Regarding “Subfascial endoscopic perforator vein surgery combined with saphenous vein ablation: Results and critical analysis”

I read with interest the article by Bianchi et al (J Vasc Surg 2003;38:67-71). Their data confirm the finding that subfascial endoscopic vein surgery (SEPS), combined with saphenous vein ablation, results in shorter and durable healing of leg ulcers. However, there appear some confusing or alarming statements in the Results section:

1. “The SEPS procedure was uniformly performed in all cases as described previously.”
2. “A mean of 3 (range, 1-7) perforating veins were ligated and divided at surgery.”
3. “Perioperative complications occurred in 12 limbs (16%) and included wound infection (7 limbs), subfascial hematoma (3 limbs), abscess (1 limb), and superficial thrombophlebitis (1 limb). All complications occurred in limbs with C6 disease ($P = .04$).”

Regarding these three statements, I found the first two confusing, and the third alarming.

In fact, the first statement is wrong since, at least in the first 23 patients, SEPS was performed without accessing the deep posterior compartment. This suggests that in these cases incompetent perforating veins were certainly missed. In fact, in the second statement the authors affirm that only a mean of three (range 1-7) incompetent perforating veins were found and interrupted.

The third (and, from my point of view, alarming) statement regards the unacceptably high rate of complications—more than 20%! if we consider only limbs with C6 disease. Overall, the high rate of infection for a “clean” surgical intervention (since the incision for the single port access is remote from the ulcer areas) should be regarded as a contraindication to the surgical treatment of C6 chronic venous insufficiency patients. Then, one could indicate for these patients medical treatment of the ulcers to be administered prior to surgery.

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REFERENCE


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Reply

We appreciate Dr. Rulli’s comments and hope the following will answer his queries:

1. The term “uniformly performed” meant only that subfascial endoscopic perforator vein surgery (SEPS) was performed by using a single port, open scope technique. We understand how one could be confused with that word choice since the deep posterior compartment was not accessed in the first 23 cases. Some incompetent perforating veins (IPVs) could have been missed by not exploring the deep posterior compartment. On the other hand, despite thorough exploration we sometimes find no IPVs to ligate in the deep posterior compartment.
2. Therefore, the number of ligated IPVs were reported as such.
3. We do not consider the SEPS procedure to be “clean” in the setting of an active venous ulcer and, as expected, the overwhelming majority of complications were superficial wound infections. We do not consider the threat of superficial wound infection to be a contraindication to surgical treatment. The other complications occurred early in our experience with the procedure, and now it is extremely unusual to have anything other than an occasional superficial wound infection complicate a SEPS procedure.

Thank you for the opportunity to clarify those issues.

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Regarding “Venous reflux repair with cryopreserved vein valves”

The timely article by Neglén and Raju (J Vasc Surg 2003;37: 552-7) describes their experience in treating deep venous reflux with cryopreserved vein implantation because repair with autogenous vein was not possible. They noted that, in a large number of patients with thrombophilia, the transplanted cryopreserved vein became occluded despite aggressive anticoagulation therapy. We were surprised that 74% of the supplied cryovalves were incompetent when thawed, requiring transcommisural repair before implantation.

To treat primary incompetence of the common femoral vein, we have used glutaraldehyde-preserved bovine pericardial monocusp patches, and more recently cryopreserved monocusp patches made from allograft pulmonary arteries. Even though these patients were not “thrombosis prone,” none of our repairs has thrombosed. The fundamental difference between our approach and that of Neglén and Raju is that we retain the posterior aspect of the patient’s own vein. This concept originated after we repaired femoral veins damaged during extracorporeal membrane oxygenator support by patching them with polytetrafluoroethylene. Those repairs in which the posterior aspect of the patient’s vein was retained remained patent without thrombosis. Patency was confirmed at duplex scanning and venography.

In patients with primary reflux in whom we have implanted glutaraldehyde-preserved monocusp patches of bovine pericardium or cryopreserved allograft pulmonary arteries, we do not use warfarin anticoagulation therapy. Our maintenance regimen is 75 mg of clopidogrel and 81 mg of aspirin, after a loading dose of 300 mg of clopidogrel. This is clearly an indicator that our group of patients is quite different from the “thrombosis-prone” patients described by Neglén and Raju.

It is important to note that the cause of venous ulceration was primary in more than 95% of our patients, which is different from what was noted in other reported series, in which there is a prevalence of deep venous valvular insufficiency secondary to venous thrombosis. Use of our technique for treatment of secondary deep venous valvular insufficiency will probably require a radically different type of anticoagulation protocol to overcome the tendency for development of thrombosis.

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REFERENCES

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Reply
We read Dr García-Rinaldi’s letter with interest, and are familiar with his report published in 2002. In his letter, Dr García-Rinaldi points out the fundamental difference in the patient populations that received treatment, which makes any comparison of patency and competency of the two techniques invalid. The monocusp patch is used in a group of patients with primary insufficiency with previous thrombotic events. In contrast, we attempted to control reflux in patients with severe thrombotic disease. Our group of patients is not only “thrombosis prone,” but the target vessel is severely diseased with thickened wall, often trabeculated lumen, and scarred, uneven endothelium. Retaining the posterior aspect of the patient’s own vessel wall might be prudent in nonthrombotic disease with smooth endothelium enabling good apposition of the monocusp, but it might prove inadequate in a postthrombotic vessel.

We recognize Dr García-Rinaldi’s excellent short-term results with the cryopreserved monocusp patch in primary disease, and look forward to evaluation of this technique when used to control reflux in postthrombotic disease.

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Regarding “Is there an increased risk for DVT with the VNUS closure procedure?”
In a letter to the Editor, Komenaka and Nguyen (J Vasc Surg 2002;36:1311) reported that deep venous thrombosis developed in 2 of 29 patients after varicose vein ablation with the VNUS closure device. This 6.8% incidence seems high, compared with the generally reported 0.8% to 1.3% risk for deep venous thrombosis with varicose vein treatment.1,2 The US Food and Drug Administration (FDA) approved the VNUS closure catheter in 1998 as “substantially equivalent to” seven older devices. Thus safety data based on results of trials in human beings for this class II approval were not submitted. The closure device generates interest for improving conventional varicose vein surgery, but, in the absence of controlled trials, reports of its advantages seem premature.3 The FDA Manufacturer and User Facility Device Experience Database (MAUDE)4 presently includes 20 reports of serious adverse events after use of this device. As a result of gross underreporting, the FDA estimates this to represent less than 1% of actual serious adverse events occurring in clinical practice.

Only one report (5%) describes a manufacturing defect, whereas 19 reports (95%) involve deep vein thrombosis or ascending thrombosis. Three reports (16%) mention pulmonary embolism, but because of patients lost to follow-up, mortality could not be assessed. Most patients (n = 12; 63%) received anticoagulation therapy, with or without thrombectomy or saphenofemoral junction ligation. Faulty technique was reported in only two patients (10%); it is surprising that the procedure was declared successful, “irrespective of the thrombosis,” in nine patients (47%).

These reports in the MAUDE database raise substantial concern about the incidence of deep vein thrombosis after VNUS closure or radiofrequency ablation of varicose veins, which must be carefully addressed by the FDA and the manufacturer.

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REFERENCES

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Regarding “Carotid artery stenting: Analysis of data for 105 patients at high risk”
I read with interest the article by Hobson et al (J Vasc Surg 2003;37:1234-9) regarding carotid artery stenting (CAS). I believe the article makes a further, important contribution to evaluating this procedure.

The article suggests some concerns about CAS. The technique involves some issues that must be debated, including indications, cerebral protection, and immediate and long-term results.

I would like to focus on indications for the technique. Hobson and colleagues suggest that CAS can be used in patients at poor or high surgical risk, including those with concomitant morbid conditions, recurrent stenosis, stenosis after cervical irradiation, and anatomic features of carotid stenosis.

From this point of view, CAS is an alternative to carotid endarterectomy (CEA), and the two should be compared. In comparing these procedures, we must take into account the current results of CEA. I agree with Hobson and colleagues regarding preference for CAS in patients with post-irradiation stenosis and recurrent stenosis. As stressed by the authors, CEA results for recurrent stenosis were not as good as for primary stenosis. To indications for CAS, I would add carotid stenosis with some anatomic characteristics, for example, stenosis involving the distal extracranial internal carotid artery. When considering CAS in the subgroup of patients with comorbid conditions, I believe some caution is needed. In the report by Hobson and colleagues, CAS was followed by complications in 2.85% of patients. After noninvasive diagnostic testing, including duplex scanning and, in some cases, multisection computed tomography angiography or magnetic resonance imaging angiography, CEA can be performed with the patient under local anesthesia. This avoids complications caused by arteriography, which is necessary for CAS and was responsible for complications in 4.7% of patients. Local anesthesia has significant advantages over general anesthesia, such as capability of neurological monitoring, lower incidence of stroke, stable cardiovascular condition,2 and better cerebral perfusion during carotid artery occlusion.3

These observations are supported by experience at our institution.4 The cumulative incidence of perioperative stroke and mortality was 0.7% in a series of 147 patients with symptomatic or asymptomatic stenosis who were operated on under local anesthesia. This series included numerous patients with comorbid condi-