Initial experience with minimally invasive in situ bypass procedure with blind valvulotomy

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Objective: The in situ vein (ISV) bypass is uniquely suited to technical modifications designed to reduce the wound morbidity of infrapopliteal revascularization. A technique of “blind” valvulotomy and selective vein branch ligation was used, and a preliminary study was performed to assess safety and efficacy.

Methods: From November 1998 to July 2001, all patients for infrapopliteal bypass procedures underwent evaluation for inclusion in the study. Thirty-five patients underwent ISV bypass procedures with an expandable, self-centering valvulotome (ESV). Intraoperative selection of veins suitable for the study was assisted with venography and duplex scanning. The ISV bypass procedures were performed with initial groin and distal incisions, with smaller incisions to ligate significant arterial branches or valves. The ESV bypass procedure is suitable for use in the ESV for blind valvulotomy, with excellent patient selection criteria and operative technique. Preliminary study warrants further study to refine patient selection criteria and operative technique to better clarify the natural history of residual AVF.

Results: Thirty-seven ISV grafts were performed from the common femoral artery to the popliteal (n = 14), tibial (n = 20), and dorsalis pedis (n = 3) arteries. In 35 cases (95%), a full-length incision was avoided. With ESV, all valves in 34 cases (96%) were effectively lysed. Proximal extension of the distal incision was performed in four cases (10.8%). The mean number of incisions per case was 3.1 ± 1.7. One graft failed within 30 days (2.7%), with successful revision. During the early follow-up period (9.9 ± 7.3 months; range, 1 to 33 months), 44% of residual AVF closed spontaneously (15 of 34 AVF; 16 patients) and two anastomotic stenoses and two symptomatic AVF were corrected surgically. Four late graft occlusions occurred, with a 1-year cumulative primary patency rate of 77% and a secondary patency rate of 92%.

Conclusion: Blind valvulotomy with ESV facilitates safe and effective minimally invasive ISV bypass. Resultant graft patency rates appear comparable with results with open techniques. This preliminary experience warrants further study to refine patient selection criteria and operative technique to better clarify the natural history of residual AVF. (J Vasc Surg 2002;35:1100-6.)

Since its introduction by Hall in 1962,1 in situ bypass with greater saphenous vein (GSV) has been shown to be a durable strategy for treatment of lower limb arterial disease.2-4 However, conventional infrapopliteal in situ bypass may be associated with an 85% incidence rate of vein injury and an 18.9% incidence rate of residual competent valves.5-8 In this study, we examined an expandable, self-centering valvulotome (ESV) that was designed to provide constant yet atraumatic contact with the vein wall. Herein, we describe the preliminary results of a strategy for minimally invasive infrapopliteal in situ bypass with the ESV for blind retrograde valvulotomy.

METHODS

From November 1998 to July 2001, patients for infrapopliteal arterial reconstruction who had ipsilateral GSV underwent evaluation for inclusion in a protocol to assess the use of blind valvulotomy for in situ ISV bypass. Selection criteria included GSV of adequate length to reach the distal target artery, uniformly adequate undistended vein caliber of more than 3.0 mm determined with supine duplex ultrasound scan or intraoperative venogram results, and absence of abnormalities that cause angulation and tortuosity of the dominant vein channel. The 2.7 mm-diameter or 2.0 mm-diameter Lemaitre ESV (Vascutech, Burlington, Mass) used in this study was designed with four spring-mounted cutting blades oriented at 90 degrees for retrograde valvulotomy. All patients underwent preoperative aspirin therapy (81 to 325 mg/day), which was continued indefinitely after surgery.

Study data were recorded prospectively and analyzed retrospectively. Data included patient characteristics, indi-
cations for operation, intraoperative variables, such as number of incisions, technical feasibility, and details of valve lysis and vein branch/arteriovenous fistula (AVF) ligation. Postoperative information included wound morbidity and other complications, LOS, persistent AVF, and graft patency as assessed with serial duplex ultrasound scan study and clinical follow-up examination. Duplex ultrasound scan examinations were routinely scheduled 1 month after surgery, at three monthly intervals for the 1st year and at six monthly intervals thereafter. Findings of reduction in overall graft flow velocity to less than 40 cm/s or regions of increased peak systolic flow velocity to a ratio more than 3.5 compared with the adjacent vein were reasons for further evaluation with arteriography.

Patients were declared lost to follow-up examination if no patient contact had occurred within 12 months. Limb salvage was defined as freedom from major amputation through the calf or thigh. Primary patency rate was defined in accordance with suggested reporting standards of the Ad Hoc Committee of the Society for Vascular Surgery and the North American Chapter of the International Society for Cardiovascular Surgery. Thus, reoperation for AVF ligation was not included in calculations of patency and reoperation for anastomotic stenosis was included. Cumulative graft patency was calculated with the life table method, with standard errors calculated with the Greenwood method. Continuous variables were compared with Student t test. Mean ± standard deviation values are reported. A P value of less than .05 was considered statistically significant.

Operative technique. Intraoperative selection of suitable veins was made with transcutaneous and direct palpation and visual inspection, assisted with supine venography and duplex ultrasound scanning. When venography was used, the distal end of the GSV was exposed at the ankle and a 20-gauge catheter was inserted and secured. A radiopaque measuring marker (Vascutech) was secured to the leg adjacent to the course of the GSV. Full-strength iodinated contrast material (30 to 50 mL) was hand injected via the distal catheter to obtain images of the vein from distal calf to mid thigh level. A groin incision was made to mobilize the proximal GSV and common femoral artery. The distal GSV and target artery were exposed through the calf or thigh.

The distal GSV then was ligated and divided, followed by gentle dilation of the vein with infusion of heparinized saline solution containing papaverine hydrochloride. The ESV then was introduced through the distal end of the GSV and passed proximally to the level of the proximal anastomosis. The cutting blades were deployed, and the device was slowly withdrawn to just above the end of the GSV. The cutters were resheathed, and the ESV again was advanced to the proximal anastomosis. After rotation 45 degrees, the cutters were deployed and the device was withdrawn and removed after resecting just above the distal end of the vein. The Mills valvulotome then was used to fracture remaining valve leaflets in the distal GSV. The end of the vein was occluded with a bulldog clamp. Sterile continuous wave Doppler scan then was used to survey the proximal vein for AVF, with a technique previously described. Branches that caused flow through-out diastole were defined as significant and were exposed through existing incisions or through short longitudinal incisions and ligated. Branches that did not cause pandiastolic flow were marked at the skin level with a skin staple. The bulldog was released from the end of the vein. If pulsatile flow emerged at a vigorous rate, no further instrumentation was performed. If poor flow existed, the ESV was passed once again to lye residual valve leaflets. The vein was occluded once again, and the distal anastomosis was created with tourniquet inflow occlusion. Continuous wave Doppler scan then was used to repeat the survey of previously marked or new AVF, once again ligating any AVF that allowed pandiastolic flow. When available, duplex ultrasound scan was used to assist in review of the vein and anastomotic regions. Completion angiography was routinely performed with 30 to 50 mL of full strength contrast via a 20-gauge catheter inserted into the proximal vein graft. Any residual AVF that caused prompt filling of the deep venous system was exposed and ligated. Any technical imperfections, strictures, or suspicious lesions that suggested residual valve leaflets were addressed and revised as necessary. Wounds were closed with subcutaneous absorbable suture and skin staples.

RESULTS

Thirty-seven in situ infrainguinal graft procedures with ESV were performed in 35 patients. The study consisted of 22 male and 13 female patients with a mean age of 68.5 ± 13.4 years. Patients had the expected risk factors for ath erosclerotic disease and its systemic effects (Table I). Indications for operation were disabling claudication (n = 3), rest pain (n = 8), and necrosis (n = 26). One patient had undergone a previous femorofemoral bypass procedure to the ipsilateral femoral artery, another had undergone a previous aortobifemoral bypass procedure, and a third had undergone adjunctive common femoral aneurysm resection and grafting. The only secondary reconstruction was in a patient who had a failed femoropopliteal prosthetic bypass but a GSV that was suitable for in situ bypass. The proximal anastomosis was constructed in the groin in all cases. The distal anastomosis was to the above-knee popliteal artery in four grafts, the below-knee popliteal artery in 10 grafts, the tibial vessels in 20 grafts, and the dorsalis pedis in three grafts.

The GSV was assessed during surgery with palpation and direct inspection, assisted with venography (n = 12), with duplex ultrasonography (n = 7), and with combined duplex scan and venography (n = 1). The ESV was passed
Table I. Characteristics of 35 patients who underwent in situ bypass procedures

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>22 (62.9%)</td>
</tr>
<tr>
<td>Female</td>
<td>13 (37.1%)</td>
</tr>
<tr>
<td>Mean age</td>
<td>68.5 ± 13.4 years</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>18 (51.4%)</td>
</tr>
<tr>
<td>Tobacco use</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>4 (11.4%)</td>
</tr>
<tr>
<td>Former</td>
<td>15 (42.9%)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>19 (54.3%)</td>
</tr>
<tr>
<td>Dialysis dependence</td>
<td>7 (20.0%)</td>
</tr>
<tr>
<td>Dyslipidemia</td>
<td>15 (42.9%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>25 (71.4%)</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>21 (60.0%)</td>
</tr>
<tr>
<td>No. of comorbidities</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>34.3%</td>
</tr>
<tr>
<td>4</td>
<td>34.3%</td>
</tr>
<tr>
<td>≥5</td>
<td>17.1%</td>
</tr>
</tbody>
</table>

A mean number of 2.2 ± 0.5 times (range, 1 to 4) to provide pulsatile vigorous outflow from the end of the vein. A mean number of 2.4 ± 1.8 vein branches (range, 0 to 7) were ligated with selection criteria as described. In two grafts (5.4%), the valve cutters were inadvertently deployed within the hood of the proximal anastomosis, which resulted in a linear tear in the hood of the graft repaired with patch angioplasty in one case and in disruption of the anastomotic suture line repaired with a stitch in the other case. One patient underwent proximal extension of the distal incision to allow direct visualization of ESV valvulotomy when vein duplication was noted at the time of dissection of the distal GSV; the ESV cleared all valves in the exposed segment without incident. In five instances (13.5%), the incision was lengthened to provide wider exposure of the vein for investigation of poor flow through the graft after ESV valvulotomy. The entire vein was exposed through a continuous incision in two cases. In both instances, the vein was found to be less than 3.5 mm in diameter and use of a Mills valvulotome to lyse residual valve leaflets resulted in satisfactorily improved flow. In two cases, the Mills valvulotome detected no unlysed valve leaflets, but an AVF was found and ligated with satisfactory improvement in flow. In the third case (patient TB), the Mills valvulotome encountered one residual uncut valve located at a slight angulation in the vein and missed with the 2.0-mm ESV. With exclusion of the two cases that were converted to full-length leg incisions, the mean number of incisions was 3.1 ± 1.7 per bypass. Measurements of skin incision length compared with preserved intervening skin were made in nine patients, with an average of 50% (range, 40% to 61%) of the distance between the proximal end of the groin incision and the distal end of the distal incision remaining uncut. Mean operating time was 221.6 ± 50.4 minutes.

One patient had calf wound debridement at the time of bypass, followed by interval skin grafting during the same hospitalization. Six patients underwent toe amputations in conjunction with the revascularization procedure. One patient with a patent femoropopliteal in situ bypass needed a pedal extension 6 days later to augment perfusion to toe amputation sites. No patient underwent below-knee or above-knee amputation during the perioperative and follow-up periods.

Two deaths (5.4%) occurred within 30 days of surgery, one from myocardial infarction at 3 days and one from ischemic colitis at 21 days. Major morbidity occurred after three procedures (8.1%): nonfatal myocardial infarction in two instances and readmission for lower gastrointestinal bleed as the result of coagulopathy and diverticulosis in one case. Deep groin wound infections necessitating antibiotics and dressing changes occurred after three procedures (8.1%). Mild incisional erythema treated with oral antibiotics alone was noted after three additional procedures. No instances of “flap” necrosis or graft revision for exposed conduit were seen. Two patients had a pattern of noninvasive linear erythema and induration representing phlebitis of a subcutaneous GSV side branch. One bypass had distal occlusion (see subsequent) within 30 days of surgery, for an early postoperative graft failure rate of 2.7%.

Overall mean hospital LOS was 9.7 ± 6.6 days (range, 3 to 29 days), with a mean postoperative LOS of 8.2 ± 6.2 days (range, 3 to 29 days). All patients were ambulatory at discharge; 18 patients (49%) were discharged to a rehabilitation facility and 17 patients (46%) were discharged directly home. With exclusion of the two patients who died before discharge, mean postoperative LOS after surgery for claudication or rest pain (n = 11) was 5.2 ± 1.7 days (range, 3 to 8 days) compared with 9.2 ± 6.7 days (range, 4 to 29 days) after surgery for necrosis (ulcer or gangrene; n = 24; P = .01). Exclusion of the three patients who needed postoperative bypass revision, AVF ligation, or skin grafting reduced the mean postoperative LOS to 6.5 ± 3.4 days (n = 32; range, 3 to 17 days). Additional exclusion of the two patients with myocardial infarction reduced the mean postoperative LOS further to 5.9 ± 2.2 days (n = 30; range, 3 to 14 days).

The mean follow-up period of the 35 operative survivors was 9.9 ± 7.3 months (range, 1 to 33 months), with data available on 31 patients (89%) within 12 months of reporting. At duplex ultrasound scan 1 to 3 months after surgery, 34 AVF were identified in 16 limbs (45.7%) among the 35 patients who survived surgery (Table II). By the follow-up examination at 4 to 18 months after surgery, 15 of the AVF (44%) had spontaneously closed. Of the remainder, seven remained patent in six patients with no significant symptoms or objective clinical signs. Ten AVF were ligated at a mean interval of 4 months. A bothersome thrill was the indication for ligation of two AVF in one patient, and three asymptomatic AVF were ligated incidental to graft revision for neointimal hyperplasia in two patients. Two new AVF were noted within 8 days after surgery in a patient with a patent bypass and ankle-brachial index of 0.43, with ligation resulting in change of ankle-brachial index to 0.53. Finally, three AVF were found 3 weeks after surgery in a patient whose distal femoropopliteal graft...
occluded with preservation of the graft to the knee level by virtue of fistula flow. The distal vein had been found angulated and of small caliber at the time of bypass with the 2.0-mm ESV. Ligation of the AVF and replacement of the distal segment with an end-to-end vein interposition to the same outflow anastomosis resulted in reocclusion within 1 day, necessitating successful repeat surgery with a vein interposition graft to the anterior tibial artery.

The 1-year cumulative primary patency rate was 77% ± 8%, with the exclusion of reoperations for AVF ligation. Two grafts had three patch angioplasties for anastomotic stenosis detected at 6 weeks and 8 months. One graft had vein interposition at 5 months for a short stricture adjacent to a reincised valve cusp (patient TB) in the distal portion of the bypass. Including these three revisions for stenosis, the cumulative 1-year primary-assisted patency rate was 89% ± 6%. Five grafts occluded during the follow-up period (Table III), with one revision yielding a cumulative secondary patency rate of 92% ± 5% at 1 year. In addition to the two early postoperative deaths, four patients died during the late postoperative follow-up period.

DISCUSSION

These preliminary data suggest that blind valvulotomy in conjunction with a Doppler scan-based protocol for identification of potentially hemodynamically significant AVF may be a safe and effective technique for minimally invasive in situ infrainguinal bypass. Vein injury was detected in two of 37 vein grafts (5.4%), with both injuries resulting from a deployment of the cutting head within the hood of the proximal anastomosis. This compares favorably with previously reported rates of vein wall injury during blind valvulotomy ranging from 17% to 85%. Minor intimal defects that were counted in previous studies with completion angioscopy may have been missed with the present strategy with duplex scan, angiography, and Doppler ultrasound scan to assess the completed vein graft. More significant intimal disruptions leading to longer hyperplastic stenoses were not noted on routine follow-up duplex scanning or angiography when performed for patients with significant duplex scan findings. In the case of one patient whose graft occluded at 3 weeks after surgery, the ESV and

### Table II. Natural history of 34 AVF in 16 patients

<table>
<thead>
<tr>
<th>Patient</th>
<th>Distal anastomosis</th>
<th>Postoperative AVF</th>
<th>Follow-up interval</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>JB</td>
<td>Popliteal</td>
<td>3</td>
<td>20 months</td>
<td>Unligated, asymptomatic</td>
</tr>
<tr>
<td>MR</td>
<td>Tibial</td>
<td>2</td>
<td>2 months</td>
<td>2 ligated during revision of distal anastomosis</td>
</tr>
<tr>
<td>PR</td>
<td>Tibial</td>
<td>3</td>
<td>13 months</td>
<td>1 spontaneous closure, 2 ligated for bothersome thrill</td>
</tr>
<tr>
<td>AC</td>
<td>Peroneal</td>
<td>2</td>
<td>1 week</td>
<td>Ligated for postoperative ABI 0.45; increased to 0.58 after ligation</td>
</tr>
<tr>
<td>MH</td>
<td>Tibial</td>
<td>1</td>
<td>11 months</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>JM</td>
<td>Peroneal</td>
<td>1</td>
<td>1 month</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>EG</td>
<td>Tibial</td>
<td>3</td>
<td>7 months</td>
<td>1 spontaneous closure, 2 unligated, asymptomatic</td>
</tr>
<tr>
<td>JH</td>
<td>Tibial</td>
<td>1</td>
<td>6 months</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>HS</td>
<td>Tibial</td>
<td>3</td>
<td>12 months</td>
<td>2 spontaneous closure, 1 unligated, asymptomatic</td>
</tr>
<tr>
<td>FO</td>
<td>Popliteal</td>
<td>3</td>
<td>4 months</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>FB</td>
<td>Tibial</td>
<td>2</td>
<td>5 months</td>
<td>1 spontaneous closure, 1 ligated during jump graft revision of distal vein graft stricture</td>
</tr>
<tr>
<td>CG</td>
<td>Popliteal</td>
<td>1</td>
<td>6 months</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>BC</td>
<td>Tibial</td>
<td>3</td>
<td>5 months</td>
<td>Spontaneous closure</td>
</tr>
<tr>
<td>WM</td>
<td>Peroneal</td>
<td>3</td>
<td>1 month</td>
<td>Provided proximal runoff for distally occluded vein graft</td>
</tr>
<tr>
<td>MC</td>
<td>Popliteal</td>
<td>2</td>
<td>3 months</td>
<td>Unligated, asymptomatic</td>
</tr>
</tbody>
</table>

**ABI**, Ankle-brachial index.

### Table III. Features of occluded infrainguinal in situ bypasses

<table>
<thead>
<tr>
<th>Patient</th>
<th>Distal anastomosis</th>
<th>Time to failure</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>MW</td>
<td>Distal popliteal</td>
<td>20 months</td>
<td>Lost inflow from previous femorofemoral bypass; no redo after graft failure, no amputation at 30 months</td>
</tr>
<tr>
<td>JH</td>
<td>Posterior tibial</td>
<td>15 months</td>
<td>Severely diseased runoff vessel; graft without stenosis at 5 months; new femoral-peroneal bypass with composite arm and leg vein</td>
</tr>
<tr>
<td>FS</td>
<td>Posterior tibial</td>
<td>6 months</td>
<td>Converted to full-length incision at first operation because of small vein/missed valves/AVF; wound dehiscence at ankle; duplex scan without significant graft disease at 2 months; new femoral-plantar bypass with nonreversed vein patent at 5 months</td>
</tr>
<tr>
<td>WM</td>
<td>Peroneal</td>
<td>3 weeks</td>
<td>Extended distal incision at first operation because of small, angulated vein; proximal vein patent via runoff through AVFs, distal vein occluded; first redo (jump graft from midvein graft to peroneal); failed in 1 day, second redo midvein graft to anterior tibial artery with arm vein, patent at 4 months</td>
</tr>
</tbody>
</table>
Mills both were passed across an angulation at the narrowed distal vein, leading to speculation that intimal injury not apparent on the completion angiogram may have contributed to this early graft failure.

The efficacy of this approach for blind valvulotomy is supported with a 30-day graft failure rate of 2.7% and a 1-year primary patency rate of 77%, comparable with the range reported for other techniques of in situ bypass.\(^2\)\(^4\)\(^23\) No residual valves were noted on completion studies, with the inclusion of five grafts in which poor flow prompted adjunctive use of a Mills valvulotome. In one case in which the distal incision was extended and the Mills valvulotome found a valve cusp just above an angulation, and in the two cases that were converted to full-length incisions and Mills valvulotomy, the vein caliber was noted to be less than 3.5 mm in the segments harboring uncut valve leaflets. This limitation of valvulotome function may be corrected with subsequent versions of the ESV that possess a smaller housing for the cutting blades.

Evidence suggested causes of failure were possible valvulotomy injury to small angulated vein at 3 weeks, small vein and distal wound dehiscence/infection at 6 months, poor anterior tibial runoff at 15 months, and loss of femorofemoral inflow at 20 months, and no suggestive evidence was seen in one instance of occlusion at 4 months. A previous study of graft failure after in situ bypass has reported 9.8% contribution with valvulotome injury to overall nonocclusive stenosis and occlusion in a large series.\(^24\)

Although the exact cause of graft failure in this smaller pilot study is indeterminate and likely to be multifactorial, no suggestion exists of an untoward increase in valvulotome-related graft failures from the collected clinical data. A longer follow-up period would help clarify this point.

Overall graft failure also does not appear to be significantly influenced by residual AVF that are inherent to the protocol presented in this study. A spontaneous closure rate of 44% was found during the mean follow-up period of 9.9 ± 7.3 months, similar to that seen by other researchers.\(^25\)\(^26\) Of the two patients who underwent reoperation for ligation of AVF, only one was noted to have a hemodynamic decrement from persistent fistulae. Previous work also has noted that AVF have no correlation with graft failure or clinical symptoms of ischemia.\(^27\) Some researchers have suggested that AVF may even enhance patency.\(^26\) Indeed, in the case of the one patient who had distal occlusion of the vein graft, with the cause of failure postulated to be related to possible valvulotome injury plus angulation and small caliber of the vein, that the proximal vein conduit patency was maintained with outflow to two residual AVF is interesting to note. This patent proximal vein graft then was able to be used for the jump graft revision. In addition, one patient had an AVF that incidentally preconditioned a large arterialized vein branch, which then was conveniently used as an interposition graft when a focal stricture of an already small distal vein necessitated revision. Further work is necessary to characterize the relationships between anatomic size, physiologic flow, and natural history of AVF and their relevance to graft function.

The limitations of this technique for minimally in situ bypass relate to the selection of suitable vein, with an initial requirement of the presence of an adequate ipsilateral GSV, a criterion not satisfied in as much as 23% of patients.\(^28\)

Which method, venography or duplex scanning, is better at verification of the adequacy of vein size (>3.5 mm) and quality (absence of angulation or duplication) is unclear. A new smaller (1.8-mm) cutting head for this ESV also might possibly make smaller veins eligible for blind valvulotomy. Interesting to note, however, is that even in this pilot study, which included the learning curve for the technique, in which there might be a lower threshold for reversion to the conventional open technique, there was a conversion rate of only 5.4%. The combination of ESV with direct valvulectomy of the most proximal valve and Mills valvulotomy of the distal most vein conduit helps maintain the method as minimally invasive yet effective at safely rendering valves incompetent.

The wound morbidity rate of this approach appears to be an improvement on previous reports after conventional in situ bypass.\(^5\)\(^6\) In addition, this technique may avoid the additional expense of angiographic or duplex scanning equipment. The protocol of Doppler ultrasound scan for assessment of the vein for hemodynamically significant AVF, with selective ligation of these vein branches, makes this a potentially simple method. Data on hospital LOS as presented here may be more influenced with patient variability than the possible effects of minimized leg incisions on recovery after revascularization.

This study is primarily limited by the relatively short and variable length of follow-up period. Although these preliminary data are encouraging, further work is clearly needed to assess the longer term outcomes of this particular ESV device and the policy of leaving selected vein branches open at the time of surgery. A more complete hemodynamic assessment of effects of AVF during surgery (eg, Doppler scan flow volume measurements) would aid a prospective definition of important AVF. Further study, with a more standardized assessment of the ESV valve-saving efficacy, will also be needed to define the selection criteria for veins for which this ESV is appropriate. These preliminary results with a protocol for blind valvulotomy provide the rationale and impetus for further investigation.

REFERENCES


DISCUSSION

Dr Frank LoGerfo (Boston, Mass). I am trying to imagine what it is like to use this device. You do your proximal anastomosis and slide this up at that point, right?

Dr Sidhu Gangadharan. That is correct.

Dr Gangadharan. The standard protocol was to pass it once and then rotate it 45 degrees for the cutting blades to engage the vein at a slightly different angle. Whether it was passed an additional time or not was dependent on basically the squirt test from the end of the vein and what the flow was like after the large side branches were ligated.

Dr David R. Campbell (Boston, Mass). Thank you very much. I enjoyed this paper. I think, like many, I was alarmed by Dr Kronenwett’s revelation of Medicare data showing that for the first time in the history of vascular surgery in the last 5 years our amputation rate is going up, not down. Some have postulated this is due to age and other factors, though we have seen today some patients with very severe disease with good results. Others have noted that it is associated with increase of use of endovascular techniques, though that obviously cannot be proven and we also saw a paper today with no arteriography performed with a lower trauma rate than I would otherwise have done. Thank you.

Dr Gangadharan. We share your concerns with the possibility of endothelial injury with this device. We do not look at the inside of the vein with angiography, so our readout here will be whether valves were retained and whether there was gross injury to the vein and then indirectly what was the early graft failure rate and what was at least the early patency data. Going out to a mean follow-up period of 9.9 months, our patency data appear to be adequate, meaning that we are not seeing an intimal hyperplastic lesion that may have arisen from the injury caused by this valvulotome in this small series, but with bigger series, those numbers may indeed come out.

Dr Jack L. Kronenwett (Lebanon, NH). I have three questions. As you know, you can do a minimally invasive approach and still lyse valves with direct vision with an angioscope, without making a long incision. So, my first question is, what do you have against the angioscope?

I have found that the multiple incision approach tends to lengthen the procedure because of the difficulty in localizing small
venous side branches through small incisions. We had found that with preoperative vein mapping we have reduced our wound complication rate associated with one long incision because it is located accurately over the vein with no skin flaps. Have you noticed any increase in your procedure length and where the tradeoff is?

Finally, you reported that three grafts occluded distally but patency was retained because of a patent AVF. In your follow-up duplex scan surveillance, can you tell us that they did not occlude because of that fistula? In other words, was the fistula reducing the velocity in the distal graft prior to occlusion?

Dr LoGerfo. I am so glad that it was Dr. Cronenwett who asked the question about angioscopy and not I.

Dr Gangadharan. I will address the last question first. Just to clarify, only one graft was occluded distally with proximal patency. It was maintained by three AVF, and it is a good question. We do not know that the steal from those AVF did not contribute to the occlusion of that graft, but I can tell you that the revision of that graft subsequently did fail as well, which made us think that the cause was poor runoff. A subsequent complete revision to another runoff vessel remained open.

The question about the duration of the operation and whether it was difficult to localize these small venous side branches, I think we can look at in two ways. First, the average time of the operation was 220 minutes. In 12 cases, venography was used prebypass to localize the side branches, and in seven cases, duplex scan was used to prebypass localize these side branches, which means that in nearly half of the cases we just localized them with Doppler scan. Using that strategy, I think our overall operating time was within the realm of what we had with a complete open leg incision. The other aspect of that is that with this technique you are not obligated to ligate every single side branch and with that strategy in mind you can cut down on some of the operating time.

Regarding the first question about angioscopy, there is really no personal animosity, I believe, within the group against angioscopy, but this was offered as a potential method for folks that do not have angioscopy available or are desiring to try another technique that may be simple without learning and acquiring an angioscope.

Dr Richard Murphy (Concord, NH). We actually have been using this technique for a couple of years and have been very happy with it. I will share with you that I have given up trying to do selective ligation. I just do not have the patience and end up making a leg length incision and tying off fistulae.

My question pertains to your statement, because I am inspired to maybe try this again being selective. In the patients in whom you found fistulae after surgery, you said those were clinically significant. Could you expand on what criteria you use for determining what is a clinically significant fistula?

Dr Gangadharan. Of the patients that had postoperative revisions for decrease in graft flow or stenoses, those revisions were done for anastomotic stenoses. The clinically significant fistulae actually were clinically insignificant fistulae, meaning that in three patients they had fistulae ligated but those fistulae were not causing any clinically relevant symptoms, either a change in their symptomatology or a marked decrease in their follow-up duplex scan.

Dr Murphy. I guess that is what I am trying to get at. I assume you follow these grafts in the vascular lab. What vascular lab criteria do you use to evaluate these fistulae?

Dr Gangadharan. Unfortunately, with this retrospective review, we were unable to have the actual hemodynamic or any parameter like an ankle-brachial index to help guide us when looking at that specific issue. I think in the future when we investigate the significance of the AVF, we would like to have baseline ankle brachial indexes and additionally we would like to measure flow in the operating room to understand how much flow is going through the AVF and the degree through the persistent AVF and what effect that might have on the eventual outcome. We do not know those answers from these data.