SAPHENOUS SPARING TREATMENTS SHORT REVIEW

An Overview on Venous Valvuloplasty and Saphenous Sparing

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Abstract Venous valvuloplasty (VV) has been proposed for over 50 years to obtain functional reconstruction in patients with chronic venous insufficiency. The various techniques used have given long-term positive results in about 80% of the cases treated, which is moderately better than ablative techniques for the same pathologies. VV seems to be advisable in cases of poor compliance of the deep venous system following ablation of the great saphenous vein. Furthermore, it allows the saving of the saphenous conduit, which represents a precious advantage in case of need for arterial replacement surgery. So far it did not get widespread. Reasons for this include: rather strict eligibility criteria, which reduce the number of possible beneficiaries; the greater complexity of the procedure, both diagnostic and operative, compared to the endovascular ablative techniques proposed in recent decades; the scarce availability of adequate medical devices. Current research seems oriented towards the development of prosthetic neo-valves, made of biomaterials engineered with innovative techniques, which can be positioned by catheter in the deep venous system.

Keywords Chronic venous insufficiency, Saphenous sparing, Venous valvuloplasty, Venous neovalve, Hemodynamic patterns of venous reflux.

Introduction

Venous valvuloplasty (VV) is a surgical technique that aims to remodel and correct the morphology and/or repair the function of the venous valves (generally bicuspid, in the shape of a swallow's nest), applicable in selected cases of anatomical or functional valve defect. In the most common case, the technique is applicable to valves that do not function correctly due to the elongation of the free edge of the valve flaps or cusps which, for this reason, have lost the ability to face each other in the closed position; therefore, such valves are no longer able to maintain the unidirectional flow of venous blood, resulting in valve insufficiency or incompetence. This condition involves the onset of reflux (retrograde, inverted, pathological flow) and, consequently, chronic venous insufficiency (CVI): a generally progressive syndrome with various clinical features, including varicose veins (VVs), edema , dermatitis, ulcer and other complications. In these cases, VV is one of the techniques that implement the conservative/reparative treatment strategy and contrasts the commonly used ablative strategy through venous stripping, endovascular thermosclerosis, and more.

Surgical techniques

Two main surgical techniques have been developed to perform VV: internal valvuloplasty and external valvuloplasty. The first consists of anatomical repair of the valve with access to the vein lumen. It is performed with the aim of shortening the free edge of the valve flaps by plicating them, performed near their apical insertion on the venous wall. It was first proposed by Kistner RL[1] and then with modifications by Raju S[2], Sottiurai VS[3], Tripathi R[4] and others. External valvuloplasty, on the other hand, does not require access to the venous lumen, having the objective of reducing the valve axial diameter by positioning, outside the valve, a suitably calibrated medical device in order to involve a rearrangement of the valve leaflets and therefore their mutual rapprochement during closure with the repair of their function. It was first proposed by Hallberg D[5] and, with modifications, by Jessup G[6], Lane RJ[7] and others[I]. A variant of the technique aims to neutralize the excess length of the valve leaflets by inducing an appropriate and selective increase of the inter-commissural diameter of the valve, which is finally ovalised. This selective deformation is obtained by the application, around the valve, of an oval section medical device which exerts an inelastic compression orthogonal to the valve leaflets (Zukowski SL)[8, II] or an elastic traction parallel to these leaflets on the intercommissural axis (Camilli S)[9, III]. Internal valvuloplasty is applicable only to the most functionally relevant and easily accessible valves of the deep venous system, but not to those of the superficial circulation which are smaller in size, while external valvuloplasty is also practicable on the greater saphenous vein (GSV), usually at the groin.

At the same time, in case of anatomical or functional defect of the venous valves, other researchers have preferred a different approach: valve replacement with an implantable prosthesis by open access (Taheri SA et al)[10] or by percutaneous catheterization (Quijano RC[IV], Pavcnik D[V], de Borst GJ[VI], Gonzales-Perez F[VII], et al.), but short-term complications, mainly thrombotic, have so far prevented its clinical use. However, a preliminary clinical study of a bioprosthetic valve device (VenoValve) is still ongoing, with promising results[VIII]. Other researchers have preferred to experiment with the creation of an autologous venous neovalve, generally performed at the level of the common femoral vein, with encouraging results, although found on a limited series of patients affected by primary or post-thrombotic deep venous insufficiency (Opie JC[11], Maleti O[12]).

Eligibility and indication

In order to obtain the desired technical and functional success, VV requires adequate length and freely floating valve flaps in the venous lumen, although they must not to be hypo-plastic or sclerotic. In order to visualize and to evaluate the valve morphology and its dynamics, an accurate preoperative study by duplex scanning is necessary, while for the deep venous system a descending/ retrograde venography is also advisable in most cases. Indeed, the eligibility requirements for the procedure are present just in selected cases. These requirements are more easily found in young patients or with recent VVs and a clinical history free from phlebitis or venous thrombosis.

Internal VV is usually reserved for one or two proximal femoral vein valves, usually in primary deep venous insufficiency (PDVI). External VV, on the other hand, is feasible on both the femoral and saphenous veins, usually at the saphenofemoral junction (SFJ). A useful contribution to the execution can derive from the intraoperative use of a flexible angioscope[13]. The positioning of the medical device and its correct calibration are crucial for the functional result. Moreover, it should be considered that, even in the case of correct indication and positive outcome of VV, the repair of one or two functionally relevant proximal valves does not completely solve the pre-existing reflux in the more caudal venous duct, as it is fed by tributary veins. Furthermore, in the case of incompetent tributaries, these too must be evaluated and possibly treated with one of the techniques in use for the interruption of the escape points (selective ligation, phlebectomy or targeted sclerosis, etc.), but still preserving the whole outflow route (GSV plus SFJ). Finally, the outflow in the treated vein will still have a bidirectional motion, mainly orthograde/ascending in the systolic muscular phase, but also retrograde/descending in the diastolic phase, with re-entry through the caudal perforating veins. In this way it is possible to obtain a significant reduction in the volume and/or speed of venous reflux, a better and more lasting overall hemodynamic balance, and thus also slow down the natural worsening evolution of CVI.

The final hemodynamic result partly shares the so-called CHIVA strategy (Cure Consérvatrice et Hémodynamique de l' Insuffisance Veineuse en Ambulatoire, proposed by Franceschi C)[14] which however often requires the interruption of the SFJ and therefore the definitive abolition of the orthograde saphenous outflow.

Discussion

In phlebology, the need and the impetus for the conservative strategy, above all of the GSV, derive from the fact that the ablative strategy, commonly adopted in case of superficial venous reflux, generally allows excellent results in the short-term follow-up (f-u), but in the medium to long term f-u results of are not as good and often disappointing. In fact, already about 3 years after the ablative treatment, both the stripping techniques and the intravenous ablation techniques lead to the VVs recurrence in about 20% of cases, which rises to 30-50% 5 years after the treatment, while the rate of reoperations approaches 40 percent, whatever the ablative technique adopted[15-20]. Some authors, who have reflected on these data, have concluded with clear perplexity about the advantages of the so-called "endovenous revolution", both in terms of clinical and economic benefit, and propose to question the guidelines suggesting intravenous thermal ablation as a first choice technique in the treatment of VVs[21].

Table I

Definition and prevalence of the hemodynamic patterns of venous reflux

	Pattern		prevalence (%)
1	Incompetence of the SFJ and GSV trunk, with substantially competent perforating veins		30-40
2	Reflux circuits with large incompetent perforating veins, but with hemodynamic predominance of the reflux from		
	2.a	the incompetent GSV	20-30
	2.b	the femoral-popliteal vein axis	5-15
	2.c	the deep femoral vein	4-8
3	Atypical reflux, with competent SFJ and VVs fed by reflux from veins of the abdominal wall or pelvis-perineal region. Pelvic varicocele or pelvic congestion syndrome or venous malformations may be present.		10-30

SFJ - Saphenous Femoral Junction; GSV - Greater Saphenous Vein; VVs - Varicose Veins. Details in the text.

Among the causes of long-term disappointment or failure of the ablative strategy is that it depends on the functional integrity of the deep system. This prerequisite is almost a-priori assumed and shared by most doctors, while the compensatory role of deep veins is, on the other hand, an uncertain expectation and therefore always to be evaluated carefully in the preoperative phase.

In the period 1986-2004, one of the authors developed an observational study on a single center cohort of about 1500 unselected patients, affected by primary and secondary VVs, including descending/retrograde phlebography during the Valsalva maneuver[22]. The study highlighted some different hemodynamic reflux patterns, summarized in 3 main ones: a typical reflux pattern (pattern 1), with incompetence of the SFJ and trunk of the GSV, with substantially competent perforating veins; a combined pattern of reflux (pattern 2.a-b-c), consisting of a variegated basket of reflux circuits with large incompetent perforating veins, but with hemodynamic predominance of the reflux in the incompetent GSV (2.a) or in the femoral-popliteal vein axis (2.b) or in the deep femoral vein (2.c); and finally an atypical reflux model (pattern 3), with substantially competent SFJ, but with VVs fed by reflux coming from veins of the abdominal wall or from the pelvis-perineal region, in the presence or absence of pelvic varicocele or pelvic congestion syndrome or other venous malformative pathologies.

In case of GSV ablation, the deep system will be able to demonstrate an optimal supply function in patterns 1 and 3; on the contrary, no good functional substitute can be guaranteed a priori in pattern 2.a and will surely be inadequate in pattern 2.b-c.

The statistical prevalence of hemodynamic patterns (Table I) was estimated summarily: pattern 1 was frequent and was estimated at 30-40%; pattern 2.a was estimated at 20-30%; pattern 2.b at 5-15%; pattern 2.c at 4-8%; pattern 3 at 10-30%. The variability and difficulty of the estimate depended on the cohort of cases examined per year and on the study and adopted evaluation method. In clinical practice, in the individual patient, a mixture of the patterns described can be found. Excluding patients with a history of deep vein thrombosis (DVT), patterns 2.a-b-c are sometimes difficult to identify and require special attention, especially in the initial phase, when reflux may be variable or sporadic, seasonal, related to the menstrual cycle or to the lifestyle or the physical activity of the individual patient, even in the hours preceding the hemodynamic examination.

Considering all the above, the deep venous system, although efficient in most cases (i.e. in patterns 1 and 3), may be more or less inadequate to compensate saphenous duct ablation (GSV and SFJ) in the long term: this can happen in pattern 2.a, but it certainly happens in pattern 2.b-c. In all these cases, belonging to pattern 2, it can reasonably be argued that the ablation of the superficial venous collector (the GSV) and the interruption of the orthograde outflow path (the SFJ) can be considered – per se - an aggravating factor of an already present inadequate compliance of the deep venous system and which favors the development of collateral venous circuits, pre-existing or newly formed (neoangiogenesis ?) and with the consequence - in the long period of time - of varicose recurrences and reoperations. Therefore, in order to obtain a better and more lasting hemodynamic balance, it appears useful and necessary to pursue not only the elimination - as far as possible - of the reflux, but also - in eligible cases - the preservation of the orthograde outflow route, adopting a conservative/restorative technique. This should include: valve repair with one of the VV techniques, the most appropriate to the individual case (to achieve abolition or reduction of predominant reflux); preservation of the orthograde outflow pathway (the GSV and SFJ); and also selective vein disconnection of incompetent tributaries (for the abolition of the escape points). The adoption of this treatment strategy seems particularly rational in young patients or with recent VVs and long-life expectancy. Indeed, these patients are generally eligible for conservative treatment and can also benefit from the preservation of a venous heritage that can be valuable, in the future, as an autologous substitute in the vascular field. Saphenous sparing appears particularly advisable in secondary VVs in the early stage of DVT, in which the pathogenesis of saphenous incompetence is mainly related to hemodynamic overload into the superficial venous system induced by increased outflow resistance in deep venous vessels.

Concerning the prevalence of eligible cases, it should be considered that the deep venous system can play an adequate role of compliance in patients with patterns 1 and 3; therefore, saphenous sparing does not seem necessary for hemodynamic purposes, though it would have value as preservation of a vascular conduit. Conversely, saphenous sparing would be indicated in patients with combined reflux (pattern 2.a-b-c): with warm recommendation in subgroup 2.a, but with strong recommendation in subgroup 2.b-c, also associating femoral VV in the case of PDVI or the construction or implantation (?) of a neovalve in the case of post-thrombotic or malformative CVI. In conclusion, the prevalence of cases that could benefit from valve repair and saphenous sparing (great eligibility) can be estimated at approximately 30% of all CVI cases with combined reflux (pattern 2.a-b-c), while actual saphenous sparing depends on the reflux pattern found and valve morphology assessment in the individual patient, but also on the materials and devices available.

Criticisms and perspectives

The first attempts to perform VV date back to over 50 years ago. The various published case studies, generally limited and not homogeneous, declare results considered positive on average over 80 percent of cases, even in the mid-long term (3-5 years) and the hemodynamic degradation - anyway evolutionary - is slowed down and probably related to a better or more stable overall hemodynamic balance. However, none of the various VV techniques have become widespread. On the contrary, the ablative strategy is implemented widely, and sometimes in a superficial and uncritical way. Among the various explanations of the widespread preference for ablative procedures, conservative/reconstructive treatments require more diagnostic attention and surgical experience; are applicable only to carefully selected eligible cases; require a more structured operating environment and often the use of implantable devices that are not readily available; may require planned therapeutic adjustments. Therefore, VV techniques are burdened by a fair amount of complexity and clash with the seduction of minimally invasive techniques proposed in recent decades and which have spread successfully.

However, the efforts of researchers to develop simpler and more effective devices and techniques than those proposed up to now should be encouraged, also exploring new materials and tissue engineering techniques[23-24].

Endnotes

[I] Venocuff II device, consisting of a silicone sheet reinforced with a Dacron mesh. AllVascular Inc, St Leonards (NSW), Australia.

[II] EVS device (external valve support), consisting of a sandwich of ePTFE reinforced by a lattice metallic. WL Gore & Associates Inc, Newark, USA.

[III] OSES device (oval shaped external support) consisting of a lattice Nitinol oval elastic stent. Assut Europe spa, Magliano dei Marsi, Italy.

[IV] VenPro endo-bioprosthesis consisting of a biological valve supported by a metal stent, tested by Baxter International Inc, Deerfield, USA.

[V] Endo-Bioprosthesis consisting of a biological membrane supported by a metal stent, tested by Pavcnik D et al., Portland, USA.

[VI] VenaSail alloplastic endo-prosthesis consisting of an ePTFE monocusp membrane supported by a metal stent, floating like a sail, tested by de Borst GJ et al., Vasc Surg dept, UMC, Utrecht, The Netherlands.

[VII] Hybrid endo-bioprosthesis made of engineered elastin-like and combined with a resorbable magnesium stent, still being tested. Correspondence: fernandez@ame.rwth-aachen.de

[VIII] VenoValve endo-bioprosthetic device, still being tested as a pivotal study by EnVVeno Medical corp. Irvine,Ca, USA.

References

1) Kistner RL: Surgical repair of a venous valve. Straub Clin Proc, 1968:24-41.

2) Raju S: Venous insufficiency of the lower limb and stasis ulceration: changing concepts and management. Ann Surg, 1983;197: 688-97.

3) Sottiurai VS: Technique in direct venous valvuloplasty. J Vasc Surg, 1988;8:646-8.

4) Tripathi R, Ktenidis KD: Trapdoor internal valvuloplasty: a new technique for primary deep vein valvular incompetence. Vasc Endovasc Surg, 2001;22:86-9.

5) Hallberg D: A method for repairing incompetent valves in deep veins. Acta Chir Scand, 1972;138:143-5.

6) Jessup G, Lane RJ: Repairing incompetent venous valves: A new technique. Surg Gyn Obst, 1988; 8:569-75.

7) Lane RJ et al: The treatment of varicose veins using the venous valve cuff. Phlebology, 1994 9:136-45.

8) Zukowski SL: Device for restoring competence to venous valves. Patent No. WO 97/40755, 1997.

9) Camilli D, et al: Use of a novel device in reconstructive venous surgery: preliminary results. Int J Angiology, 2020;29(4) 245-9.

10) Taheri SA, Schultz RO: Experimental prosthetic vein valve. Long-term results. Angiology 1995;46(4):299-303.

11) Opie JC et al: Monocusp - novel common femoral vein monocusp surgery uncorrectable chronic venous insufficiency with aplastic/dysplastic valves. Phlebology,2008;23(4):158-71

12) Maleti O, Lugli M: Neovalve construction in postthrombotic syndrome. J Vasc Surg, 2006;43(4):794-9

13) Yamaki T et al: Great saphenous vein sparing surgery by angioscopic valvuloplasty combined with axial transposition of a competent tributary vein – 5 years follow-up. Eur J Vasc Endovasc Surg 2009;37:103-8.

14) Franceschi C et al. CHIVA: hemodynamic concept, strategy and results. Int Angiol. 2016;35(1):8-30.

15) Camilli S, Guarnera G.: [Surgical reconstruction in deep venous insufficiency] [Article in French]. Phlébologie 1992;45(3):331-9.

16) Guarnera G et al: External banding valvuloplasty of the superficial femoral vein in the treatment of recurrent varicose veins. Int Angiol 1998; 4:268-271.

17) Mancini S et Al: Preterminal valvuloplasty: follow-up at 10 years. XIVth UIP World Congress. Rome 2001, sept 9-14. Int Angiol 2001;20(suppl.1):279.

18) National Institute for Health and Care Excellence (NICE). Varicose Veins in the Legs: the Diagnosis and Management of Varicose Veins. CG168; 2013, nice.org.uk.

19) Rasmussen L et al: Randomized clinical trial comparing endovenous laser ablation and stripping of the great saphenous vein with clinical and duplex outcome after five years. J Vasc Surg 2013;58:421-6.

20) Agus GB: Some new considerations on venous valvuloplasty: an international online debate. Angéiologie, 2009;61(2):52-61.

21) Nelzén O: Reconsidering the endovenous revolution. BJS, 2016;103:939-40.

22) Camilli D, Camilli S: Reflux abolition and venous drainage preservation: both are essential for durability of varicose veins treatment. In Allegra C et al., eds: Tips and Tricks in Angiology. Edizioni Minerva Medica (Torino), 2016;chapt 35:150-4

23) González-Pérez F et al: Biohybrid elastin-like venous valve with potential for in situ tissue engineering. Front Bioeng Biotechnol 2022 Sep 21;10:988533. doi: 10.3389/fbioe.2022.988533.

24) Ulloa JH, Glickman M. One-Year first-in-human success for VenoValve in treating patients with severe deep venous insufficiency. Vasc Endovascular Surg 2022;56(3):277-283.