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The place of endovenous laser Ablation in the management of venous disorders.

La place du laser endoveineux dans la gestion de la maladie veineuse.

Grondin L.

Summary	Résumé
Phlebology have succeeded each other, revolutionizing	Depuis le tournant du millénaire, les progrès technologiques se sont succédé en phlébologie, transformant radicalement le traitement des désordres veineux.
establishment of duplex color-flow ultrasound, as the gold standard for evaluating patients before, during, and	La dernière décennie du XX ^e siècle a vu l'établissement de l'ultrasonographie veineuse comme méthode standard d'évaluation des conditions phlébologiques.
Little did anyone realize at the time, how much this would reset our understanding of the limitations of previous treatments, and create new treatment approaches	Cette simple adoption technologique, a transformé nos concepts des traitements antérieurs, et devint partie intégrale des traitements nouveaux, tels les mousses sclérosantes, la sclérose par radiofréquence, et le laser endoveineux.
	Ce document, présenté à la réunion de la SFP en novembre 2011, discute cette transformation de la pratique quotidienne de phlébologie.
	Mots-clés : mousses sclérosantes, radiofréquence, ablation par laser endoveineux.

Introduction: The burden of venous disease

For the longest time, varicose veins were considered as "common, affecting women more than men, and causing only an unsightly appearance to the legs" [1].

Some authors asked: "Do varicose veins require treatment at all?" [2]

In time, however, some saw the benefit of treating primary varices as a prophylaxis to the development of chronic venous insufficiency (CVI) [3], as well as a method of reducing leg symptoms [4, 5].

Grondin Louis, MD MBA FACPh DPD, Calgary, Alberta, Canada. E-mail : <u>louis.grondin@shaw.ca</u> Accepté le 7 janvier 2012 It is not until the development of vein-specific questionnaires that the extent of the symptoms caused by varicose veins, and their impact on the quality of life came to light [6, 7, 8].

Today, the prevalence of varicose veins is reported to range from 25-32% in women and from 7-40% in men, the value increasing with age [9]. Treatment of varices prior to the development of CVI is largely believed to be preventive of CVI.

In the words of Vaughan Ruckley: "advanced skin changes and chronic leg ulceration could be prevented in selected patients by means of intervention in the prodromal stages of CVI, which can initially be recognized by clinical examination and further defined by duplex scan" [10].

Foam Sclerotherapy and the limitations of traditional vein surgery

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Despite having its advocates [3, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21], liquid sclerotherapy has long been considered to have an inferior outcome to surgery [22, 23]; however, "foam sclerotherapy, in the words of John Bergan, must be looked upon as an entirely new method of treatment" [24].

It was popularized at the turn of the millennium by Juan Cabrera, a Spanish vascular surgeon who reported on 415 patients with incompetent long saphenous veins of a diameter greater than 9 mm [25].

Of these, 265 patients suffered from post-surgical recurrence of the saphenous veins; 72 patients had venous ulcers; and 31 had venous malformations.

The reported results were astounding: "After 4-6 years of follow-up, 80% of the long saphenous veins were obliterated and all superficial branches had disappeared in 95% of legs. In the post-surgical recurrence group, 81% of recurrent veins were obliterated and 90% of the branches had disappeared.

Among the patients with ulcers, the latter remain closed after a mean of 2.5 years treatment in 77% of the cases; recurrence in the remainder was due to re-canalization of perforating veins. All venous malformations were reduced in size and 9 of them had disappeared completely" [25].

The technique was elegant, simple and reproducible. It impacted the vascular community like a storm, and nothing was the same afterwards [26, 27, 28, 29].

With quality of life studies showing worse outcomes "in recurrent post-surgical varicose vein disease than in primary varicose disease" [8], and "significant improvements following ultrasound guided foam sclerotherapy sustained to at least 12 months" [30], foam sclerotherapy appeared a more desirable therapeutic approach to surgical stripping in the management of saphenous trunk incompetence.

Varicose vein surgery was already under critical scrutiny because of a higher than reported complication rate, namely deep venous thrombosis, which was reported in one study of 377 patients to be 5.3% despite liberal thromboprophylaxis [31], and higher than expected rate of recurrence [32, 33, 34].

The incidence of post-surgical recurrence lies somewhere between 20% and 80% depending on the definition of recurrence and the time of the recurrence [35].

The most significant development in the management of venous disorders in the past two decades has unquestionably been the routine use of duplex colorflow ultrasound before, during and after venous interventions [17, 36, 37].

Today, post operative varicose recurrences possess a characteristic ultrasound appearance [38], thus allowing us a more precise understanding of treatment outcomes.

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Foam sclerotherapy has a clearly superior outcome compared to liquid sclerotherapy but not to the extent that it was initially reported [28, 39, 40, 41]; foamsclerotherapy failure has been linked to increasing saphenous junction diameter [42].

Foam sclerotherapy appears to have a definite weaker outcome to endovascular ablative techniques [43]. Foam sclerotherapy is also not without risks.

Of late, gas embolization following foam sclerotherapy has been increasingly reported [44, 45, 46, 47, 48, 49]. Gas embolization to the heart seems to occur every time foam is injected in a superficial vein, regardless of the volume or method of injection [44, 50].

The clinical significance of sclerosant gas-bubbles in the heart and cerebral circulation is unknown.

Scotomas, migraines, and transient neurological deficits have been reported with liquid sclerosants [51], but less frequently than with foam-agents [40, 52].

Lately, stroke is reported increasingly following foam sclerotherapy [53, 54, 55].

Side effects following foam sclerotherapy, namely: chest tightness, dry cough, visual defects and dizziness are less common when carbon dioxide is used instead of room air [56].

To minimize embolization-related complications the European consensus [57] recommends a maximum total dosage of 10 cc of foam per session.

Endovenous Laser Ablation (EVLA)

EVLA was also introduced near the turn of the millennium by yet another Spanish vascular surgeon: Carlos Bonè.

The technique was popularized in the United States by Luis Navarro [58] and Robert Min [59]. Initially, an 810 nm laser-beam and a bare-tip fiber were utilized.

The simplicity, safety and efficacy of the technique outpopularized, and out-performed the traditional surgical stripping procedure [60]. Parallel to the introduction of EVLA, endovenous radiofrequency (EVRF) made its appearance [61].

Initially some felt that EVLA was likely to induce superficial thrombophlebitis and subsequent recanalization [62], and openly favored EVRF claiming that "vein perforations, extremely high intravascular temperatures, failure to cause significant collagen *shrinkage, and intact endothelium* (in animal studies) justified a closer look at the endovenous laser technique" [63].

Indeed, early-on superficial burns, paresthesias and vein rupture were observed [64], as well as rare heat-induced arterial-venous fistulas [65], and lately ischemic stroke has been reported [66].

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> The success and burn-complications of earlier lowerwave-length-lasers are proportional to the energy delivered [67], upon its principal chromophore: hemoglobin [68].

> In an attempt to bypass the problems associated with laser absorption by hemoglobin, longer wave length lasers were introduced [69], which predictably carry fewer complications.

> Today, laser systems with higher wavelengths such as 1320, 1470 and 1540 nm with a higher absorption for water, have become the preferred systems showing less discomfort and bruising following the procedure [70, 71, 72].

The use of radial-tip fibers has further reduced the energy requirements and adverse effects compared with the original bare-tip laser fibers [73].

After much debate, both long wavelength lasers and modern RF devices seem to occupy the podium as the first-line treatment for incompetent saphenous trunks.

Speaking for the Society of Vascular Surgery and the American Venous Forum, Peter Gloviczki stated:

"For treatment of the incompetent great saphenous vein (GSV), we recommend endovenous thermal ablation (radiofrequency or laser) rather than high ligation and inversion stripping of the saphenous vein to the level of the knee (GRADE 1B).

We recommend phlebectomy or sclerotherapy to treat varicose tributaries (GRADE 1B) and suggest foam sclerotherapy as an option for the treatment of the incompetent saphenous vein (GRADE 2C)" [74].

Mechanism of action

The exact mechanism of action of EVLA and EVRF still eludes us.

Based upon a study of 31 limbs on twenty-six patients, and measuring D-dimers post-operatively :

- **Proebstle** concluded that EVLT inducing thrombotic vessel occlusion, and heat injury of the inner vein wall by steam bubbles formation originating from boiling blood is the likely mechanism of action of EVLT [75],
- Van der Geld and Van den Bos proposed that the boiling bubbles during EVLA behave according to a heat-pipe mechanism maintaining an even temperature of 100° Celsius over a distance of 20 mm causing irreversible vein wall injury [76].
- EVRF works in the same manner [77].

Fan and **Rox-Anderson** argued against the steam bubble theory, and claimed that the likely mechanism of action of EVLA involves initial energy absorption by residual blood in the vein, leading to carbonization of the fiber tip, which in turn creates a secondary intensely light-absorbing interface delivering high temperatures (in excess of 1000°C) leading to fibrotic vein occlusion [78].

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However recent reports, using radial fibers show similar results without carbonized fiber tip [79, 80], negate the necessity of carbonization and high heat in obtaining fibrosis.

It is likely that an **energized liquid-gas** (plasma) acts as the heat-carrying medium during the EVLT process [76].

Outcomes

Short- and mid-term studies of EVLA, regardless of wavelength used, seem remarkably consistent, typically reporting ablation of refluxing saphenous veins in 90% or more of cases [81, 82].

Currently available evidence suggests that EVRFA and EVLT are at least as effective as surgery; however there is insufficient data to comment on USGFS [83].

Labropoulos et al reported that in 5% of ablated GSV, multiple small vessels are found directly adjacent to the involved vein segments forming arterial-venous fistulas within the obliterated vein, and postulated that this process may be responsible for recanalization or recurrence after endovenous ablation procedures [84].

Long-term outcome studies are still pending.

Conclusion

Thermal ablation has unquestionably made a powerful impact in Phlebology.

At present it occupies the podium as the treatment of choice for saphenous vein incompetence, pushing traditional stripping to a far lesser status and relinquishing ambulatory phlebectomy, foam and liquid sclerotherapy to the management of non-saphenous branches.

Whether EVLA or EVRF will ultimately be crowned the overall best treatment remains to be seen.

At present technological developments such as "Closure Fast" and "Radial fibers," narrow the margin of distinction between the two technologies to insignificance.

We are presently conducting a comparative trial between the bare tip 980 nm laser technique and the radial fiber 1470 nm laser technique.

We expect to complete the trial in the next 3 years. Unfortunately with the racing pace of innovation in thermal ablations, newer and more effective techniques are likely to appear within this time frame.

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