From Sclerotherapy and Ablative Surgery to Three-Dimensional Regenerative Ambulatory Phlebotherapy (T.R.A.P.)

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Abstract

Our aim is to permanently restore the perforating and superficial circulation in the lower limbs. This objective can be achieved by reducing the diameter of the vessels and strengthening the vessel walls, thereby reducing their excessive capacity and restoring valvular continence. Logically, this cannot be achieved by means of an obliterative or ablative procedure, but only a "regenerative" method. The phenomenon that we call "regeneration" involves fibrosis that is neither sclerotic nor obliterative. Three-dimensional regenerative ambulatory phlebotherapy (T.R.A.P.) is a non-obliterative "sclerotherapy" which extends to the superficial and perforating network. T.R.A.P. is carried out by injecting, sodium salicylate 6% in an alkaline hydroglycerin vehicle, (from 10.5 to 31.5 ml) into all visible vessels, including those visualised by means of transillumination. T.R.A.P. yields an aesthetic and functional result. The results obtained have proved to be stable after six years, thus demonstrating the functional effect of the method.

Introduction

The functional anatomy of the venous circulation in the lower limbs reveals that the valvular insufficiency of the perforating veins and the ectasia of the truncal veins, reticular veins, venules and telangiectasias are, except for rare cases (mechanical obstructions, traumas, arteriovenous fistulas, congenital angiopathies, excessive functional performance (1), prolonged exposure to heat or sun, cortisone application, radiodermatitis, inflammation, chronic skin disorders, etc) due to congenital miopragia of the vessel walls (1, 2, 3, 4, 5). This condition is manifested under the influence of hemodynamic pressure,

age, hormones, posture, habits and numerous other pathogenic factors. Miopragia involves, albeit to different degrees, the entire superficial and perforating circulation. The progressive weakening of the walls of the vessels that connect the superficial circulation with the deep circulation causes the valves to become incontinent. The resulting anomalous pressure in the superficial circulation causes the vessels to dilate, an effect which is first manifested in those vessels whose anatomical structure is least resistant.

Valvular insufficiency is dynamic. Contraction of the so-called 'peripheral heart', which is constituted by the leg muscles, generates the highest venous pressure: up to 300 mm of mercury (6, 7). This region, which is of strategic importance for the correct functioning of the venous circulation, contains about 100 perforating veins (8), as well as the origin of the small saphenous vein. By contrast, the valvular and ostial incontinence of the great saphenous vein is of marginal importance with regard to pressure, since the hydrostatic pressure at the ankle is 80/100 mm of mercury regardless of whether the valves are continent or not (9,10).

Venous insufficiency therefore displays multiple clinical manifestations, but what is evident is that the ectatic veins that can be seen with the naked eye and those that can be seen only by means of transillumination represent the quantity of blood that escapes from the deep circulation. The ectatic vessels therefore constitute escape valves for hemodynamic hypertension. If we reduce this venous network without treating the cause of the disorder, the pressure on the superficial circulation will increase and the initial unsightly conditions will soon restored.

The anatomical-physiological considerations outlined above, and the fact that phlebectasias very often recur after traditional obliterative sclerotherapy and ablative surgery, have prompted us to adopt a radically different approach. Since it is not conceptually possible to obliterate or remove the entire superficial circulation together with all the perforating veins we have experimented a method that is not obliterative or ablative. Three-dimensional regenerative phlebotherapy shifts the focus of the therapy from the superficial ectatic vessels and some of the major perforating vessels to the entire superficial and perforating circulation. Rather than obliterating the vessel, it aims at reducing the caliber of the lumen and thickening and strengthening the vessel walls. To describe these non-obliterative fibrotic effects on the vessel wall, we have adopted the term "regeneration". This term has been chosen in order to highlight the fact that the vascular structure is restored to its pre-phlebectasia condition. Histological examination reveals reduced calibre of the lumen and consolidated the connective structure of the treated vessels (fig.1)

The solution

On the basis of studies and experimentation on non-aggressive effective solutions, we adopted a 6% solution of sodium salicylate in an alkaline hydroglycerin vehicle (Bisclero) (11). The 6% "regenerative" solution exerts a strengthening effect and can be injected without risk at high individual or

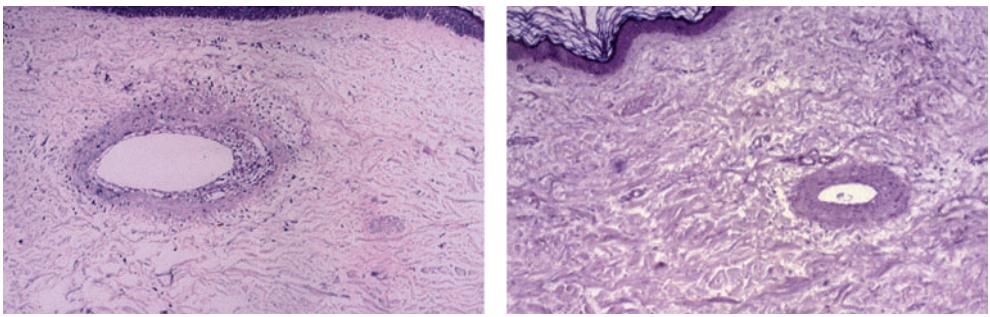

*Figure 1 (*Left*) Histological section of skin (fixed in 10% buffered formalin, paraffin embedded and routinely processed; Weigert stain; enlargement 20 X). Dermal venule of medium-large calibre. The structure of this type of venule is characterised by sparse elastic fibres – not organised into a true, continuous elastic lamina – in the context of fibrous connective tissue of the wall. The vessel (visible "*in vivo*" as a phlebectasia) has a large eccentric lumen. The wall displays a non-uniform thickness and disorganised layers at several sites, and is permeated by a scant inflammatory infiltrate consisting mainly of lymphoid and monocytoid cells. The endothelial lining lacks continuity. Sub-endothelial microvacuolation is also seen. (*Right*) Histological section of skin. The same patient, the same area and a vein of equal size, seen after treatment with 6% Bisclero. Weigert stain; enlargement 20 X. The wall is of regular thickness. The internal endothelial layer is continuous. The wall shows no inflammatory infiltrate. Bisclero treatment has restored uniform wall thickness, reduced the calibre of the lumen and consolidated the connective structure of the vessel wall. We have summarised these effects with the term "regeneration".*

total doses. In addition to the 6% solution, we also use a 10% solution, which is injected primarily in cases of hemodynamic matting. The solutions were formulated in 1992 and their formulae were published in 1993 (12). Sodium salicylate was chosen because it has both anti-inflammatory and an anti-clotting effect. Its alkaline pH is useful in that it limits the absorption of the salicylate, neutralizes its metabolites and accelerates its excretion. The hydroglycerin vehicle slows down the flow of the solution in the vein, thereby allowing the sodium salicylate to remain in contact with the endothelium for a longer time.

Technique

The lower limb is subdivided into three functional regions: medial, posterior and lateral. First, the medial region of the foot, lower leg and thigh is injected; a week later, the posterior region is treated, followed in the third week, by the lateral region. During the fourth week, the first region is treated again, and so on. If the disorder is mild, two regions, or even the entire limb, may be treated in the same session. Once the skin has been disinfected, the 6% Bisclero solution, to which 0.5 ml of 1% lidocaine chlorhydrate has been added inside a 3 ml vial, is injected. The addition of lidocaine is useful on account of its analgesic, anti-inflammatory (13) and vasodilatory action (14, 15). The operator begins by injecting the phlebectatic corona in the foot. In

Tab. 1

Sclerotherapy	*T.R.A.P.*
Obliterative action	"Regenerative" non-obliterative action
Highly inflammatory action	Slightly inflammatory action
Only clearly pathological vessels and the reticular veins connected to ectatic venules and telangiectasias are injected	Systematic injection of all vessels visible even by means of transillumination
Acts on the effect of the disorder	Acts on both the cause t and the effect of the disorder, i.e. on the entire perforating and superficial circulation
Injecting large amounts of solution engenders risks	Injection of large amounts of solution is risk-free
Efficacy proportional to the concentration of the solution injected	Efficacy proportional to the quantity of solution injected*
Several solutions or concentrations used according to the size of the vessels: the larger the vessel, the higher the concentration	A single concentration (6%) is mainly used*; the higher concentration (10%) is reserved only for the treatment of residual telangiectasias and matting **
The solution is not forced into the underlying vessels	The solution is forced into the underlying vessels
The action is two-dimensional; telangiectasias and superficial veins; in rare cases three-dimensional: main perforators. Three-dimensional action is exerted in limited areas and does not extend to the entire circulation	Three-dimensional action extends to the entire superficial and perforating circulation
Pre-established amounts of solution are injected into telangiectasias	The amount of solution injected into the vessels is determined by the resistance to the plunger of the syringe
The size of the vessels is important	The pressure of the vessels is important
Treatment generally begins at the top	Treatment begins at the bottom
Anti-platelet therapy is normally contraindicated	Anti-platelet therapy is mandatory
Complications arise even if the procedure is performed correctly	No complications if the procedure is performed correctly.

*In the event of residual varicosity following T.R.A.P., an obliterative solution is used (see text).
**Our traditional use of the solutions involves three concentrations (6%, 8% and 10%).

this area we add 1 ml of lidocaine to the 3 ml vial. Working upwards towards the root of the thigh, the operator injects in order, from 10.5 to 31.5 ml into all visible vessels encountered, including those visualized by means of transillumination. The principal concepts that we modified are outlined in Tab. 1

Results

The effect of T.R.A.P. is clearly visible on the surface of the skin (Fig.2, 3). The fact that the results obtained (tab.2), seem to be permanent is the most convincing proof that functional integrity has been restored.

Discussion

Traditional obliterative sclerotherapy and surgical ablation do not respect

*Figure 2 (*Above*) Phlebectatic corona. (*Center*) Immediately after the second session. (*Below*) Result after the third session.*

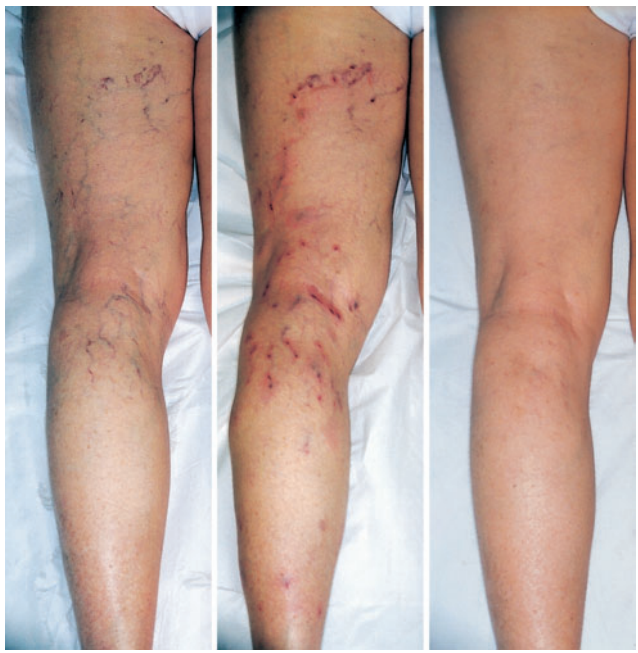

*Figure 3 (*Left*) Patient who had never undergone any therapy. (*Center*) Immediately after T.R.A.P. in the posterior region of the left leg, 28 ml of solution have been injected. (*Right*) Result after three sessions.*

the anatomical and functional integrity of the circulation, nor do they correct miopragia. They act exclusively on the full-blown aspects of the alteration in venous circulation, while the disorder is sustained by perforating vessels which reveal their insufficiency only when the patient runs or walks. Clearly then, the insufficiency of even a small percentage of these vessels, which cannot be revealed by means of the instruments available, can thwart any traditional treatment and give the erroneous impression that ectatic veins can form without a hemodynamic cause, apart from the causes listed above. T.R.A.P. constitutes a step forward from traditional sclerotherapy, which mainly treats the effect of valvular insufficiency, to a non-obliterative therapy that extends to the entire superficial and perforating circulation, thereby treating the cause of the disorder as well as its effect. T.R.A.P. uses a non-aggressive well-tolerated solution that exerts a constant action and can be injected in large quantities. In patients with very evident varices, superficial varicosity may remain even after proper blood flow has been restored. The rare residual varicose veins must either be obliterated by injecting a small amount of obliterative sclerosing solution or be excised. Any varicosity that remains after T.R.A.P. will involve vessel segments in which, as a result of dilation, the wall has become too thin to respond to the therapeutic action of the “regenerative”solution Bisclero

Tab. 2 Efficacy of T.R.A.P on 100 patients (only one limb)*

Patient Classification des patients	Number of patients	Number of sessions	Cumulative dose of 6% solution	Results		
				1st	2nd	3rd
A) isolated capillary ectasias	10	2÷3	12÷27			100%
B) isolated capillary and venular ectasias	24	2÷4	18÷36		5%	95%
C) diffuse capillary ectasias	6	2÷8	18÷72		30%	70%
D) diffuse capillary and venular ectasias	40	9÷12	108÷144		10%	90%
E) diffuse capillary, venular and venous ectasias	20	9÷18	135÷243	70%	20%	10%

*The limb chosen is that in which objective clinical signs are more evident.
Visual reference parameters; control: contralateral limb. Results: 1st) vessels no longer visible at a distance of 150 cm. 2nd) vessels no longer visible at a distance of 50 cm. 3rd) vessels no longer visible on observation with a magnifying glass.

Conclusion

The limits to three-dimensional regenerative ambulatory phlebotherapy will only be established when the method is more widely used, more complex disorders are treated and the results are monitored over a long period. At present, however, the minimal invasiveness of the technique, its preservation of anatomical integrity, its ease of execution, the high quality and persistence of the results, the rapidity with which they are achieved, the absence of complications and the satisfaction of the patients treated indicate that, in terms of efficacy and safety, T.R.A.P. is far superior to any of the techniques that we previously used, surgery inclused.

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Competition of interest: the author holds the patent for the invention of the Bisclero solutions (11)