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Balloon sclerotherapy: A new method for the treatment of truncal varicose veins

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Summary

Background: Truncal varicose veins may be treated by conventional surgery or endovenous therapy. Endovenous ablation, such as laser or radiofrequency treatment, is less invasive but technically demanding, not cheap and has still the possibility of important side-effects. Moreover the treatment requires in the best case tumescent anesthesia. Catheter based endovenous sclerotherapy has the potential of systemic effects of sclerosing agent and air. We therefore aimed to develop a simple, minimal-invasive and cheap method for the treatment of truncal varicose veins reducing the potential risk of systemic effects of the sclerosing agent to a minimum.
Methods: A double lumen double balloon catheter was developed. Thereby a treatment site within a vein can be isolated from blood for localized administration of a sclerotherapeutic agent. Later, a substantial portion of the therapeutic agent can be removed from the isolated segment thus minimizing the amount necessary. Occlusion of longer varicose segments is achieved by pointwise repetition of the manoeuvre or careful retraction of the expanded balloons with the "catched" sclerotherapeutic agent in between.
Results: The application was filed as United States Patent No. 6,726,67 B2. 18 balloon prototypes successfully passed an extensive test series (leak tests, dimension tests, mandrel –, guide wire – and introducer compatibility tests, destructive tests). Three patients with varicosity of the greater saphenous vein and the vena saphena accessoria lateralis, respectively, were successfully treated with complete occlusion of the vessels 10, 6 and 2 months after the intervention.
Conclusions: Balloonsclerotherapy combines two well-established procedures (balloon catheter therapy and sclerotherapy, namely) and promises to be a minimal-invasive and cheap endovenous therapy of truncal varicose veins, requiring local anesthesia at the puncture site only and reducing possible systemic side effects of the sclerosing agent.

Key words: Balloon angioplasty, balloon catheter, sclerotherapy, varicose veins, endovenous ablation

Zusammenfassung

Ballonsklerotherapie: Eine neue Methode zur Behandlung der Stammvarikose
Hintergrund: Die Stammvarikose kann entweder durch konventionelle Chirurgie oder neuerdings durch endovenöse Therapie behandelt werden. Die endovenösen Verfahren wie Lasertherapie oder Radiofrequenzablation sind weniger invasiv, aber technisch herausfordernd, nicht billig und bergen immer noch die Gefahr bedeutender unerwünschter Nebenwirkungen. Zudem benötigt die Methode im besten Falle eine Tumeszenzanästhesie. Die endovenöse kathetergestützte Schaumsklerosierung hat das Potential systemischer Nebenwirkungen durch Sklerosierungsmittel oder Luft. Unser Ziel war deshalb die Entwicklung einer einfachen, wenig invasiven und nebenwirkungsarmen Methode zur Behandlung der Stammvarikose, welche in Lokalanästhesie durchgeführt werden kann.
Methode: Wir entwickelten einen doppellumigen Doppelballon-Katheter. Dadurch kann ein Venensegment in-vivo vom Blutfluss isoliert, flüssigkeitsfrei gemacht und lokal sklerotherapiert werden. Später wird das Sklerosierungsmittel weitgehend abgesaugt. Damit ist es möglich, benötigte Sklerosierungsmittelmenge und damit potentielle systemische Nebenwirkungen zu reduzieren. Die Verödung längerer variköser Segmente geschieht durch punktweise Wiederholung des Vorganges oder durch langsames Zurückziehen der entfalteten Ballone mit dem zwischen ihnen "gefangenen" Sklerosierungsmittel.
Ergebnisse: Die Methode konnte als US- Patent Nr. 6,726,67 B2 patentiert werden. 18 Ballon-Prototypen wurden einer eingehenden Testserie unterworfen. Es erfolgten Prüfungen der Dichtigkeit, der Dimension, der Kompatibilität von Mandrel, Führungsdraht und Einführungsbesteck und schlussendlich Zerstörungstests.
Drei Patienten mit Varikose der Vena saphena magna bzw. der Vena saphena accessoria lateralis wurden erfolgreich behandelt, mit komplettem Verschluss der Gefäße 10, 6 bzw. 2 Monate nach Behandlung.
Schlussfolgerung: Die neue Methode der Ballonsklerotherapie kombiniert zwei wohlbekannte Verfahren, nämlich die Ballonkathetertherapie und die Sklerotherapie. Sie verspricht eine wenig invasive, nebenwirkungsarme und billige endovenöse Therapie der Stammvarikose zu werden, die in Lokalanästhesie durchgeführt werden kann.

VASA 2008; 37: 165–173

Introduction

The classical operation for varicosity and incompetence of saphenous trunks consists of ligation and division of the saphenous trunk and, in case of the great saphenous vein, all proximal tributaries and is followed either by stripping of the vein or by avulsion phlebectomy [3]. Proximal ligation requires a substantial incision at the groin crease or the knee hollow and may occasionally cause neovascularization [2, 13]. Stripping of the vein requires additional incisions at the knee or below and is associated with the possibility of intra- and postoperative surgical complications. Also mostly minor, there are also major surgical side effects (injuries to large arteries, veins and lymphatics, nerve injuries, infections, deep venous thrombosis, pulmonary embolism or even death) [5]. Avulsion phlebectomy requires multiple 2- to 3-mm incisions along the course of the vein and can cause damage to adjacent nerves and lymphatic vessels. The whole procedure is often performed on an inpatient basis under general or at least spinal anesthesia with its possible side effects, incurring also high costs and leading to prolonged convalescence.
Endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, is an effective and less invasive treatment of varicose veins and has a lower complication rate in association with a more rapid recovery and lower costs [12]. The physician inserts a catheter into the abnormal vein using ultrasound guidance and the ablation probe is guided up the saphenous vein. Tumescent anesthetic is administered around the vein; again using ultrasound radiofrequency or laser energy is then applied to the inside of the vein. This heats the vein and essentially seals the vein closed. Possible complications of endovenous ablation are induration, swelling, periphlebitis, infection, thermal skin burns, paresthesia, ekchymosis, pigmentation, nerve injuries or, not so rarely, deep venous thrombosis [7, 9, 10].
Endovenous ablation avoids general anesthesia but tumescent anesthesia is still mandatory (which in rare cases can lead to severe side effects as fasciitis or pulmonary edema [1, 4]). Moreover the procedure is still a pretty expensive procedure and can logistically be complicated.
Sclerotherapy of the truncal varicosity using high-percentage sclerosing substances such as polidocanol or in recent years microfoam under duplex monitoring (with or without using a catheter) has the advantages of a well known procedure, but involves also the disadvantages of this method, namely possible damage to the common femoral vein and systemic effect of the sclerosing agent (thrombosis, pulmonary embolism) [11, 15].
It was therefore our goal to develop a minimal invasive, simple and cheap method for the treatment of truncal varicose veins, requiring local anesthesia at the puncture site only and reducing the potential risk of systemic effects of the sclerosing agent to a minimum.

Methods

The idea was to develop minimally invasive apparatus and methods for localized administration of a sclerotherapeutic agent in order to treat varicose veins. Moreover a substantial portion of the agent should be removable from the vein to reduce the amount of the sclerotherapeutic agent necessary and to minimize possible systemic side effects.
For this purpose a double lumen double balloon catheter was developed.
The catheter has a guide wire lumen extending between its proximal and distal ends, and an inflation lumen extending between its proximal end and the inflatable member. The inflatable member comprises proximal and distal regions, and a central region disposed therebetween. The inflatable member is reversibly expandable from a collapsed delivery configuration to an expanded deployed configuration.
The central region of the inflatable member has a reduced cross-section in the deployed configuration, as compared to the proximal and distal regions.The central region further comprises one or more perforations extending through the inflatable member. When the inflatable member has been fully expanded to the deployed configuration via an inflation fluid delivered through the inflation lumen of the catheter, additional injection of a volume of the fluid causes a substantially equal volume of the fluid to exit through the one or more perforations.
When deployed in a blood vessel at a treatment site, the proximal and distal regions of the inflatable member sealingly engage an interior wall of the vessel, establishing an isolated vessel segment in the vicinity of the central region. Continued injection of the inflation fluid post-engagement of the vessel wall provides localized delivery of the inflation fluid to the isolated segment. Upon collapse of the inflatable member back to the delivery configuration by withdrawing the inflation fluid through the inflation lumen, a substantial portion, for example, a majority, of the inflation fluid delivered to the isolated segment is also withdrawn from the vessel through the perforations in the central region.
When the inflation fluid comprises a sclerotherapeutic agent, localized, minimally invasive sclerotherapy is achieved.

This application was filed as United States Patent No. 6,726,67 B2.
In collaboration with Invatec S.r.l., Roncadelle (Bs), Italy a number of prototypes of the catheter was produced (Fig. 1). An extensive functionality test verification series was performed:
Three lots with 6 catheters each were manufactured, based on a MOMA® catheter (Invatec S.r.l., Roncadelle (Bs), Italy) with the following differences:

– No distal part
– Two proximal type balloons on the main shaft dilated by one connection at the junction
– Three holes between the balloons connected to the second connection at the junction

No new materials and no new processes were used compared to the CE-approved MOMA catheter. The same packaging was used and also the same validated ETO sterilisation process was applied.
Tests were performed according to: "Test plan Varicose Vein Catheter CP-074 Rev 001".
A first test-series was performed after manufacturing and before sterilization as 100% tests, where all basic functions responsible for the proper function of the device were tested (not-destructive).
A second test-series was performed after sterilization using samples of each lot. These tests included also destructive tests simulating in-vivo conditions.

First test series
The 100% final inspection was done according to Table I.

Second test series
The goal of the second test series was to repeat some of first tests (e.g. dimensional measurements) and to also perform destructive tests simulating an in-vivo situation.

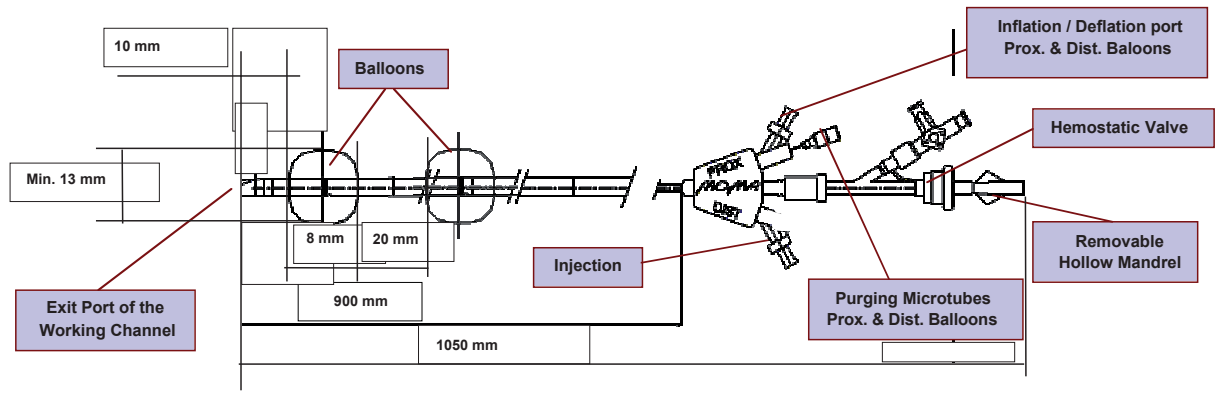

Figure 1: Schematic drawing of the balloon catheter and its dimensions

Table I: Protocol of the first test series (100% final inspection)

Test	Method	Specification	Samples
Labeling	IST/03C/07.01.02–23 Rev. 1	Correct printing	All
Balloon leak test	IST/03C/07.01.02–23 Rev. 1	Keeps ø 8 mm for 10 min. constantly	All
Dimensions Usable length: Crossing profile Marker distance	IST/03C/07.01.02–23 Rev. 1	 900 ± 100 mm Max 3.35 mm 25 ± 3 mm	All
Mandrel compatibility Guide wire compatibility	IST/03C/07.01.02–23 Rev. 1	Mandrel insertion possible 0.035" Guide wire insertion possible	All
Venting positioning verification	IST/03C/07.01.02–23 Rev. 1	Proximal to the first inflation port	All
Balloon length:	IST/03C/07.01.02–23 Rev. 1	8 ± 1 mm	All

VASA 2008; 37: 165–173

To simulate in-vivo conditions the catheter was inserted into and afterwards removed from a model simulating a 270° curve with a radius of 50 mm to test trackability of the catheter. In order to measure the balloon length and its distance the balloon was inflated to a small diameter only (6–7 mm). Afterwards the catheter was inserted into a silicone tube with an inner diameter of 12 mm and the balloon was inflated with a pressure of approximately 2 bars. Subsequently Polidocanol 5% (Sclerovein® 5%, Resinag, Zug, Switzerland) was injected. 5 minutes later (90 minutes later in two catheters) pressure was increased up to the rupturing of one of the two balloons. Then the catheter was removed from the silicone tube, the ruptured balloon was sealed by hand and the second balloon was inflated until rupture in air. During this inflation the maximal diameter achieved was measured.
A detailed list of all tests performed are listed in Table II.

Results

Results of the first test series (100% final inspection) (Table III).

All manufactured catheters passed the 100% final inspection.

Results of the second test test series (including destructive tests)

Mandrel compatibility

All 6 tested mandrels could be easily inserted into the catheter, the length of the mandrels was correct, meaning that the mandrel tip forms the catheter tip. Therefore mandrel compatibility was within specification.

Guide wire compatibility

The used guide wire could be inserted without difficulties into all 6 tested catheters. Even under high bending (reached in the insertion model) the guide wire could be moved backwards and forwards without signifi-

Table II: Protocol of the second test series

Test	Method	Specification	Sample
Mandrel compatibility	Insert delivered mandrel	Insertion possible	6
Guide wire compatibility	Insert guide wire 0.035“	Insertion possible	6
Introducer compatibility - Profile measurement	ISO 10555-1; part 5.1	 Max. 3.35 mm	6
Length – Total length – Usable length – Tip length	ISO 10555-1; part 5.2	 1050 ± 100 mm 900 ± 100 mm 10 ± 5 mm	6
Balloon distance	ISO 10555-1; part 5.2	15–20 mm	6
Balloon length	ISO 10555-1; part 5.2	15–20 mm	6
Balloon diameter	ISO 10555-1; part 5.1	Up to 13 mm	6
Insertion into model	Inner ø 4.5 mm Radius approx. 50 mm Angle approx. 270°	Insertion without damage	6
Balloon leakage Balloon resistance against a sclerosing agent	Insertion into a silicon tube ø(12 mm) Balloon inflation Injection of Sclerovein® 5% 5 minutes in Sclerovein® 5%	No rupture	6
Burst pressure in a sclerosing agent	Inflate balloon until rupture after 5 minutes in Sclerovein®	For characterization only	6
Burst pressure in air	Inflate second balloon until rupture in air	For characterization only	6
Long-term behaviour in a sclerosing agent	Store balloon part of the catheter 90 minutes in Sclerovein®, then inflate balloon until rupture	For characterization only	2
Bond strength	ISO 10555-1; part 4.5	Min. 15 N	6

Table III: Results of the first test series (100% final inspection)

Test	Specification	Samples	Result
Labeling	Correct printing	18	Passed
Balloon leak test	Keeps ø 8 mm for 10 min. constantly	18	Passed
Dimensions Usable length Crossing profile Marker distance	 900 ± 100 mm Max 3.35 mm 25 ± 3 mm	18	Passed
Mandrel compatibility Guide wire compatibility	Mandrel insertion possible 0.035" Guide wire insertion possible	18	Passed
Venting positioning verification	Proximal to the first inflation port	18	Passed
Balloon length	8 ± 1 mm	18	Passed

Table IV: Results of the second test series: Introducer compatibility (mm)

Lot-Device #	Shaft	Welding 1	Welding 2	Tip
Specification	**Max. 3.35**	**Max. 3.35**	**Max. 3.35**	**Max. 3.35**
01477301-1	3.29	3.16	3.17	3.27
01477301-2	3.30	3.27	3.22	3.26
01477401-1	3.30	3.30	2.99	3.14
01477401-2	3.30	3.09	3.07	3.30
01477501-1	3.33	3.26	3.16	3.24
01477501-2	3.32	3.24	3.31	3.13

cant increase of friction and fulfilled therefore specification.

Introducer compatibility

Introducer compatibility was measured at 4 points: At the shaft, the tip and at the 2 welding points of the balloon. At all points diameter was measured in a 0° and 90° position and the average was calculated. The results are listed in Table IV (in mm).

All measured values were below the tolerated maximum of 3.35 mm and therefore within specification.

Length

The total length, the usable length and the length of the tip was measured. The results are listed in Table V (mm).

All measured values were within specification.

Introduction into model

To simulate trackability the catheter was introduced into a model. All 6 catheters could be inserted without any difficulties and without any damage and fulfilled therefore specification.

Balloon dimensions

The balloon length, the distance between the two balloons and the diameter of the balloons were measured. The diameter of the second balloon was measured immediately after rupture of the first balloon in Sclerovein®. The results are listed in Table VI (mm).

In one case balloon distance was out of specification. In general the balloon distance was at the upper limit

Table V: Results of the second test series: Length (mm)

Lot-Device #	Total length	Usable length	Tip length
Specification	**1050 ± 100**	**900 ± 100**	**10 ± 5**
01477301-1	1072	907	7
01477301-2	1067	900	8
01477401-1	1084	920	8
01477401-2	1076	908	7
01477501-1	1073	912	8
01477501-2	1071	909	9

VASA 2008; 37: 165–173

Table VI: Results of the second test series: Balloon dimensions (mm)

Lot-Device #	Balloon length	Balloon distance	Balloon diameter
Specification	**8 ± 1 mm**	**15–20 mm**	**Min. 13 mm**
01477301-1	dist: 8 / prox: 8	19	17
01477301-2	dist: 8 / prox: 7	20	17
01477401-1	dist: 8 / prox: 7	20	17
01477401-2	dist: 7 / prox: 7	21	17
01477501-1	dist: 9 / prox: 9	20	–*
01477501-2	dist: 7 / prox: 7	20	16

* One balloon diameter was not measured, because this was forgotten by the operator

of tolerance, which can lead, in the worst case, to balloon rupture and to increased release of sclerosing agent. By limitation of the amount of sclerosing agent used per patient to the maximal usable dose according to the instruction for use of the sclerosing agent this value can be accepted.

Balloon leakage

None of the 6 tested balloons ruptured after 5 minutes at a pressure of approximately 2 bars in Sclerovein®. Therefore the balloons fulfilled the requirements. In addition the 2 balloons which were tested 90 minutes did not rupture either. This demonstrates that the balloon material has good resistance against the sclerosing agent Sclerovein® and fulfills also the long-term requirements.

Balloon burst pressure

For characterization the burst pressure was measured.

The results are listed in Table VII (bar).

The balloons ruptured in air showed a smaller burst pressure than the balloons ruptured in the silicon tube in Sclerovein®. This is due to the higher diameter reached in air compared to the one in the silicon tube. In other words the silicon tube "reinforced" the balloon. No sign was found for weakening of the balloon material by the sclerosing agent.

Bond strength catheter tip

The bond strength of the tip of the catheter was measured and the results are reported in Table VIII (N). One sample was below the specified minimal value of 15 N. However, all samples fractured within the tip material and not at the connection, which demonstrated clearly that the fracture is within the strength of the tip material.

Table VII: Results of the second test series: Balloon burst pressure (bar)

Lot-Device #	Balloon rupture in Sclerovein®	Balloon rupture in air
Specification	**For characterization only**	**For characterization only**
01477301-1	5	4
01477301-2	4	3
01477401-1	4	4
01477401-2	5	4
01477501-1	4	3
01477501-2	5	3

First clinical experiences

So far three patients have been treated with balloonsclerotherapy. In all three cases the intervention was successful. The whole procedure was performed in a supine position in the angio suite.

The first patient was a 66-year-old man with varicosity of the left vena saphena magna accessoria lateralis from the groin to the left lateral knee. Vena sectio at the knee level (distal insufficiency point) was performed by the vascular surgeon after local anesthesia with lidocain 2% (Lidocain HCl 2%, Bichsel, Interlaken, Switzerland). A French 10 introducer sheeth (Cordis, Miami Lakes, FL, USA) and a 0.035" Terumo guide wire (Terumo, Somerset, New Jersey, NJ, USA) were inserted. The leader tip was then placed in the common femoral vein under fluoroscopic control. Over the wire the double balloon catheter was inserted and the leading balloon was placed exactly at the confluence of the vena saphena magna accessoria and the great saphenous vein itself. The balloons were insufflated with a solution of 50% sodium chloride and 50% contrast medium (for visibility of the two balloons) (Visipaque 320; GE Healthcare, Chalfont St. Giles, UK). The space between the two balloons was emptied by vacuum extraction in order to reduce a mixture of sclerosing agent with blood as good as possible. Then 2 ml of Aethoxysclerol 3% (diluted to 2% by contrast medium) was injected (Kreussler, Wiesbaden, Germany). The double balloon catheter was then slowly withdrawn (approximately 10 seconds per 2 cm) from the groin to the introducer sheet without withdrawing any fluid from the balloons nor the space in betweeen. The loss of sclerosing agent into sidebranches of the vein was visibly minimal so that the concentration of the liquid can be considered almost the same

Table VIII: Results of the second test series: Bond strength catheter tip (N)

Lot-Device #	Bond strength Tip
Specification	Min. 15 N
01477301-1 (sample 1)	17.6
01477301-2 (sample 2)	15.4
01477401-1 (sample 3)	16.9
01477401-2 (sample 4)	13.3
01477501-1 (sample 5)	15.8
01477501-2 (sample 6)	17.3

during the manoeuvre. During the withdrawal process self adhesive elastic bandage was continuously and immediately applied, beginning at the groin. At the end only, first the sclerosing agent and then the fluid in the balloons were withdrawn and the catheter removed. Finally the puncture site was closed by manual compression and then compression bandage. The same evening and the following morning the patient received Fragmin® 7500 IE subcutaneously (Dalteparinum natrium, Pfizer, New York, NY, USA). The patient was instructed to wear thigh high compression stockings during the day for the next 6 weeks.

On days 1 and 20 and 5 and 10 months after the intervention duplex sonography was performed and demonstrated a completely occluded vessel.

The second patient was a 33-year-old woman with varicosity of the right great saphenous vein from the groin to the proximal calf (Fig. 2a and b). After premedication with Voltaren retard® 75 mg (Diclofenac, Novartis, Basel, Switzerland) and Dormicum® 7.5 mg (Midazolam, Roche, Basel, Switzerland) the identical procedure was performed (Fig. 3).

On days 1, 14 and 30 and 6 months after the intervention duplex sonography was performed and demonstrated a completely occluded vessel (Fig. 4). On day 13 after the intervention the patient developed some pain

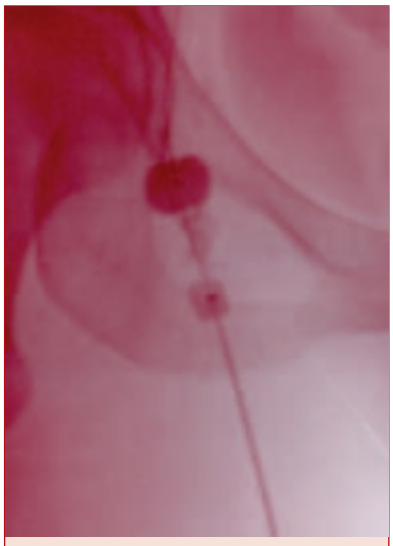

Figure 3: Insufflated balloon catheter at the junction of the greater saphenous vein and the common femoral vein in the same patient. The sclerosing agent is mixed with some contrast medium and is therefore visible as a "cloud" between the two balloons

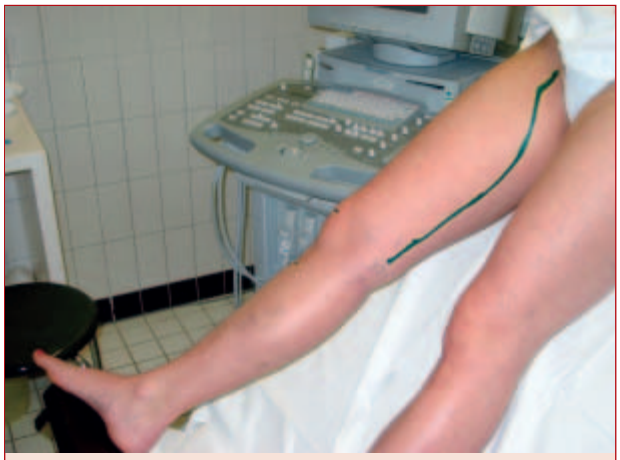

Figure 2a: 33-year-old female patient before the intervention with marked insufficient greater saphenous vein on the right

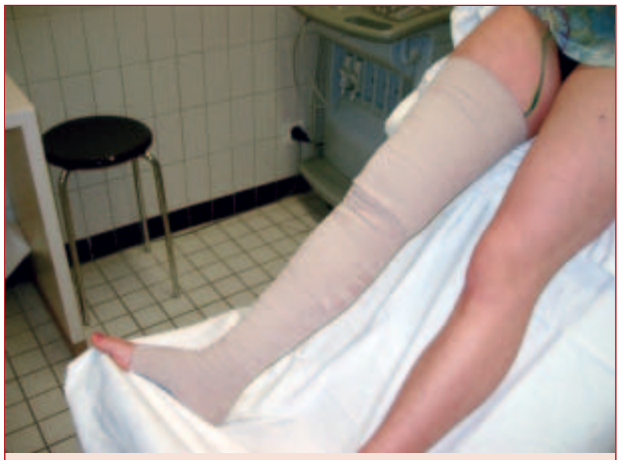

Figure 2b: The same patient 1 day after the intervention with compression bandage. The most proximal part of the bandage has already been removed

VASA 2008; 37: 165–173

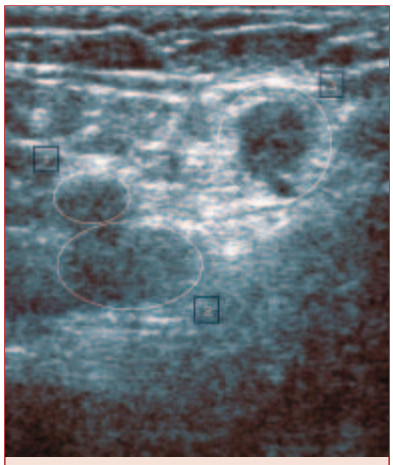

Figure 4: Compression duplex sonography at the groin one day after the intervention
1 = Common femoral artery
2 = Common femoral vein
3 = Completely occluded greater saphenous vein near the junction with the common femoral vein

and redness at the medial thigh which disappeared two weeks later under a local therapy with Flector EP Tissugel® (Diclofenac epolaminum, IBSA, Lugano, Switzerland).

The third patient was a 62-year-old man with varicosity of the right great saphenous vein from the groin to the proximal calf.

After premedication with Voltaren retard® 75 mg (Diclofenac, Novartis, Basel, Switzerland) and Dormicum® 7.5 mg (Midazolam, Roche, Basel, Switzerland) the identical procedure was performed.

On days 1, 10, 30 and 60 after the intervention duplex sonography was performed and demonstrated a completely occluded vessel. The patient had no side effects apart from some tenderness in the course of the great saphenous vein up to one month after the intervention.

Discussion

Therapy of truncal varicose veins seems to shift from conventional surgery to endovenous ablation. Laser and radiofrequency treatment are nowadays the two most used endovascular methods. From a technical point of view both methods are demanding and they are not cheap [6, 8].

Balloonsclerotherapy combines two well-established methods. Percutaneous transluminal balloon angioplasty is widely used for the reopening of arterial and, more rarely, venous obstructions. However, so far treatment of varicose veins was not part of its use. Sclerotherapy is a method known for decades with sort of a renaissance due to foam sclerotherapy in the recent years [11].

Balloonsclerotherapy uses the armamentarium of percutaneous transluminal balloon angioplasty adding a second balloon and thus providing a space in between the two balloons which can be emptied to a maximum possible of blood and refilled with a sclerosing agent. The balloons keep the delivered agent in place. The latter can be in a liquid or also in a foam form. After sclerosing the vessel wall a substantial portion delivered to the isolated segment can be withdrawn. This reduces amount necessary and possible systemic side-effects of the sclerosing agent. The manoeuvre of sclerosing a longer vein segment can be achieved in two ways. The catheter can be withdrawn step by step with insufflation, sclerotherapy, withdrawal of polidocanol and emptying of the balloons thus sclerosing the varicose vein pointwise. On the other hand it is possible to withdraw the catheter slowly with fully expanded balloons and the "catched" sclerosing agent in between. Thereby the concentration of the sclerosing agent is supposed to remain almost the same (loss into side branches of the vein seems to be minimal). This manoeuvre will potentially also lead to a mechanical irritation of the endothelium thus adding to the occlusion process. The supine position of the patient and the self adhesive bandage continuously and immediately applied during the withdrawal procedure leads to an empty vein technique thus also taking advantage of the venous spasm known from conventional sclerotherapy [11].

The whole intervention was so far performed under fluoroscopic control. However, there is no doubt that the treatment will also be possible under duplex sonography guidance only.

Apart from reducing the amount of sclerosing agent necessary the big advantage of this therapy is the need for local anesthesia at the puncture site only. In our three patients vena sectio was performed. It is, however, the goal to perform direct percutaneous puncture in the future. Apart from slight premedication (probably not always necessary) no further preparations are necessary.

We are convinced that thromboprophylaxis is important to avoid the most feared possible complication, namely deep venous thrombosis and pulmonary embolism. We think that 7–10 days of treatment with low molecular heparin (e.g. Dalteparin 7500 IE) will be reasonable to be "on the secure site". Apart from support of the occlusion process compression bandage points in the same direction and therefore 4–6 weeks seem appropriate to us [14].

Balloonsclerotherapy is a promising method, which is less invasive, potentially cheap and might have less side effects. The method can easily be learnt by angiologists, phlebologists, vascular surgeons and radiologists. Further studies (including standardization of all parameters such as e.g. puncturing procedure, concentration of the sclerosing agent, velocity

of withdrawal etc.) are now required to introduce balloonsclerotherapy as a routine procedure.

Acknowledgments

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