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Clinical Research

The V-Block Occlusion Stent and Sclerotherapy Device for Varicose Vein Treatment: A Retrospective Analysis

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Background: The procedure aims to show our results with a novel nontumescent, nonthermal technique to treat varicose veins. The V-block occlusion stent is a minimally invasive device for treating reflux of the great saphenous vein (GSV). It is an office-based procedure that does not require tumescence anesthesia. The V-block stent is a self-expandable device that functions as a vein occluder and blood clot trap. Once the V-block is in place, further treatment of the saphenous vein such as ultrasound-guided sclerotherapy can be performed. The V-block device is intended to eliminate the possibility of forwarding passage of clot and sclerosant (embolization) to the deep and pulmonary circulations.

Methods: Patients were treated in an outpatient setting with the V-block occluding device. Follow-up was performed using duplex ultrasound to assess occlusion of the saphenous vein as well as the Aberdeen Varicose Vein Questionnaire and Venous Severity Scoring to determine changes in quality of life after the procedure. Patients were followed up at 1 week, 1 month, and 3 months after V-block placement. Duplex scanning was performed to confirm GSV occlusion at all follow-up visits. After deployment of the occlusion stent, a maximum of 2% polidocanol foam was injected with a double barrel syringe which simultaneously evacuated blood from the greater saphenous vein. Follow-up assessment for safety included evaluation of potential complications, device migration, and potential injury at the deployment site.

Results: Fifty-one symptomatic subjects with documented GSV reflux were enrolled in the study. Complete occlusion of the GSV was achieved in 98% of the patients during the 7-day postprocedural visit. There was no injury at the deployment site. No migration of the V-block device was observed. No deep vein thrombosis or any other complication was recorded. One patient of the 50 patients and 51 procedures experienced an adverse event, phlebitis that resolved under conservative therapy within 4 days with no residual effect. There was a significant improvement in the Aberdeen Vein quality of life measurements and the pain scores. After 3 years, 18 patients were willing to undergo a duplex follow-up examination. The occlusion rate after 3 years was 77.8. There were no device-related complications after this period.

Conclusions: The study demonstrated a good safety and performance profile without any major adverse events. The primary end point of vein occlusion and obliteration was met.

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The V-block occlusion stent is an endovenous device for treating reflux of the great saphenous vein (GSV). It was used as part of an office-based procedure without tumescence anesthesia. The V-block stent is a self-expandable device which functions as a vein occluder and blood clot trap. It was initially designed to be used in combination with ultrasound-guided sclerotherapy blocking reflux of a sclerosant as well as thrombus which could be dislodged into the deep venous system.

Several treatment modalities exist for varicose veins. These currently include sclerotherapy, laser ablation, radiofrequency treatment, and surgical stripping, as well as ultrasound-guided foam sclerotherapy and endovenous application of acrocyanate glue.[1–3]

Sclerotherapy is one of the most widely used medical procedures for ablation of varicose veins and spider veins. Delivery of a sufficient concentration of sclerosant to the endothelial wall may require placement of long endovenous catheters and infusion under ultrasound guidance. In a retrospective study, we wanted to evaluate the long-term performance of a permanent superficial venous implant in patients who were treated for symptomatic varicose veins.

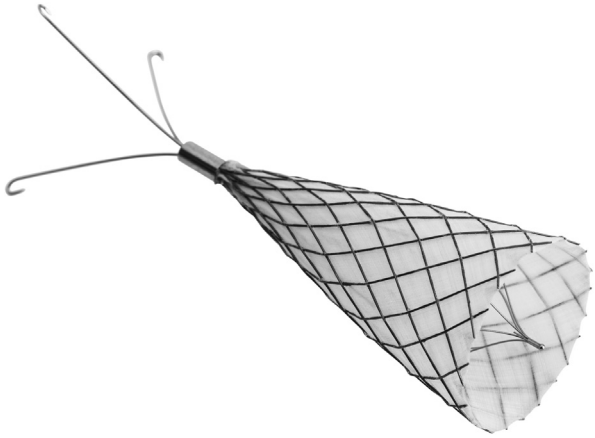

Fig. 1. V-block occlusion stent.

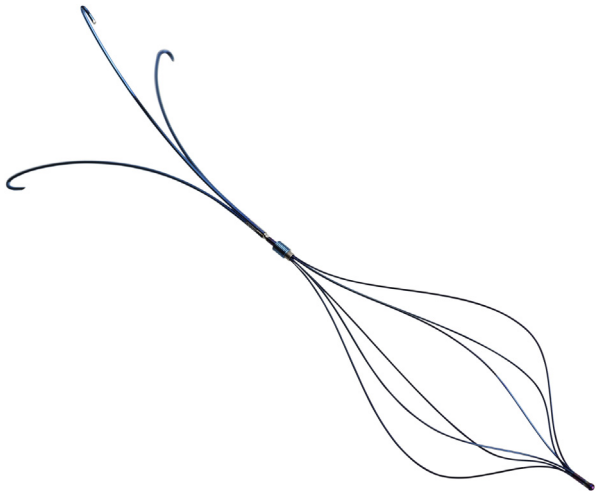

Fig. 2. Nitinol stent with hooks without polytetrafluoroethylene cover.

MATERIALS AND METHODS

V-Block Device and Delivery System

The V-block device (VVT Medical Ltd, Kfar Saba, Israel) was designed for percutaneous occlusion of the proximal GSV. It consists of a conical, nitinol frame partially covered by a thin polytetrafluoroethylene membrane (Fig. 1). A coil-shaped nitinol filter, attached to the inner base of the device, serves to capture and retain thrombus to avoid pulmonary embolism. The V-block procedure is indicated for occlusion of veins that are greater than 3–4 mm in diameter and smaller than 14 mm. Three anchoring hooks, made of nitinol wire, are released to provide additional safety against proximal migration (Fig. 2). The V-block device is packaged in its open configuration, in a proprietary 6F delivery system which consists of a low-profile introducer catheter, a magazine containing the preloaded V-block, and a pusher rod which allows for V-block deployment (Fig. 3). The occluding stent is pulled back into the introducer sheath with the help of the funnel and attached to the flexible sheath. The pusher rod contains an inner lumen that can be used for injection of liquids while the cavity between the external grooves of the pusher and the catheter can be used for negative suction, which can maintain a negative pressure at the tip of the delivery catheter. Upon percutaneous insertion, using the Seldinger technique, the V-block delivery sheath is advanced, under ultrasound guidance, into the GSV and positioned with its tip 1 to 2 cm distal to the saphenofemoral junction and immediately distal to the superficial epigastric vein. The magazine containing the V-block is engaged with the sheath. The pusher is used to advance the device to its final, predeployment position in the GSV. The sheath is then pulled back to expose the constrained device which can still be repositioned if necessary. The device is released using a trigger wire and when fully deployed adopts its open conical configuration. The V-block device, when open, leads to significant flow restriction within the vein. A dual procedure syringe system, containing the sclerosing agent is attached to the catheter. This syringe is mechanically coupled to a

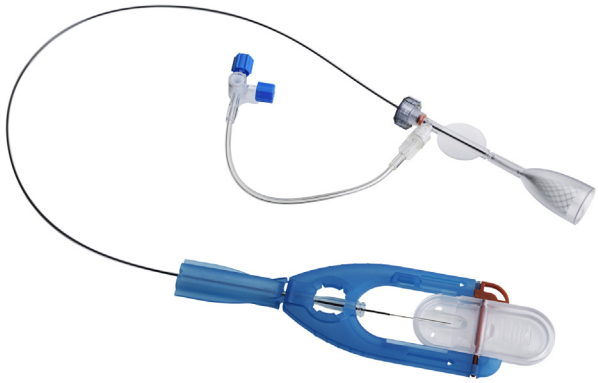

Fig. 3. Delivery catheter with V-block occluding stent. After removal of the introducer (funnel), the catheter tip is attached to the flexible sheath.

Fig. 4. Double barrel syringe that evacuates blood in the GSV while simultaneously injecting sclerosant.

second syringe, such that when the first syringe is pushed the second syringe is simultaneously withdrawn. As a result, the second syringe creates a vacuum that results in the removal of blood from the vein (Fig. 4). The vacuum, in turn, causes the collapse of the vein wall towards the delivery catheter and a reduction of the volume of blood between the catheter and the vein wall. A maximum of 10 ml polidocanol foam (2%) was injected with the leg in an elevated position (Fig. 5).

Postoperative Treatment

The patient was advised to class 2 wear compression stockings for 5 days (30—40 mm Hg) upon completion of treatment at daytime only.

Assessments

On the day of the procedure, ultrasound was performed to exclude evidence of deep vein thrombosis and to evaluate the targeted vein. Standardized perioperative analgesia and anesthetic agents, as well as low-molecular-weight heparin, were administered after a protocol, specific to the clinic. Procedures

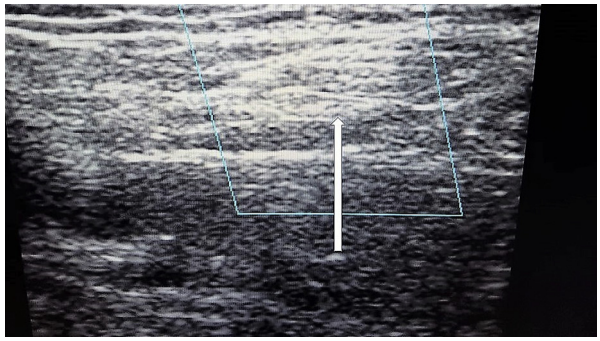

Fig. 5. A stent (*white arrow*) fully incorporated in GSV.

were performed under duplex control by an experienced vascular surgeon.

As part of a retrospective study, duplex scanning was performed to confirm GSV occlusion. Retrospective assessment for safety included evaluation of potential complications, device migration, and potential injury at the deployment site. Ethics Committee approval, as well as internal review board clearance, were obtained before using the CE marked device. Informed consent forms had to be signed by all patients before the procedure, explaining in detail that an occluding stent and a permanent implant were used to treat GSV reflux. Also, the Venous Severity Score and the Aberdeen Varicose Veins Questionnaire, as well as pain assessment data, were recorded in each case.

All measured variables and derived parameters were listed individually and tabulated by descriptive statistics. The primary efficacy end point was the occlusion of the treated segment measured by duplex ultrasound. Additional end points were no clinically significant migration of the occluder from the deployment site and no injury at the deployment site defined as not having perforation or hematoma as an adverse event.

RESULTS

Fifty-two symptomatic subjects with documented GSV reflux were enrolled in the study. Twelve males and 38 females with mean age of 60.83 (standard deviation [SD] of 12.77). Mean height was 172.60 cm, and mean weight was 73.02 kg. CEAP classification was 98% of C2 and 2% of C3 (Table I). Two patients were excluded since the device could not be implanted due to vein accessibility. In one patient, both legs were treated. Demographic details are as follows: 12 males and 38 females with a mean age of 60.83 (SD of 12.77) were included in the study. CEAP classification was C-2 in 98% and C3 in 2%.

Table I. Patient demographics

	N	%
Clinical classification C2-varicose veins	49	98.0
C3-edema	1	2.0
Etiologic classification Ep-primary	50	100.0
Anatomic classification As-superficial veins	50	100.0
Pathophysiologic Pr-reflux	50	100.0

Complete occlusion of the GSV was achieved in 98% of the patients during the 7-day postprocedural visit. Pain level using the Wong-Baker FACES Pain Rating Scale (0−5) indicated minor pain level (mean of 1 in a 0−5 scale) during the procedure which decreased to 0.2 after a week and no pain at all during a long-term follow-up visit.

Primary Safety End Points

There was no injury at the deployment site. No migration of the V-block device was observed. No deep vein thrombosis or any other complication was recorded. One patient of the 50 patients and 51 procedures experienced an adverse event, phlebitis that resolved under conservative therapy within 4 days with no residual effect.

Primary Outcome Measure—Occlusion of GSV

At 1 week after the V-block implantation, 92% ($n = 48$) of cases demonstrated GSV occlusion at the treated segment on duplex scanning. At 1-month follow-up, of 45 cases, 1 GSV of 45 was still patent with reflux. Successful obliteration of the GSV at the last follow-up visit after 3 months did not change.

Postprocedural, 30-day, and 3-month duplex evaluations showed no migration from the deployment sites in any patient. There was no skin injury or breakdown at the deployment site. After 3 years, 18 patients were willing to undergo a duplex follow-up examination. The occlusion rate after 3 years was 77.8%. In 6 cases, a telephone interview could be organized after 36 months. Although occlusion of the GSV could not be established over the phone by duplex ultrasound, the patients had not experienced any device-related complications. In 2 of 4 cases with a patent GSV, sclerotherapy of the GSV was performed, and in one case, GSV occlusion was accomplished with Cyanoacrylate glue (VenaSeal Closure System, Medtronic Minneapolis, MN, USA).

In one case where the patient had gained more than 45 kg body weight, the diameter of the GSV had increased to 22 mm. In this case, although the V-block was firmly incorporated into the saphenous vein, there was reflux in the color-coded duplex examination on the lateral side of the saphenous vein during Valsalva maneuver due to a 3-mm lateral leak. This patient was converted according to his wishes to a stripping procedure.

The mean preprocedure quality of life score using the Aberdeen Varicose Vein Questionnaire (AVVQ) was 6.03 (SD of 4.11). Postprocedural score at 1-month follow-up was 1.63 (SD of 2.44) and at 3 months 0.63 (SD of 0.35). Comparing preprocedural and postprocedural improvements in quality of life score, the mean (±SD) reduction in AVVQ score was 5.4 at 3 months which lead to statistically significant improvement in the quality of life ($P < 0.001$ by paired t-test) (Table II). Mean varicose vein disease severity score at baseline was 3.27, 0.6 at 1-month follow-up, and 0.13 at 3 months, which indicated a statistically significant score ($P < 0.001$ by paired t-test).

DISCUSSION

Endovascular techniques have emerged as a real treatment alternative to conventional stripping procedures with excellent results.[4] During the last few years, thermal-based techniques such as laser and radiofrequency venous ablation have primarily replaced conventional stripping procedures.[5] Both techniques have excellent venous closure rates and equally good results compared with surgery.[6,7] Duplex-guided foam sclerotherapy can easily be repeated in case of long-term failure yet has a small risk of pulmonary embolism or neurological symptoms especially in patients with a patent foramen ovale. Thermal-based techniques require tumescent anesthesia to separate the saphenous vein from the skin and to prevent heat-induced skin injury, which is associated with a certain discomfort for the patient.

There is an increased interest in office-based nonthermal—nontumescent techniques (NT—NT). Among these are sclerotherapy duplex and catheter-guided procedures as well as the catheter-based cyanoacrylate injections and mechanical—chemoablation.

One significant advantage of NT—NT techniques like the one described is not only the fact that it does not require an operating room setting but

Table II. Results of Aberdeen Varicose Vein Questionnaire before and after treatment with V-block occlusion stent

	N	Mean	SD	Median	Min	Max	*P*-value by paired *t*-test
30 days postprocedure	45	−4.77	4.02	−3.76	−22.05	−0.67	<0.001
Median term follow-up (4.2 months postprocedure)	45	−5.40	4.10	−4.64	−22.05	−0.33	<0.001

Max, maximum; Min, minimum; SD, standard deviation.

also that there is no capital investment required. The endovenous blocking stent prevents any dislodgement of thrombus into the deep venous system. Also, reflux is blocked which in combination with the chemoablation of the GSV is the main reason for our midterm results.

The endovenous blocking device can be placed as close as 1 cm to the saphenofemoral junction under the duplex guidance and repositioned. The technique described requires a short learning curve facilitated by the visibility of the endovenous blocking device.

The study shows that like other endovenous techniques the V-block occluding stent has a comparable safety and feasibility profile.[8,9] It can be used in combination with duplex mapping as well as venography using a mobile C-arm.

The results of chemoablation are enhanced by combining sclerotherapy injection with a dual chamber syringe which evacuates blood when simultaneously the sclerosing agent is injected. This reduces the dilution of the sclerosant in the intraluminal blood of the GSV and increases the amount available for chemoablation. The double syringe technique was designed to increase the efficacy of sclerotherapy by reducing blood volume and pretarget dilution of the sclerosant as well as a reduction of phlebitis by eliminating injection-induced elevation of intraluminal pressure and sideways escape of sclerosant to the deep system via patent perforating veins.

Migration or dislodgement of the blocking device was not observed, which is due to the radial force of the nitinol stent as well as the hooks attached to it. Tissue encapsulation occurs 1−2 weeks after the procedure as could be seen during follow-up duplex ultrasound examinations.

Meanwhile, we have follow-up examinations available in some patients throughout 3 years. After 3 months, there was a complete encapsulation of the device by scar tissue. The formula and concentration of polidocanol can be discussed. In most clinics, higher concentrations of up to 3% are used without increasing the risk of complications such as phlebitis. Many venous specialists prefer foam sclerotherapy for occlusion of the greater saphenous vein. In our own experience, this works well without any additional side effects. It can be speculated that the addition of the V-block vein occlusion stent reduces the number of bubbles that can access the deep venous system causing neurological problems such as a migraine.

In our series of patients, the phenomenon of heat-induced thrombosis causing pulmonary emboli could not be observed.[10] We assume that thrombus that forms in the greater saphenous vein cannot migrate past this mechanical barrier proximal to the saphenofemoral junction.

The V-block occluding stent can be combined with not only foam chemoablation but also cyanoacrylate, causing rapid closure of the venous segment treated (VenaSeal Closure System).[11,12] After placement of the occluding stent, the catheter with cyanoacrylate is advanced, and the glue is injected while using the double action syringe to create a vacuum. This reduces the amount of residual blood in the vein which should prevent the incidence of phlebitis. An observational study combining V-block occlusion stent with VenaSeal acrocyanate occlusion was meanwhile initiated in our institution.

Further studies must show which combination of treatment options yields optimal results.

In cases of recanalization of the greater saphenous vein at a later stage, duplex-guided reinjection was not a technical problem. After placement of a 3F sheath, 3% polidocanol foam was injected without any necessity for further wire or catheter manipulation.

The V-block occluding stent is a permanent implant like any other venous stent on the market. When discussing this treatment option with our patients, this fact was explicitly mentioned but never a reason for concern on the patient's side. This can partially be explained by the fact that many patients have a general knowledge of stents and their increasing role in vascular medicine as well as the fact that this stent can easily be removed if necessary

by a minor surgical procedure under local anesthesia with flush ligation of the saphenous vein.

A significant drawback of the study results presented is the small sample size as well as an insufficiently large number of patients, who were available for long-term follow-up. Another problem is the fact that currently, only one size is available. In the end, a smaller size for very slim patients must be available so that the patient does not feel the stent under the skin.

CONCLUSION

The study demonstrated a satisfactory safety and performance profile. The primary end point of vein occlusion and obliteration was met. There was only one mild nondevice-related adverse event, yet no device migration or injury at the deployment site. Secondary end points of pain and quality of life improved to be statistically significant.

The V-block occlusion stent is another NT—NT technique which can be offered to patients with varicose vein.[4,13—16] We could show satisfactory intermediate-term results as well as an excellent safety profile.

SUPPLEMENTARY DATA

Supplementary data related to this article can be found at https://doi.org/10.1016/j.avsg.2019.01.025.

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