

Saphenous sparing treatments: The ASVAL Method

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Abstract The ASVAL method is based on a bottom-up concept of the evolution of venous disease from the tributaries to the saphenous axes, as opposed to the traditional top-down theory where reflux, conversely, appears first on the saphenous axes and then spreads to the tributaries.

The bottom-up evolution has led to a change in treatment paradigm, no longer based on effective suppression of saphenous reflux, but on reversibility of the latter by ablation of the varicose tributaries, eliminating the filling effect at the origin of the hemodynamic disturbance.

As the ASVAL strategy has its limits, depending on the stage of progression of saphenous damage, it is necessary to establish the indications where it can be applied, before the saphenous vein is irreversibly damaged (diameter larger than 8 mm, multiple ectasia, extended reflux above and below knee), or the clinical staged too advanced (skin changes). Various authors have reported on these criteria for applying the ASVAL method in the right indications considering hemodynamic data (ostial reflux, extent of truncal reflux), anatomical data (saphenous diameter, reflux location, volume of varicose reservoir) and clinical data (age, nulliparity, trophic disorders, presence of symptoms). Complications and side effects are limited if the indications and principles of the miniphlebectomy technique are respected. All the cohort studies reported show that after treatment using the ASVAL method (removal of varicose tributaries and ad integrum respect for the saphenous vein), reflux abolition is achieved in between 50% and 80% of cases, depending on the patients selected. Above all, these studies show that improvement in symptoms and quality of life is systematic, whatever the result on the saphenous vein. A recent randomized controlled trial shows that endovenous laser and ASVAL are clinically equivalent, with a cost/effectiveness ratio in favor of ASVAL.

In conclusion, The ASVAL method leads to an alternative concept of an ascending or multifocal evolution starting on the epifascial tributaries and enabling to set an individualized “à la carte treatment” since every patient has a different clinical and hemodynamic situation of the disease at the time of treatment, which cannot match to a “one size fits all” that represents the traditional strategy. We have now at our disposal simple tools to evaluate the patients, select the good indications and perform properly the ASVAL method by mini-phlebectomy.

Keywords ASVAL, Saphenous sparing, Ascending evolution, Miniphlebectomy, Tumescence local anesthesia

BASICS OF ASVAL METHOD

PATHOPHYSIOLOGICAL BASIS

At the opposite of the theory of descending progression, a new ascending pathophysiological concept for the evolution of the varicose disease has emerged more than 15 years ago: varicose disease could come about at the level of the epifascial veins that could be the first to dilate through decompensation of their parietal weakness¹ Progression could initially remain epifascial, creating a dilated and refluxing venous network called “varicose reservoir” that creates a reflux by “filling” effect (that can be likened to a “syphon” effect) in the subfascial saphenous vein, leading to the enlargement of the saphenous vein wall, moving upwards to reach the saphenofemoral junction (SFJ) or saphenopopliteal junction (Figure 1).

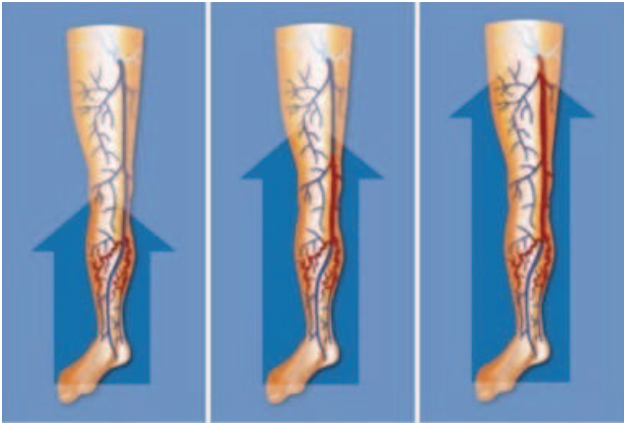


Figure 1 - the concept of ascending evolution of the varicose disease.

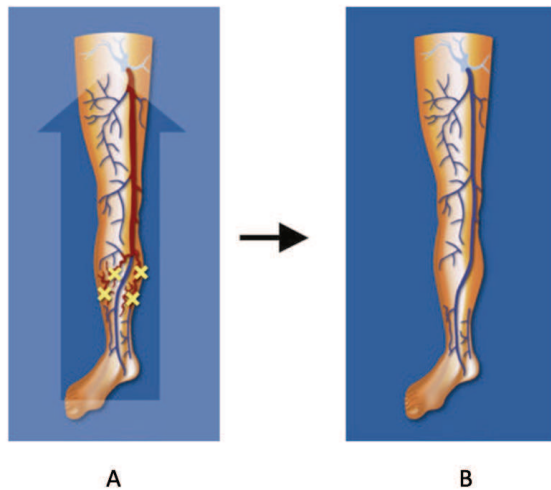


Figure 2 - Hemodynamic effect on the great saphenous vein of the treatment by ASVAL method. A : phlebectomy on varicose tributaries B: elimination of axial reflux.

Several publications support this concept²⁻⁵, citing the possibility of local or multifocal early distal evolution, sometimes ascending or antegrade.

The principles of the laws of fluid mechanics could support this bottom-up theory, in particular Bernoulli's Law, which relates the velocity and pressure of the flowing fluid to the cross-sectional area of the flow pipe. But these laws apply without taking into account thermal and viscosity effects, which are variable in the venous blood system. Generally speaking, it seems reductive to apply the laws of fluid mechanics, verified on stable systems, to a chaotic system such as the venous system, where numerous intrinsic (blood viscosity, wall elasticity, etc.) and extrinsic (ambient temperature, physical activity, etc.) variables apply.

The ascending theory makes the basis of the ASVAL method where the treatment is focused on the elimination of the varicose tributaries sparing the saphenous vein:

1. An early treatment of all varicose tributaries in presence of a competent saphenous vein would be useful in order to prevent the reflux to spread to the saphenous vein.
2. In presence of a saphenous vein reflux, and up until a certain stage of the disease (absence of skin changes, segmental truncal reflux), first-line therapy should include ablation of all varicose tributaries and not elimination of the saphenous reflux which is potentially reversible (Figure 2).

The main argument in favor of this saphenous-sparing approach is the physiological role that the saphenous vein could play in superficial drainage and, to a lesser extent, its availability as revascularization material.

However, ascending evolution alone does not explain the pathophysiology of venous insufficiency. Clinical experience shows that there are cases of saphenous reflux that cannot be explained by the presence of varicose tributaries, and Labropoulos reported in an anatomoclinical study that reflux can progress in an ascending, descending or multifocal fashion⁶.

TECHNICAL BASIS

Preoperative Skin Marking

A precise skin marking enables a more precise and less aggressive surgical gesture, enabling to reduce the risk of lymphatic complication after varicose vein surgery⁷.

Tumescent Local Anesthesia

Tumescent local anesthesia is essential. It is very efficient for the pain abolition, and reduces dramatically the bleeding by subcutaneous high pressure. The use of isotonic bicarbonate improves furthermore the efficiency of the lidocaine and allows to reduce the total amount of lidocaine, enabling to inject large volume of tumescence and therefore to treat a large surface on the lower limb⁸.

Microsurgical Technique (Figure 3)

The varicose veins are extracted by miniphlebectomy with the use of magnificent glasses. The incisions are done with an 18-gauge needle. The bevel of the needle makes a flap on the skin that facilitates the penetration of the hook through the skin and gives an excellent cosmetic result. The phlebectomy should be atraumatic, avoiding the scraping of the subcutaneous tissues with the hook to get the veins. In order to get the best cosmetic result, it is recommended to avoid to leave a piece of varicose vein, in order to limit the risk of staining.

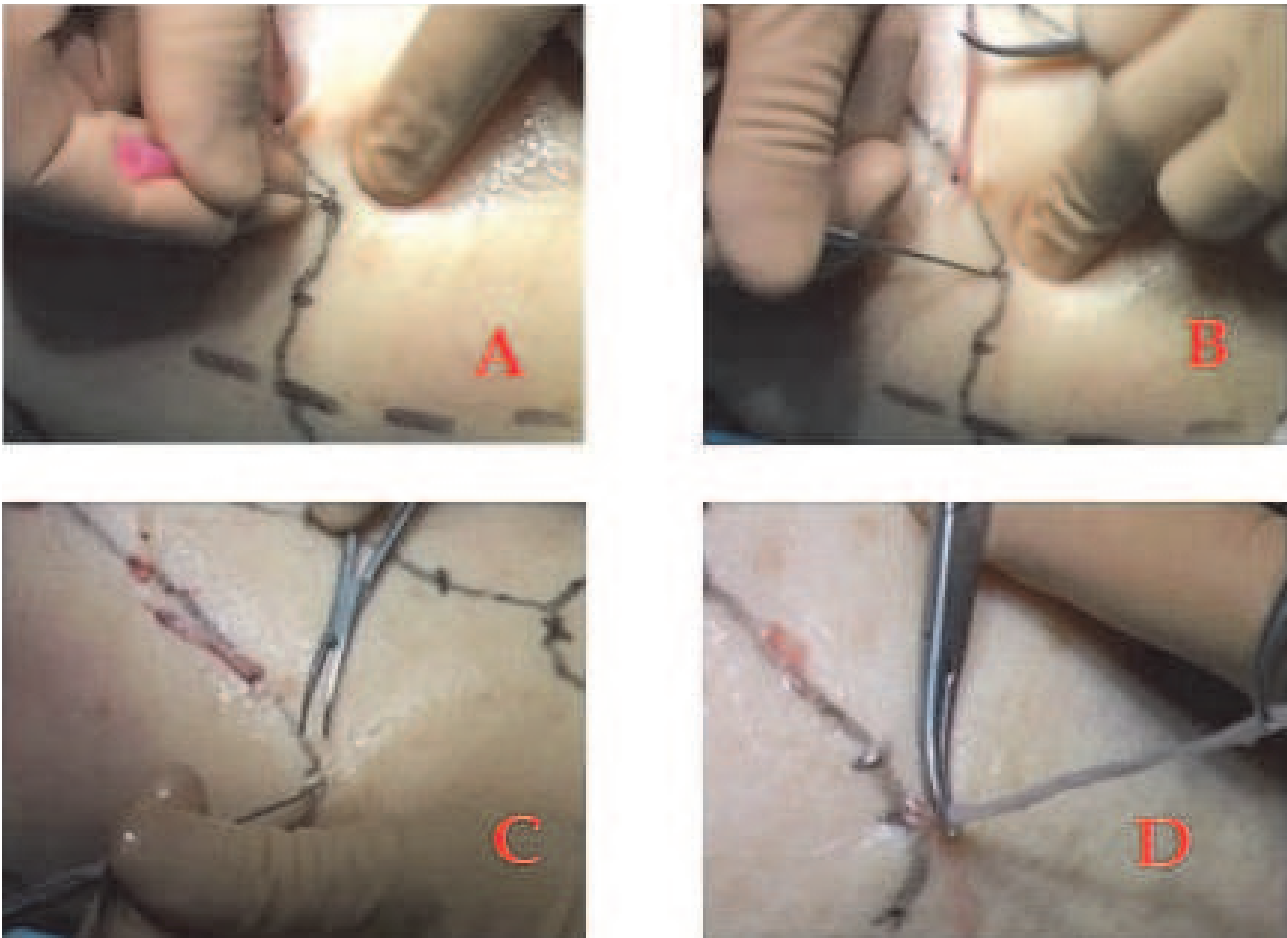


Figure 3 - A: incision with 18th G needle; B and C: vein extraction with Muller Hook; D: removal of the whole vein segment

Postoperative Management

The use of stitches is not necessary, thanks to the limited size of the micro-incisions performed with the 18-gauge needle. Stretch sterile strips are recommended in order to avoid blisters. The patient is invited to walk immediately at the end of the procedure and can usually leave the hospital or office 1 h after the end of the procedure.

In the authors' experience, wearing of compression stockings is not necessary after the first 24 h following a mini-invasive procedure^{9,10}.

RESULTS

HEMODYNAMIC AND CLINICAL RESULTS

The medium-term results at 4 years after ASVAL on a cohort of 303 limbs in 221 patients (mean age 52.7 yrs, 75.1% of female, 91.1% C2-C3 66.3% symptomatic)¹¹ showed the abolition of the GSV reflux in 66.3% of the limbs, and a significant SFJ junction diameter reduction of 25% in average. The symptom relief after 4 years and the

freedom of varicose vein recurrence in the treated lower limbs was respectively at 78.0% and 88.5%.

Biemans¹² showed frequency of abolition of the GSV reflux after single phlebectomy at 1 year in 50%, with an abolition of symptoms in 66%, but this study included unselected patients. However, they found that after the ASVAL procedure, the diameter of the GSV was significantly reduced, the CEAP classification decreased and the VCSS scores improved for all patients, independent of the hemodynamic evolution. It has been already reported that single phlebectomy has a hemodynamic effect on a saphenous vein^{13,14}.

Zolotukhin has also published their experience of ASVAL at short term¹⁵. He reported an abolition of the GSV reflux in 66% of the cases at 1 year of follow-up after an ASVAL procedure performed in an unselected population. The diameter of all the veins decreased significantly no matter if reflux disappeared or not. The overall frequency of clinical varicose vein recurrence was at 13.5%.

A: preoperative skin marking



B : preoperative Duplex-scan showing a refluxing and enlarged SFJ junction and GSV at the knee level

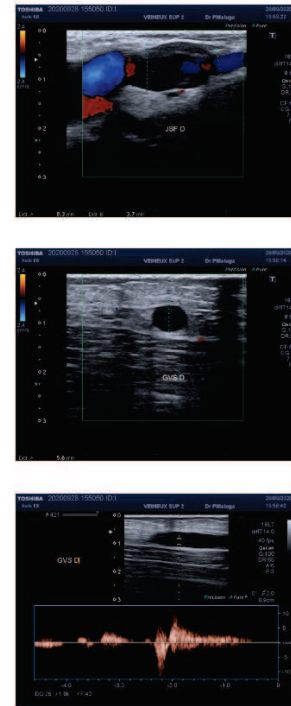


Figure 4ab - Example of clinical and hemodynamic results of treatment by ASVAL. A: preoperative skin marking. B: preoperative Duplex-scan showing a refluxing and enlarged SFJ junction and GSV at the knee level.

He observed that the reflux disappearance during the reflux elimination test (RET), a GSV diameter below 8 mm at the proximal thigh approximately 15 cm below the inguinal fold and a GSV reflux limited above the knee were associated with a lower frequency of clinical varicose veins recurrence.

Scheerders et al has recently published the first RCT comparing ASVAL with saphenous thermal ablation with concomitant phlebectomy¹⁶, with the aim to determine ASVAL is non-inferior with endovenous thermal ablation with concomitant, delayed or no treatment of tributaries, the primary outcome being VEINES-QOL/Sym score at 12 months of follow-up. A total of 227 patients were treated by single ambulatory phlebectomy and 237 by endovenous thermal ablation. The anatomical success rate was better in the endovenous thermal ablation group, but no difference was found for the VEINES-QOL and Sym score with a significant reduction of cost in the single phlebectomy group.

The ASVAL principle has been studied when specifically applied to the short saphenous vein. Similar

results were observed as with the great saphenous vein with an abolition of axial reflux, an improvement of symptoms, and an absence of varicose recurrence in respectively 75.4%, 85.6% and 90.2% at 34 months of follow-up¹⁷.

At last, a long-term result at 10 years after an ASVAL procedure was reported¹⁸: a Kaplan-Maier analysis showed an absence of saphenous reflux, an absence of clinical varicose veins recurrence, and an absence of surgical re-intervention in respectively 64.4%, 68.8% and 76.7% of the cases. A functional improvement and an aesthetic improvement in 65.7% were observed in respectively in 69.9% and 65.7% of the cases.

Despite all these publications, international guidelines give the ASVAL method a modest level of evidence and recommendation. The guidelines of American Forum/Society for Vascular Surgery published in 2011 gave it a grade 2 level of evidence C¹⁹, and their updated guidelines noticed in 2020 that “For segmental reflux associated with clinical classes C1 and C2, several panelists suggested simple branch ablation without ablating the entire saphenous vein as an alternative treatment”²⁰.

C: Postoperative picture at 6 months



D : postoperative Duplex-scan à 6 months showing a competent with diameter reduction of the SFJ junction and GSV at the knee level

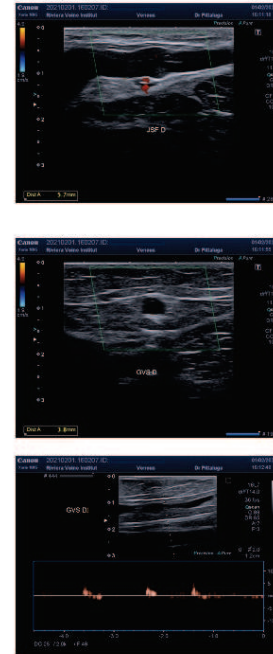


Figure 4cd - C: Postoperative picture at 6 months. D: postoperative Duplex-scan at 6 months showing competency with diameter reduction of the SFJ junction and GSV at the knee level.

The 2022 European recommendations gave a class 2B Level C to the ASVAL method²¹. The absence of RCT at the time these guidelines were drawn up explains this modest level, and consideration of the Scheerders study and perhaps other future publications should modify the level recommendations in the future.

A typical case is shown in Figures 4ab and 4cd to illustrate the treatment by ASVAL with pre and postop data.

SIDE EFFECTS AND COMPLICATIONS

Side effects and complications are very rare after a properly performed ASVAL treatment^{7,9,10}:

- Postoperative hematoma or hemorrhage: exsanguination during the procedure with epinephrine and tumescence prevents hematomas and bruising.
- Infection: it is also exceptional because the incisions are millimetric and no non-resorbable material is used. Very rare cases of skin infection (erysipelas, purulent discharge...) may lead to the prescription of antibiotics;

- Lymphatic complication: they are described in the literature with a low frequency (0.5%) if the principles of minimally invasive with delicate gestures are respected. They are, most often, lymphoceles on the anterior lower leg and on the dorsal foot. Lymphorrhagia is even rarer and lymphedemas exceptional, and almost always appear on a risky terrain (poor skin condition, history of lymph node curage or radiotherapy).

- Thromboembolic complication: thromboembolic complications are also rare thanks to local anesthesia and immediate ambulation. They are most often gastrocnemian vein thrombosis related to the ligation of large leg perforators. More significant thromboembolic complications are seen in patients with a history of thromboembolism, unrecognized thrombophilia or a neoplastic context.

- Neurological complication: dysesthesias are also infrequent thanks to local anesthesia and a gentle procedure. However, transient dysesthesia areas may be seen after ASVAL, most often on the anterior lower-leg or on the foot

DISCUSSION

Criteria of selection

Unlike the strategy of systematically removing the saphenous vein in the presence of truncal reflux, the ASVAL method, which is based on the principle of preserving the saphenous vein, requires selection of the best indications to obtain the best results, particularly for the elimination of truncal reflux.

Several criteria of selection has been reported in literature :

1. Hemodynamic/anatomical criteria

- Saphenous vein reflux patterns: The presence of a competent junction or of a segmental saphenous vein reflux^{2,11,22,23}, a saphenous vein reflux limited at the thigh^{11,12,23}, and a limited dilatation of the saphenous vein up to 8 mm^{11,12}

- The reflux elimination test (RET): the reflux elimination test is positive if saphenous reflux is abolished by digital compression of the varicose tributary, at the time of release, after the compression-release maneuver, during the ultrasound-Duplex examination in standing position. The positive predictive value of the RET for the abolition of reflux of the great saphenous vein (GSV) has been reported as 95.7% and 94.7% at 1 and 2 years of follow-up²⁴.

2. Clinical and demographic data

- The extent of varicose tributaries on the leg (surface occupied), called "varicose reservoir" that has a link with hemodynamic and clinical outcome after ASVAL, the greater the varicose reservoir, the better the hemodynamic result^{11,23}.

- The presence of a unique or limited number of varicose tributaries, especially at the thigh, increases the likelihood for the freedom of varicose vein recurrence¹¹

- The nulliparity. The benefit of the ASVAL treatment for nullipara patients has been reported for the reduction of complexity, signs, and symptoms in the event of varicose vein recurrence after pregnancy²⁵.

- The young age¹¹ and the absence of symptoms with a cosmetic concern^{11,9} are also criteria that plead in favor of the preservation of the saphenous vein.

3. Predictive Score for ASVAL indication

- Biemans et al.¹² have reported a PREST (Phlebectomy Reflux Elimination Success Test) prediction model including CEAP classification, number of refluxing segments, GSV (above the tributary), and RET result, in order to give a preoperative score that correlates with a probability of restoring GSV competence.

- According to hemodynamic and clinical criteria reported above, we have described of a Criteria of Indication for ASVAL score (CIA score)^{26,27}. An evaluation scoring system is in progress with respect to the analysis of a large clinical registry that is underway.

4. Contra-indication

- A history of extensive thrombosis of the saphenous vein and/or the absence (or a very short segment) of an intrafascial GSV in its thigh course constitute contraindications to the ASVAL method, since these situations are at high risk of saphenous thrombosis after isolated phlebectomy^{1,11,15,26}.

Abolition of saphenous reflux: not the main evaluation criterion?

ASVAL has shown that the abolition of truncal reflux is not the only element to consider when assessing the outcome of varicose vein treatment, and that reflux may not even be the main criterion for assessing a "good" result, since reflux is only one aspect alongside clinical and aesthetic results.

We have shown that at last there is a significant link between the extent of varicose tributaries on the leg (surface occupied called varicose reservoir) and the hemodynamic saphenous recovery: the larger the varicose reservoir, the better the hemodynamic result¹¹.

Biemans stated "phlebectomies probably reduce the total refluxing volume, explaining the clinical and hemodynamic improvements, even if saphenous reflux persists"¹².

The same evolution was found in another mid-term study²³: at 5 years, the freedom of presence of a persistent or recurrent GSV reflux was at 66.2% and the freedom of clinical varicose veins recurrence at 87% meaning that a significant proportion of patients had a persisting reflux without clinical consequence.

Despite randomization and the absence of patient selection based on clinical or hemodynamic criteria, Scheerders demonstrated the non-inferiority of treatment of the varicose reservoir alone compared with saphenous ablation, with a very significant reduction in the overall cost

of treatment, despite a lower anatomical success rate¹⁶. The authors therefore suggest that insurance reimbursement for varicose vein treatment should be reviewed, and no longer based solely on hemodynamic outcome.

Thus, the medico-economic evaluation that could become the main criterion for judging the efficacy of a varicose vein treatment would give the treatment of varicose tributaries the first place in the treatment strategy, before saphenous ablation, which would only come in second intention, overturning the current order of this treatment strategy. It is conceivable that establishing reliable selection criteria in the future could also help in choosing this strategy.

The characteristic of the venous wall and/or the type of valvular incontinence (commissural reflux or absence of valve, for example) could be relevant as a predictive criterion for the abolition of reflux. The study of these criteria could therefore be contributory, even if they are never cited by the various authors, probably because their study is complex in current practice, and even though the main objective of ASVAL no longer seems to be

the abolition of saphenous reflux, but rather the clinical outcome.

Conclusion

The ASVAL method calls into question the usual approach to systematically treat the SV by stripping, or by endothermal or chemical ablation in presence of VVs with a SV reflux, based on the descending theory for the evolution of venous insufficiency placing the saphenous vein at the center of concerns. It leads at the opposite to an alternative concept of an ascending or multifocal evolution starting on the epifascial tributaries and enabling to set an individualized “à la carte treatment” since every patient has a different clinical and hemodynamic situation of the disease at the time of treatment, which cannot match to a “one size fits all” that represents the traditional strategy. We have simple tools at our disposal, such as a rigorous clinical examination and detailed echo-Doppler exploration with specific measurements, such as RET, to evaluate the patients, select the good indications and perform properly the ASVAL method by mini-phlebectomy.

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