Venous leg ulcer: surgical versus nonsurgical treatments

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The estimated prevalence of venous leg ulcers is 1% to 2% in the general population in the Western hemisphere. The enormous direct and indirect costs of caring for this chronic ailment pose a public health problem.

NONSURGICAL TREATMENTS

Compression therapy has been used since antiquity to treat venous leg ulcers. Perhaps because of this long heritage, it is often referred to as the "gold standard" in comparison with other therapies. A critical review of the literature, however, will reveal that actual scientific data pertaining to this modality are sparse, the mechanism of action is uncertain, and long-term (>10 years) follow-up studies are nonexistent. However, there is an abundance of literature regarding the short-term (1 to 2 years) efficacy of compression treatment. It is generally recognized that most forms of compression treatments are successful (70% to 90%) in the short term in healing small- to medium-sized venous leg ulcers when applied intensively under supervision of a health care professional.[1-3] Large ulcers (>10 cm^2) often fail to heal with compression therapy alone. Epidemiological studies indicate that the majority of venous leg ulcers either fail to heal or have recurred within a few years after the institution of compression therapy.[4] The major cause of treatment failure is noncompliance.[2] Accurate data regarding the extent of noncompliance are unavailable, as most reports provide these data (10% to 20% reported failures) *after* institution of supervised treatment and not on an intention-to-treat basis. Furthermore, the data apply only to noncompliance in the short term for the duration of the supervised treatment (<1 to 2 years) and not beyond. A survey of patients referred to our center from primary care physicians indicates that long-term noncompliance with compression therapy may run as high as 80% without continued and persistent medical supervision. Many authors stress the importance of patient education and continued intense medical supervision to improve compliance.[1,3] A therapeutic modality that patients generally dislike and that requires some form of periodic motivational coercion can hardly be considered ideal. Here is an example of a treatment that can be successful under controlled circumstances in the individual patient, but fails on a larger scale because the majority of patients are unwilling to use it consistently on a long-term basis.

There has been little work on the reasons for noncompliance with compression therapy. Our own patients reported the following reasons for non-use of stockings (listed in order of frequency):

- "Binding" "or "cutting of circulation"
- "Too hot"
- "Did not help"
- "Poor cosmetic appearance"
- Restriction of a "free" lifestyle or unstated reason

- Physical inability (arthritis, frailty) to apply the device
- Contact dermatitis

For most patients, it appears that the daily rigid regimen of applying and keeping on the stockings from awaking to bedtime is simply too much to abide by.

Another aspect of compression therapy that has been little explored is the *quality* of treatment success. Virtually all reports focus on ulcer healing as the end point in assessment. However, pain and swelling are important features in chronic venous insufficiency. In many patients, calf or limb pain is the main presenting feature. It has been our clinical experience that compression treatment, while successful in healing the ulcer, seldom provides complete relief of pain or swelling.

Venotropic drugs

Significant recent work has focussed on the role of cytokines and cellular mechanisms that result in endothelial injury associated with venous stasis.[5] It is yet unclear whether these are cause- or result-related phenomena. Pharmaceutical agents that purport to act at the cellular level are currently available in Europe and elsewhere. Level 1 evidence that these chemical agents are of benefit in patients with venous leg ulcers is lacking at the present time. There is limited evidence that pentoxyfilline (Trental™) may be helpful in some instances of venous ulcers. This agent improves microcirculation by increasing the deformability of red blood cells.

Preparations for local application incorporating growth factors (Regrenex™) that stimulate wound healing have won limited FDA approval for use in diabetic foot ulcers. It is being promoted for "off-label" use in venous ulcers as well, but the efficacy of the product for this purpose remains unknown.

Synthetic skin grafts

Cultured skin allografts (Appligraf™) grown in culture from donated cell lines have approval for use in chronic leg ulcers. This has been reported to promote local wound healing possibly by stimulating local growth factors, even if the primary application fails to "take." The long-term utility of this product in healing venous ulcers is unknown.

SURGICAL TREATMENT

Major progress in the treatment of venous leg ulcers in the last two decades has occurred in the surgical arena. This was enabled by the development of diagnostic techniques, particularly duplex, which can accurately delineate the diseased venous segments, allowing focussed correction of detected abnormalities. Both new and improved technologies have since evolved to treat superficial, perforator, and deep venous insufficiency. In contrast with compression therapy, which is empirical, the modern surgical approach allows a lesion-oriented diagnosis and specific correction. New modalities are now available for correction of both reflux and obstruction pathologies.

Saphenous ablation

Some 30% to 50% of patients with chronic venous insufficiency presenting with leg ulcers suffer from isolated saphenous reflux.[6,7] A variety of techniques, from duplex-directed sclerotherapy, laser or radio fre-

Figure 1. Ascending venogram appears to indicate that the saphenous vein is the sole outflow with absence of deep veins (left). In fact a widely patent profunda femoris vein is evident on pelvic venography (right). The spurious ascending venographic appearance has often led to the erroneous belief that "secondary" varices should not be stripped.

quency ablation (VNUS™) to surgical stripping, are now available to abolish saphenous reflux. The nonsurgical modalities are practically noninvasive and provide superior cosmetic outcome, but their long-term efficacy is unknown. Surgical ablation is definitive and provides excellent ulcer healing.[8] Most surgeons in the US limit the stripping to the thigh segment to avoid saphenous neuralgia, commonly associated with stripping of the crural saphenous segment.

A long-prevalent canon is to avoid stripping "secondary" saphenous varices that were thought to act as an important outflow tract in the presence of deep venous obstruction.

This ancient taboo was often reinforced by the frequent venographic appearance of a contrast-filled saphenous vein with simultaneous nonvisualization of deep venous structures when an ascending venogram was performed. Adequate deep venous structures are, however, always present in these limbs, and the nonvisualization is due to failure of the contrast to enter these channels *(Figure 1)*. It has been definitively established that stripping of the "secondary" saphenous varix in the presence of deep venous obstruction is not only safe but also provides significant symptom relief with ulcer healing.[9,10]

Perforator surgery

Subfacial endoscopic perforator surgery (SEPS) has become popular in the United States following the lead from Europe. The procedure is usually carried out on an outpatient or short (24 h) hospital stay basis. Between 54% and 77% short-term (2 years) cumulative ulcer healing has been reported with the inferior results pertaining to postthrombotic ulcers.[11] Long-term results are yet unavailable.

Valve reconstruction

A variety of techniques[12] have evolved since the pioneering publication by Kistner[13] to repair refluxing valve cusps in "primary" deep venous disease *(Figure 2)* and reconstruct or transplant valves in postthrombotic disease *(Figures 3a and 3b)*. Follow-up for over 10 years[14-16] is now available with about 60% actuarial ulcer healing both in "primary" and postthrombotic disease. Surprisingly good results have been achieved even in patients with trabeculated postthrombotic veins with a daunting venographic appearance; in 83 consecutive such limbs with no exclusion from surgery except for significant comorbid conditions, actuarial healing of 62% of leg ulcers at 10 years was achieved.[17] Morbidity and mortality of these procedures have been negligible. Considering the large number of patients with postthrombotic disease worldwide, it is unfortunate that these new techniques remain confined to a handful of centers, primarily due to inherent conservative bias and frozen attitudes against deep venous reconstructive surgery. There is persistent erroneous belief that postthrombotic patients are not candidates for corrective surgery.

Venous stent placement

An exciting development is the evolution of stent placement technology *(Figure 4)*. Placement of large venous stents to correct iliac vein obstructions enjoy high patency, low morbidity, do not preclude more complex open surgery later if the stent is occluded, and can be performed on an outpatient basis employing a percutaneous approach.[18] The frequent presence of iliac venous obstruction in

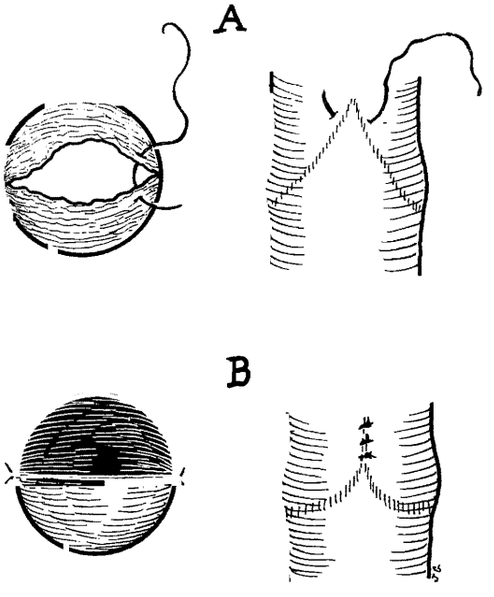

Figure 2. Transcommissural valvuloplasty. Placement of transluminal sutures (A) to tighten the valve cusps and simultaneously close the angle between the valve attachment lines is shown (B). (By permission J Vasc Surg.*)*

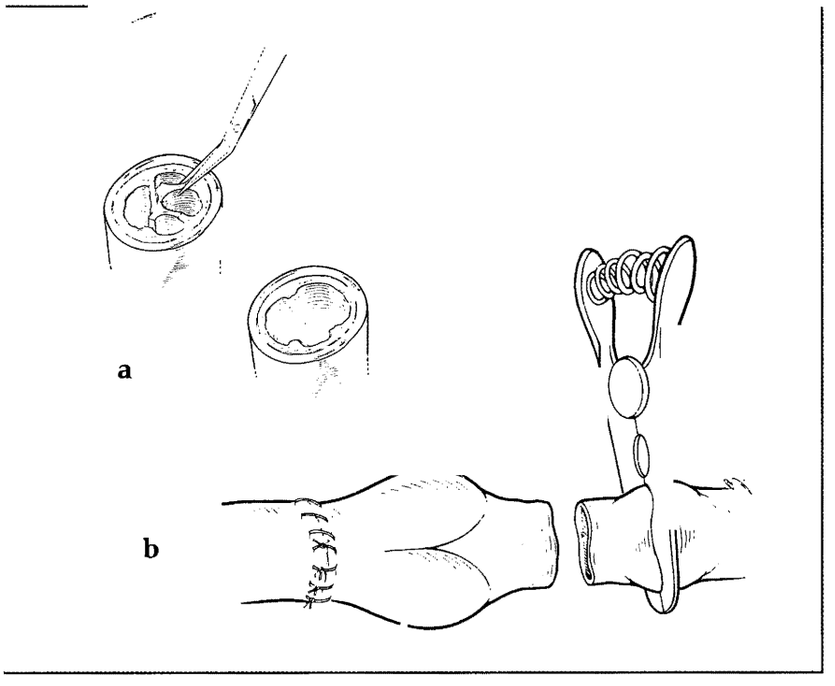

Figure 3. (a). Shows excision of intraluminal trabeculae to create a single lumen for anastamosis with axillary vein valve transplant (b). Note absence of leak with proximal clamp off due to functional valve. (By permission J Vasc Surg.*)*

SUMMARY

Viewed in terms of use prevalence, compliance, and consistent long-term use, compression therapy is a failure as a primary modality in the treatment of venous leg ulcers. Irregardless of "primary" or post-thrombotic etiology, severity of venographic appearance, or underlying pathology (reflux, obstruction, or combination), most patients with venous leg ulcers can be helped by one or more of the surgical techniques reviewed above. Many of the newer surgical options are minimally invasive, and can be carried out on an outpatient basis with very low risk. Successful surgery results in rapid healing of the leg ulcer and frees the patient from the daily tyranny of support stockings without ulcer breakdown. Most patients with venous leg ulcers are cared for by nonsurgical

both "primary" and postthrombotic disease appears to have been underestimated. In our experience, this procedure alone has resulted in actuarial ulcer healing in about 62% of limbs so treated (2-year follow-up). Actuarial curves show no signs of decline at this time, and cautious optimism for long-term favorable outcome appears warranted. As venous ulcers are generally considered a byproduct of reflux rather than obstruction, these results highlight the complex pathophysiology involved, which are as yet only poorly understood. Furthermore, significant relief of pain and swelling appears to accompany ulcer healing. Patients in our clinic are actively encouraged to abandon use of support stockings if desired, after the initial postoperative period. Most have done so or use stockings only on an intermittent basis on stressful days.

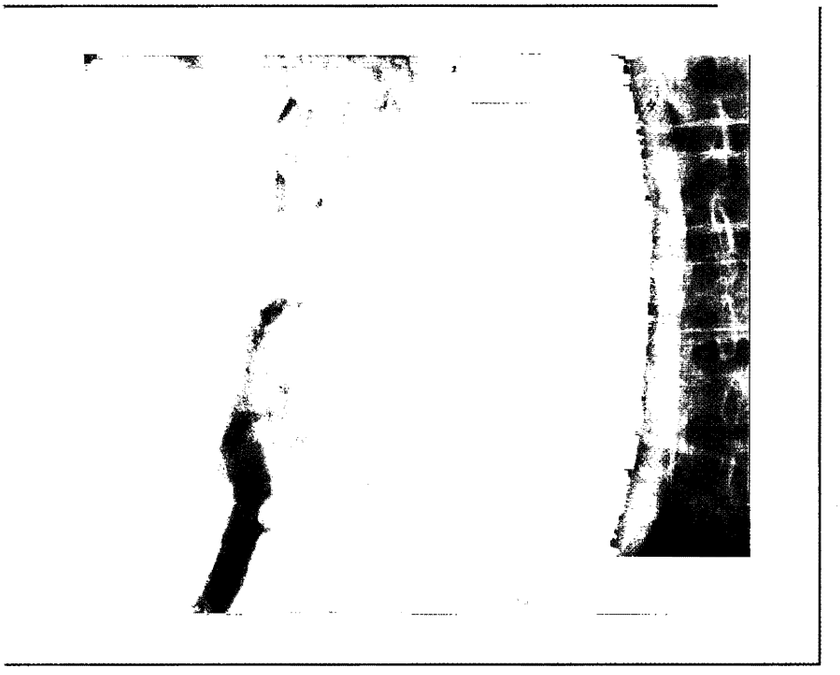

Figure 4. Recanalization of occluded vena cava by stents extending from pelvis to the right atrium. The patient presented with leg ulcer, pain, and swelling, all of which were promptly relieved after placement of the stent. Current follow-up is 8 months. There were no signs of hepatic or renal dysfunction either before or afterwards.

specialist or primary care physicians. Because of the undeserved reputation of support stockings as the "gold standard," it continues to be used as the primary therapeutic modality in many patients at the present time, without the benefit of the remarkable recent advances in the surgical arena. Long-term outcome for these patients will be vastly improved if a multidisciplinary approach to the treatment of venous leg ulcers is adopted.

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