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Internal Perivenous Compression for venous insufficiency at the Saphenofemoral Junction: Early and Midterm Results and Operative Pain

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Abstract

Objectives: To assess the postoperative pain and midterm results of patients undergoing internal perivenous compression with internal compression therapy (ICT) for venous insufficiency at the saphenofemoral junction (SFJ)

Materials and Methods: Patients managed with ICT between April and October 2019 for grade 4 venous reflux at the SFJ were retrospectively evaluated. The venous clinical severity score (VCSS) was calculated preoperatively and 1, 3, and 6 months postoperatively. Postoperative pain was assessed with the visual analog scale (VAS). Control Doppler ultrasound imaging was performed 6 months postoperatively.

Results: Forty-five patients [14 (31%) males and 31 (69%) females; mean age, 47 ± 13 years] were included. The median preoperative VCSS was 7 (5–8.5). The median VCSS at 1, 3, and 6 months postoperatively was 6 (4–7.5), 4 (3–5.5), and 3 (2–4), respectively, and these values were significantly lower than the preoperative score ($p = 0{,}001$, $p < 0.001$, and $p < 0.001$, respectively). The postoperative VAS score was 0 in 6 patients (13%), 1 in 17 patients (38%), 2 in 6 patients (13%), 3 in 15 patients (33%), and 4 in 1 patient (2%). At 6 months, reflux was absent in 9 (20%), grade 1 in 20 (44%), and grade 2 in 16 (36%) patients. A vena saphena magna diameter of >6.7 mm predicted grade >1 reflux at 6 months [87.5%, with an area under the curve of 0.78 ($p < 0.001$)]. No complications occurred.

Conclusion: ICT alleviated symptoms and reduced reflux grade in patients with venous insufficiency at the SFJ. This therapy can be applied with satisfactory patient comfort.

Keywords

Superficial venous insufficiency, internal compression therapy, saphenofemoral junction, hyaluronic acid, n-butyl cyanoacrylate

Introduction

The prevalence of varicose veins has been estimated to be 5% to 30% in the adult population.[1] It causes symptoms including pain, burning, itching, heaviness of the legs, cramps, bruising of the skin, and/or chronic leg ulcers, leading to a significant deterioration of the patients' quality of life.[2] The current surgical treatments for patients with insufficiency of the vena saphena magna (VSM) aim at increasing patients' comfort by excluding the vein with reflux. Laser or radiofrequency irradiation is primarily employed for ablation of the truncal superficial veins, but chemical embolization, glue application, or surgical removal can also be utilized.[3,4]

A technique to treat the reflux of the saphenous vein by reducing its lumen using an injectable perivenous hyaluronan solution has been previously reported; however, limited data are available on the outcomes of this technique.[5,6] Compression of the vein segment with valves enhances the coaptation of the valves and reduces venous insufficiency.[7] Internal perivenous compression also called percutaneous valvuloplasty or percutaneous exogenous reconstruction—is a modern

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approach based on the above principle.[8] A product developed for this purpose has been called ICT ("Internal Compression Therapy") by a Turkish manufacturer (RD Global/Invamed, Ankara, Turkey). ICT is applied under local anesthesia and ultrasound guidance by injecting a mixture of hyaluronic acid and cyanoacrylate around the vein with an incompetent valve. Incompetent valves of the femoral vein or the saphenofemoral junction (SFJ) are the target of this therapy. However, few studies have investigated the efficacy of this technique, and limited data are available on its outcomes.[4,9]

Local pain is an important factor affecting patient comfort during and following treatment. Patients frequently ask regarding pain before operation, which may contribute to the outcomes of the intervention, particularly of those performed under local anesthesia. The visual analog scale (VAS) is used to quantify pain (0–10 points),[10,11] and the venous clinical severity score (VCSS) is an accepted tool to assess the severity of venous disease.[12]

In the present study, we investigated the postoperative pain and midterm results of internal perivenous compression with ICT for reflux at the SFJ using VAS and VCSS, respectively.

Materials and methods

Patients

The present study was approved by the ethics committee of the Derince Research and Training Hospital, Kocaeli, Turkey. Patients managed with ICT at the Derince Research and Training Hospital between April and October 2019 were retrospectively evaluated. ICT was the only commercially available product for internal perivenous compression in the country. Symptomatic patients diagnosed with grade 4 venous reflux at the SFJ by a radiologist at the outpatient clinic and who were scheduled for ICT were included. Reflux was assessed in the upright position and classified as grade 1 (0.5–1 s), 2 (1–2 s), 3 (2–3 s), or 4 (>3 s).[13] Patients with a history of deep venous thrombosis or ultrasound evidence of post-thrombotic venous insufficiency, those who underwent a prior venous surgery, and those treated with concomitant surgical procedures with ICT were excluded. The VCSS and clinical-etiology-anatomy-pathophysiology (CEAP) classification of chronic venous disorders were used for the assessment of patients on an outpatient basis. As per the institutional protocol, all patients' complaints at admission and during the hospital stay, the VAS score for pain, and the use of analgesics during the hospital stay were noted. In all patients, the VAS was used for quantifying pain as no (0) to extreme pain (10) after the procedure and at discharge. At the first control at the outpatient clinic, pain and the need for analgesics were investigated as a part of the routine control. After 6 months of the procedure, a control ultrasound was performed with the same technique.

Operative technique

All internal perivenous compression procedures were performed in the operating room. Briefly, 10 mL of prilocaine hydrochloride was used to induce local anesthesia. All procedures were performed in the supine position using a standard aseptic method. Venous insufficiency of the leg on which the intervention was planned was confirmed with ultrasound (Esaote MyLab Seven, Linear probe 6–18 MHz, Esaote Group, Genova, Italy) using the Valsalva maneuver. The product named ICT (RD Global/Invamed, Ankara, Turkey) was used in all procedures. This system comprises one vial each of hyaluronic acid and n-butyl cyanoacrylate (NBCA) (1 mL each), a mixing unit in which hyaluronic acid and NBCA are automatically centrifuged for 5 min, and two 6 F injection units connected to the mixing unit. The anterior and posterior aspects of the SFJ over the first incompetent valve were accessed using an 18 G needle. A 0.035-inch guidewire was used to secure the perivenous position. The injection units were placed over the guidewires using the Seldinger technique. The mixture can be injected through the connection between the mixing and injection units. During injection, the diameter of the veins and the distance between the valves were visualized under ultrasound. In all cases, homogenous circumferential infiltration of the mixture around the terminal valve was performed. The venous diameter was reduced, eliminating the reflux. Venous insufficiency was evaluated immediately after the procedure with ultrasound as a part of the procedure based on the assessment of valvular coaptation.

After confirming the result, the cannulas were removed. All patients received local cold therapy for 30 min postoperatively. To patients complaining of pain, 1 g paracetamol was intravenously administered if requested. All patients were ambulated and discharged without any complications at 3 h postoperatively. Patients were encouraged to telecommunicate with the operating surgeon in the case of persistent pain or discomfort. Daily use of compression stockings below the knee level and with a pressure of 20–30 mmHg at the ankle was recommended to all patients. Paracetamol (500 mg per os) was prescribed at discharge. Purified micronized flavonoid fraction (500 mg BID) was prescribed to all patients who had not used venotonic medications previously. Following

control ultrasound, compression and medical therapies were continued in patients with venous reflux of any grade.

Statistical analysis

All statistical analyses were performed using IBM SPSS for Windows version 20.0 (SPSS, Chicago, IL, USA) and MedCalc version 14. The Shapiro–Wilk test was used to assess the assumption of normality. Numerical variables were presented as mean ± standard deviation or median (25th–75th percentile). Categorical variables were summarized as counts (percentages). Comparisons of numerical variables between groups were performed using the independent samples *t*-test, Mann–Whitney U test, or Kruskal–Wallis test. Friedman's two-way analysis of variance was used for comparisons of dependent variables. Cut-off, sensitivity and specificity values were obtained based on receiver operating characteristic curves. All statistical analyses were performed with 5% significance, and a two-sided p-value <0.05 was considered significant.

Results

Forty-five patients [14 (31%) males and 31 (69%) females; mean age, 47 ± 13 years] met the inclusion criteria. The SFJ was incompetent in the right lower extremity of 25 (56%) patients and in the left lower extremity of 20 (44%) patients.

A total of 21 (47%) patients used both venotonic medication (diosmin + hesperidin) and compression stockings, 13 (29%) used only venotonic medication, 5 (11%) used only compression stockings, and 6 (13%) used no medication or compression stockings.

The mean reflux time was 5.57 ± 0.4 s. The mean VSM diameter was 7.1 ± 1.3 mm. Patients' preoperative clinical stage according to the CEAP classification was C3 in 44 (97.7%) patients and C4a in 1 (2.3%) patient. All patients presented with primary superficial venous disease with reflux at the SFJ.

The procedural duration was 20 min, and 2 mL of the hyaluronic acid and NBCA mixture was administered to all patients.

The postoperative VAS score was 0 in 6 patients (13%), 1 in 17 patients (38%), 2 in 6 patients (13%), 3 in 15 patients (33%), and 4 in 1 patient (2%). Only 1 patient with a VAS score of 4 was administered intravenous paracetamol.

The VAS score at discharge (3 h postoperatively) was 0 in 41 (91.1%), 1 in 2 (4.4%), and 2 in 2 (4.4%) patients. Two patients required paracetamol after discharge. No patient complained of pain 24 h postoperatively.

The median preoperative VCSS was 7 (5–8.5). The median postoperative VCSS was 6 (4–7.5), 4 (3–5.5), and 3 (2–4) at 1, 3, and 6 months, respectively. All patients showed symptom improvement (Figure 1).

The postoperative VCSS at 1, 3, and 6 months was significantly lower than the preoperative VCSS ($p = 0.001$, $p < 0.001$, and $p < 0.001$, respectively).

The postoperative VCSS at 1 month was significantly different from that at 3 and 6 months (both $p < 0.001$), but there was no significant difference between postoperative VCSS at 3 and 6 months ($p = 0.165$).

In ultrasound at 6 months, reflux was absent in 9 (20%) patients, grade 1 in 20 (44%), and grade 2 in 16 (36%).

At 6 months, the median postoperative VCSS was 3 (2–4) in patients with grade 2 reflux and 3 (1.25–5) in patients with no or grade 1 reflux ($p = 0.95$).

The preoperative VSM diameter was 6.77 ± 1.17 mm in patients with no or grade 1 reflux at 6 months and 7.9 ± 1.16 mm in patients with grade 2 reflux at 6 months.

A VSM diameter of 6.7 mm was determined to be the cut-off between grades ≤1 and 2 reflux at 6 months, with 87.5% sensitivity [95% confidence interval (CI), 61.7–98.4] and 62% specificity (95% CI, 42.3–79.3) on the receiver operating characteristic curve analysis [area under the curve, 0.78 ($p < 0.001$)] (Figure 2).

Discussion

In the present study, we evaluated the early and mid-term results of internal perivenous compression with ICT at the SFJ. Our results revealed that ICT could be applied with acceptable operative and postoperative pain. Our study population comprised patients treated with ICT for grade 4 reflux at the SFJ. At 6 months

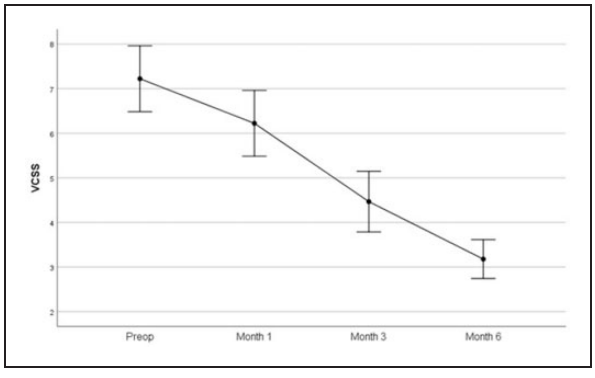

Figure 1. The median VCSS among preoperative assessment (Preop) and at the follow up at first (Month 1), third (Month 3) and sixth (Month 6) months.
VCSS: The venous clinical severity score.

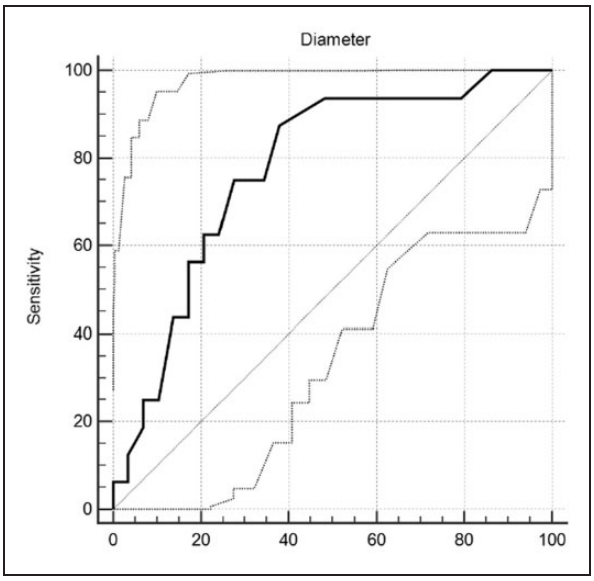

Figure 2. The receiver operating characteristic curve analysis for a VSM diameter of 6.7 mm as the cut-off between grades $\leq$I and 2 reflux.
VSM: vena saphena magna.

following the intervention, patients exhibited significant improvements in symptoms and reflux grade.

Endovenous ablation for treating the insufficiency of the VSM was first introduced in 1999.[14,15] Owing to its less invasive nature and favorable outcomes, this procedure has replaced surgical vein stripping and high ligation. Consequently, endovenous ablation is now the standard of care for the surgical management of venous insufficiency.[16] However, despite being preferred for its favorable patient outcomes and comfort, this therapy is invasive and leads to specific complications. The reported frequency of thrombotic events is 1.7% and that of deep venous thrombosis is 0.3% following endovenous ablation of the saphenous vein.[17] The most recent therapeutic modalities, such as ultrasound-guided venous ablation, are non-invasive, enabling the procedure to be performed without incision and even puncture, while preserving the aim of venous ablation.[16] The saphenous vein is the most often used vascular autograft, and its preservation is potentially beneficial for patients. In the past, surgical treatment for preserving the saphenous vein was performed via external banding valvuloplasty rather than vein stripping or obliterating with ablation catheters. External banding valvuloplasty aims to ameliorate the coaptation of valves at the SFJ. Despite its favorable early outcomes and aim of treating the vein rather than removing it, this procedure has not found popularity.[18]

J.C.Ragg first described an alternative approach to treat the reflux of the saphenous vein by reducing its lumen with an injection of hyaluronan solution.[5,19] In ICT, a perivenous injection of hyaluronan and NBCA combination is administered to reduce vein diameter and enhance valve coaptation by external compression. Both types of intervention obviously can eliminate venous reflux, but the ICT substance used in this study is supposed to be more effective and potentially more durable due to the contents of acrylic glue. A recent study has reported favorable long-term outcomes of ICT for primary femoral vein insufficiency.[9,20]

In the present study, reflux could be eliminated in all patients following ICT, and no patient presented with persistent reflux, requiring a second injection. All patients were treated with a single kit containing 1 mL each of hyaluronan solution and NBCA, which could be easily and homogeneously infiltrated circumferentially around the vein without the need to move the injection units. The intraoperative assessment of reflux at the end of the procedure was performed in the supine position. Technically, ultrasound in the standing position was not feasible during the procedure; therefore, the reflux may have been underestimated.

In general, duplex ultrasound examination of the vein is recommended for monitoring complications and recurrence following endovenous interventions for venous insufficiency.[17] To assess complications or recurrence following the relatively recent ICT, we performed Doppler ultrasound following the intervention. No complications of ICT were observed. Owing to its extravascular nature and ultrasound-guided application, the risk of complications of ICT is relatively low.

The median VCSS gradually decreased following therapy, indicating symptom improvement in all patients (Figure 1). The optimal symptomatic relief is achieved in the third month. The improvement of VCSS in the third and sixth months did not differ significantly. ($p = 0.165$) The observed preoperative VCSS and CEAP stage were lower than the values reported previously. This was expected, as the previous study performed ICT for deep vein insufficiency.[9] In another study, the correlation of the symptoms of venous disease with the severity of reflux has been demonstrated.[3] Even if the symptoms of the patients do not reflect directly the severity of the disease it is an important factor for the indication of the treatment and patient satisfaction. The reflux grade was reduced parallelly with symptom improvement in the present study. During the follow-up, grade 4 reflux was improved to grade <3 in all cases. Moreover, residual reflux grade at 6 months was correlated with preoperative VSM diameter. In Doppler ultrasound at 6 months, no patients presented with a reflux of grade >2. Such a reduction in reflux grade and improvement of symptoms demonstrate the success of ICT.

In the presence of truncal reflux of the VSM, the vein diameter gradually increases starting from the SFJ, and the diameter at the SFJ is related to the severity of the venous disease.[3] By considering interventions in SFJ for venous insufficiency, high ligation was also used for the preservation of the greater saphenous vein. However, due to the high recurrence of reflux,[21,22] and thrombosis[23,24] this method lost popularity and is no more adviced.[25] However, ligation of the saphenous vein is still applied to adequate patients where the Conservative and Hemodynamic Correction of Venous Insufficiency (CHIVA) technique is used. In contrast to high ligation, the CHIVA method reduces the recurrence of varicose veins and has few side effects.[26] In patients with type 3 shunt according to CHIVA classification the ligation of the incompetent collaterals is performed as a first step and high ligation of the saphenous vein is left to a second step to avoid venous stasis and thrombosis at the greater saphenous vein.[27] However, patients with a competent terminal valve rarely need the second step.[28] It is stated that patients requiring the second step may be predicted by the presence of an incompetent terminal valve on the great saphenous vein.[28] At this point the use of ICT could be used considered to restore valve function instead of ligation as a second step. Additionally, this procedure might also be performed at a single session in the first step as no stasis in the saphenous vein is expected following ICT. The fall in venous pressure with saphenous sparing techniques results in size reduction of the varicose veins.[29] Our results demonstrated that patients with a preoperative VSM diameter of >6.7 mm were more likely to present with a reflux of grade >1 at 6 months. Accordingly, ICT can be selected as the first-line approach to manage patients with grade 4 reflux at the SFJ and a VSM diameter of <6.7 mm (Figure 2). These results indicate that, internal perivenous compression administration at the early stages of venous disease can result in the preservation of the saphenous vein by reducing the need for endovenous ablation as stated recently.[30] The presence of advanced varicose disease has been reported as a risk factor for the failure of external banding valvuloplasty due to preoperative damage of the cusp.[18,31]

In a previous study, a VAS score of <5 was defined as mild pain for vascular surgical procedures and a VAS of >3 as a threshold for the use of parenteral analgesics.[11] In the present study, 87% patients experienced local pain following the intervention. However, the VAS score for pain and need for intravenous analgesics (only 2% patients) were relatively low. Moreover, pain did not last for over 24 h. In the present study, the highest pain score related to the procedure was 4 points according to the VAS, indicating high patient comfort.

There are some limitations in this study due to its retrospective nature. We recommended the use of compression socks to patients who did not use them previously. Additionally, purified micronized flavonoid fraction was prescribed to patients who did not use venotonic medications previously. The effects of these additional interventions might have ameliorated VCSS at the outpatient control. At our outpatient clinic, compression therapy is offered to all patients with symptomatic venous disease; however, adherence to compression therapy could not be assessed. Additionally, measurement of leaflet coaptation surface, vein diameters, remaining hyaluronan/glue volumes were not noted during the study as the changes of these during the follow-up could predict the durability of the repair.

Conclusion

The long-term results of ICT for venous insufficiency at the SFJ remain unknown. However, the use of ICT as the first-line treatment can be potentially beneficial for patients in terms of improved symptoms, reduced reflux, and increased comfort. Owing to its less invasive nature, internal perivenous compression is superior to other treatments. Additionally, this therapy has the advantage of alleviating or curing the disease while preserving the saphenous vein. Moreover, endovascular procedures can still be performed in case of treatment failure in the long term. In symptomatic patients with a low vein diameter, internal perivenous compression is expected to reduce reflux in the long term. However, the long-term results are not yet known.

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Ethical approval

The study was approved by the Ethics Committee of Health Science University Derince Training and Research Hospital

Guarantor

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Contributorship

Study Design: AAA and HP; Collection: HP; Statistical Analysis: AAA; Data Interpretation: AAA, HP; Manuscript Preparation: AAA, HP; Search: AAA, HP.

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