.

Overall completeness and applicability of evidence

The meta-analysis findings provide strong evidence that postprocedural compression reduces pain however, the window of optimal benefit is currently unclear due to heterogeneity in the timings of pain measurement across studies, meaning that this 1-2 week window is the best estimate allowed by the current data. Robust assessment of the clinical impact of this reduction was not possible as few studies reported generic HRQoL outcomes and in those which did, meta-analysis was precluded by differences in measurement tools and clinical heterogeneity. Access to individual patient data may have allowed for some standardisation and facilitated further hypothesis testing but this was not possible. Studies were more likely to report disease specific HRQoL as a marker of procedural success. These disease specific instruments are useful in measuring symptomatic improvement from SVI but are not designed to assesses postprocedural morbidity and recovery and the use of compression itself is allocated a negative score.

The optimal form of compression remains unclear, and practice varies widely[20,21]; however, improved results were seen with higher interface pressures supporting the hypothesis that a “dose effect” is present in addition to a duration effect. This combination of findings provide evidence to recommend a window of compression of one to two weeks post SVI treatment.

The finding by Travers et al that very long-term compression reduces disease recurrence is interesting but challenging to interpret. The study was performed at a time when detailed duplex mapping of venous anatomy and pathophysiology was not in use and procedures were not specifically designed to meet a patient’s anatomy and pathophysiological needs. Furthermore there was no objective assessment of procedural quality[37]. It is therefore difficult to assess the relevance of these findings to modern venous practice. Moreover, long term compression is unpopular with patients and given the low rates of clinical recurrence especially following endothermal ablation; is unlikely to be cost effective as a standard treatment[17,49].

Limitations

Review findings are limited by the limitations of the included studies. Assessment of pain perception can be impacted by factors outwith the control of investigators such as anxiety in addition to other factors that were not controlled for in the included studies such as analgesia consumption.

Notwithstanding this, the consistency of the findings on pain are an accurate estimate of the true effect size.

The effect of concomitant phlebectomy on the need for compression is an important area not explored by most studies in this review. Concomitant tributary management significantly reduces reintervention rates, improving disease severity and quality of life[50,51], and may be the reason compression is prescribed rather than the axial treatment [21].

Half the included studies omitted to assess compliance with compression therapy altogether. In the other half reporting was disparate as some studies reported the proportion of time where patients were compliant, and others reported the proportion of patients categorised as compliant; without a clear definition of how this distinction was made.

Limitations of the review process include the potential for publication bias given the English language inclusion restriction. A few C6 patients were entered into the analyses as their data could not be separated from other patients. There is strong evidence that early intervention alongside compression is the optimal management option for these patients[52]. These patients represent a small minority (<1%) of the sum of patients included in this review and thus are unlikely to have biased the results. Study data on NTNT methods was not found in the search strategy, however, one protocol was identified for an ongoing study that has yet to publish results comparing compression to no compression post mechanochemical ablation[53].

Agreement/disagreement with the literature

A previous review included seven suitable studies and concluded that there was insufficient evidence to make recommendations regarding compression therapy post SVI intervention[13]. An additional eleven studies were identified in this review increasing the total number of limbs analysed to some 2500. All the established treatments of SVI were well represented with EVTA being used in eight studies, UGFS in four and open surgery in six.

The findings in this review agree with recent international consensus guidance in recommending compression post SVI treatment with an interface pressure >20mmHg, however, where the guidelines were equivocal on the duration of compression, meta-analysis here strongly favour a 1–2 week window[24].

Research implications

Whilst there were no differences observed in VTE rates, studies were not powered to detect this complication, which whilst relatively rare; is of clear clinical significance. Furthermore, the use of chemical thromboprophylaxis is poorly documented in trials. Larger studies are needed to inform practice as to the optimum VTE preventative strategy.

Compression devices come with a cost to healthcare providers. This review answered the question on optimal postprocedural compression duration, but the effect size difference between compression and no compression remains unclear in terms of postprocedural pain and morbidity. An adequately powered RCT is needed to measure this effect, in order to facilitate decision making in terms of effectiveness and cost effectiveness. Further research may then be undertaken on the optimal type of compression and interface pressure including the impact on compliance.

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