Remote superficial femoral artery endarterectomy: Multicenter medium-term results

David Rosenthal, MD, Peter J. Schubart, MD, Edward V. Kinney, MD, John D. Martin, MD, Rashmi Sharma, MD, John H. Matsuura, MD, and Michael D. Clark, MD, Atlanta, Ga

Objective: The results of percutaneous transluminal angioplasty, atherectomy, and laser angioplasty for the treatment of long-segment (>10 cm) superficial femoral artery (SFA) occlusive disease have proved disappointing. Remote superficial femoral artery endarterectomy (RSFAE) is a minimally invasive procedure, performed through a single limited groin incision that may offer patency rates comparable with those of above-knee femoropopliteal (AKFP) bypass graft. In this retrospective multicenter study the medium-term results of RSFAE are examined.

Methods: Sixty patients were included in this study. Indications for the procedure were claudication in 52 patients and limb salvage in eight patients. RSFAE was performed with the MollRing Cutter device through a femoral arteriotomy. The distal “flip” of atheroma was anchored by balloon/stent angioplasty through the femoral arteriotomy. All patients underwent a follow-up examination with serial color flow ultrasound scanning.

Results: Ten patients with heavily calcified SFAs failed as “intentions to treat”; these patients underwent AKFP bypass grafting. The mean length of the endarterectomized SFAs was 22.3 cm (range, 8-37 cm). The primary cumulative patency rate by means of life-table analysis was 61.4% ± 9% (SE), (mean, 12.9 months; range, 3-36 months). During follow-up, percutaneous transluminal angioplasty was necessary in 14 patients, for a primary-assisted patency rate of 82.6% ± 8%. The locations of the restenoses after RSFAE were evenly distributed along the endarterectomized SFAs. There were no deaths and one wound complication (hematoma), and the mean hospital length of stay was 1.4 days ± 0.8 days.

Conclusions: RSFAE is a safe and moderately durable procedure. If long-term patency rates are similar to those of AKFP bypass graft, RSFAE may prove to be a minimally invasive adjunct for the treatment of SFA occlusive disease that will lower operative morbidity, reduce hospital LOS, and shorten recuperation. (J Vasc Surg 2001;34:428-33.)

In 1947, the Portuguese surgeon Cid Dos Santos performed the first successful “disobstruction” of an atherosclerotic superficial femoral artery (SFA) by removing the diseased inner layer of the artery wall. Dos Santos termed this procedure thrombendarterectomy. Since this initial report, the popularity of SFA endarterectomy has waxed and waned, but the technique was gradually abandoned in the United States because published reports indicated that above-knee femoropopliteal (AKFP) bypass graft offered patency rates that were superior to those of SFA endarterectomy.

The advent, however, of minimally invasive procedures, such as percutaneous transluminal angioplasty (PTA), laser-assisted balloon angioplasty, and atherectomy, the results of which have been disappointing in treatment of long-segment (>10 cm) SFA occlusive disease, stimulated a reassessment of SFA endarterectomy.

Two 1993 reports advocated a semiclosed endarterectomy technique in which a ring stripper was used that achieved patency rates similar to those of AKFP bypass graft. Although this procedure required two incisions, it avoided the use of prosthetic grafts or harvesting of the saphenous vein, which could be used for subsequent cardiovascular or peripheral reconstructions. With the development of the remote endarterectomy technique reported by Ho et al, a minimally invasive operation performed through a single incision in combination with endovascular stent or stent-graft placement was devised.

The purpose of this study was to examine the medium-term results of remote superficial femoral artery endarterectomy (RSFAE) in a retrospective multicenter study.

METHODS

Between March 1996 and October 2000, 60 patients underwent RSFAE as part of a retrospective multicenter study. The study centers and their respective number of RSFAEs were Atlanta Medical Center, Atlanta, Ga (16); O’Connor Hospital, San Jose, Calif (27); Baptist East Hospital, Louisville, Ky (8); and Anne Arundel Medical Center, Annapolis, Md (9). The indications for operation were claudication in 52 patients and limb salvage in eight patients. Forty-six patients were men, and the mean patient age was 66.2 years (range, 49-81 years). Twenty-eight patients (46.7%) had a history of cigarette smoking, 29 (48.3%) had hypertension, 26 (43.3%) had diabetes mellitus, and 21 (35.0%) had coronary artery disease.
The technique for RSFAE has been previously described by Ho et al\textsuperscript{10} and is illustrated in Fig 1. In summary, the common, proximal profunda femoral, and proximal SFAs are exposed through a small groin incision. After systemic heparin administration, a 3-cm arteriotomy is made from the origin of the SFA distally, and an endarterectomy is started between the inner and outer media. This intimal core is transversely cut at the SFA origin and threaded into the loop of a conventional (Vollmar) ring stripper. The ring stripper is advanced distally down the SFA beyond the occluded segment, the location of which has been determined with intraoperative arteriography and “road mapping.” The ring stripper is exchanged for the MollRing Cutter device (Vascular Architects, San Jose, Calif), which transects the distal atheroma core under fluoroscopic surveillance. The entire core is removed, and arteriography is performed to confirm a patent distal artery.

**Fig 1.** Diagram to illustrate current technique of remote endarterectomy. A, Endarterectomy has been performed with ring stripper (not shown) just distal to end of occlusion. B, MollRing Cutter passed to same position in endarterectomy plane (inset shows ring cutter closed). C, Ring cutter transects atheroma at chosen level (inset shows relative movement of rings). D, Atheromatous core removed proximally leaving free edge of cut atheroma. E, Diagrammatic representation of Palmez stent in position. (Reprinted with permission from Whiteley MS, Magee TR, Tarrie EP, Galland RB. Minimally invasive superficial femoral artery endarterectomy: Early experience with a modified technique. Eur J Vasc Endovasc Surg 1998;16:254-8.)

**Fig 2.** A, Arteriogram after RSFAE. Note distal “shelf” at endarterectomy end point. B, Balloon/stent angioplasty. C, Completion arteriogram.
Under fluoroscopic guidance, a guidewire is passed across the distal SFA endarterectomy end point, and balloon/stent angioplasty is performed, “tacking” the distal plaque to prevent further dissection (Fig 2). Completion arteriography verifies RSFAE patency and any outflow tract obstruction. Loose debris, visualized with arteriography, is removed with a Fogarty embolectomy or graft thrombectomy catheter (Edwards Lifesciences, Vascular Division, Irvine, Calif). The arteriotomy may be extended proximally to perform an open endarterectomy of the common femoral artery or profunda femoris ostia, as necessary.

Technical success was defined as any recanalization of an occlusive lesion on completion arteriography. All patients underwent clinical evaluation during the 30-day postoperative period with duplex color flow ultrasound scanning. The patients were followed up at 3-, 6-, and 12-month intervals and at 6-month intervals thereafter with color flow duplex ultrasound scanning. RSFAE patency was confirmed with duplex scan or arteriographic evaluation. The primary end point was any occlusion or radiologic or surgical intervention before occlusion. Cumulative primary- and primary-assisted patency rates were calculated with the actuarial life-table method based on the number of procedures performed (Fig 3). Because the study was retrospective in nature, all statistical analyses must be guarded.

RESULTS

Initial technical success was achieved in 57 (81.4%) of 70 cases. In three patients who underwent successful RSFAE, the guidewire could not be passed across the residual popliteal plaque, and the procedure was abandoned. In 10 other patients with heavily calcified femoral arteries, RSFAE could not be performed when the ring stripper could not be passed distally, and the patients were excluded from the study. All of the patients in whom RSFAE could not be performed underwent uneventful AKFP bypass grafting.

Therefore, the study group consisted of 60 patients who underwent RSFAE. The mean length of endarterectomized SFAs was 22.3 cm (range, 8-37 cm). In 32 patients, a common femoral artery and profunda femoris ostia endarterectomy was performed, also. Completion arteriography demonstrated SFA thrombus in five patients, which was successfully removed with a Fogarty balloon catheter. In two other patients, arteriography showed residual fractured plaque, which was removed with a Fogarty graft thrombectomy catheter. Three patients had extravasation of contrast at completion arteriography, but this was self-limiting and required no intervention. Thirty-nine of the 60 arteriotomies were closed with patch angioplasty (16 with autogenous vein and 23 with prosthetic patch material).

The primary cumulative patency rate by means of life-table analysis was 61.4% ± 9% (SE), (mean, 12.9 months; range, 3-36 months) (Table). Repeat radiologic intervention was necessary in 14 patients (9 PTA, 5 stent angioplasty), for a primary-assisted patency rate of 82.6% ± 8%. The locations of the stenoses after RSFAE included 6 that were over the course of the SFA and 4 at the adductor canal in long (>20 cm) endarterectomies, 2 at the SFA origin, and 2 at the distal stent. One below-knee amputation was performed during follow-up in a patient who was diabetic and dialysis dependent with gangrene of the forefoot. He underwent successful RSFAE, but amputation was necessary despite a patent SFA endarterectomy. There were no deaths and one wound complication (hematoma), and the mean hospital length of stay was 1.4 ± 0.8 days. The ankle/brachial indices rose from 0.61 (± 0.16) preoperatively to 0.97 (± 0.05) postoperatively.

DISCUSSION

RSFAE, in combination with popliteal artery balloon/stent angioplasty, offers the vascular surgeon a minimally invasive alternative to radiologic endoluminal procedures for the treatment of infrapopliteal occlusive disease. The disappointing results reported for long-segment (>10 cm) SFA occlusive disease with PTA, laser-assisted balloon angioplasty, and atherectomy led van der Heijden et al to reassess semiclosed endarterectomy because “debunking” of the SFA would hopefully improve patency. They reported
a technical success rate of 89% and a 5-year secondary patency rate of 61% in 259 SFA endarterectomies, which compares favorably with the results of conventional bypass operations. With this technique, a ring stripper was introduced through arteriotomies at the common femoral and above-knee popliteal arteries, and endarterectomy was performed. The distal popliteal artery plaque was “tacked” with sutures. The development by Ho et al 10 of the remote endarterectomy technique, performed through a single short groin incision in combination with distal plaque balloon/stent angioplasty, offered several advantages. It was minimally invasive, a second distal incision was avoided, and common femoral and profunda femoris ostial endarterectomy could be easily performed, as necessary. It avoided use of prosthetic material, it could be used in the absence of saphenous vein, and, alternatively, it allowed preservation of the saphenous vein for subsequent reconstructions in the cardiovascular or peripheral circulation.

The 12-month (74.9%) and 36-month (61.4%) primary cumulative patency rates in this study were similar to those reported by Ho et al 14 and were comparable with rates expected after AKFP bypass graft. Part of the “learning curve” of any new procedure is patient selection. In this study, patients with heavily calcified SFAs (ie, patients with renal failure) fared poorly and are likely not candidates for this procedure. The incidence, however, of stenosis formation after RSFAE was important in that 14 (23.3%) of 60 patients required an adjunctive procedure (9 PTA, 5 stent angioplasty) to maintain SFA patency. Although the incidence (23%) of early (<2 years) stenosis in this study, likely due to intimal hyperplasia, was less than that reported by Ho et al 11 (46% at 1 year) and by Galland et al 12 (69% at 15 months), the reason is unclear, but remains a major concern. The endarterectomized SFA, because of its long length, tortuosity, small caliber, and relatively low flow, may not be able to withstand exuberant intimal hyperplasia formation and arterial recoil. Interestingly, we observed that when an RSFAE failed, the patient’s symptoms were, in general, less severe than before the procedure, which may be due to “opening” of collaterals at the time of endarterectomy, or the benefit of an adjunctive profunda femoris endarterectomy in 32 patients. This remains to be proven.

Debulking and SFA endografting, however, may sufficiently obviate the problem of restenosis along the SFA to offer patency rates comparable with those of AKFP bypass graft. Nevertheless, information, on SFA endografting is limited. For example, polytetrafluoroethylene (PTFE) node size has been reported to be significantly smaller in dilated, thin-walled expanded PTFE grafts without change in internodal distance after dilation, and the healing mechanisms of high-porosity versus standard PTFE grafts are not understood. 13,14 The controversy surrounding the incidence of SFA endograft stenosis is interesting, because some authors 15–17 think the stent-graft limits formation of neointimal hyperplasia, whereas others think that the presence of an endograft accelerates neointimal hyperplasia formation.

REFERENCES

DISCUSSION

Dr. Stanley O. Snyder (Nashville, Tenn). In Nashville when we need someone dependable to do a good job, we give the ball to Eddie George. At the Southern Association of Vascular Surgery, when we need someone dependable, we give the data and the podium to president-elect David Rosenthal. Once again David has chosen an interesting clinical procedure and compiled an impressive number of cases for review. The concept of superficial femoral endarterectomy, though certainly not new, has been resilient for a number of years with numerous advocates and reasonable long-term patency results in patients with short segment disease. Dr. Jim DeWeese, an honorary member of our society, and his associates reported at our 1985 SAVS meeting in Palm Springs on 94 patients undergoing various open and semi-closed localized SFA endarterectomy procedures performed between 1980 and 1984 with a 7-year patency rate of 57%.

The concept presented today of a “remote” SFA endarterectomy for long-segment occlusive disease combined with endovascular techniques is attractive for its potential avoidance of prosthetic graft material. However, 23 arteriotomies were closed with prosthetic patches. It is also attractive for the fact that no bridges have been burned to prevent later, more distal reconstruction attempts. The primary cumulative patency of 69% at 36 months is impressively high but represents only a few patients with this follow-up at risk. In reviewing the manuscript (that impressively arrived several weeks ago), the follow-up tables were presented on only 60 patients, while 10 others were excluded as failed intention-to-treat secondary to calcified femoral arteries. I applaud Dr. Rosenthal and his colleagues for this presentation and for bringing this interesting procedure and data to our attention.

I do have three questions:

1. A high restenosis rate was noted with 14 of 60 patients requiring a later adjunctive endovascular procedure. Hø et al. recently reported in the July JVS issue that early elevation of peak systolic velocities after this procedure often return to normal with follow-up. What were your noninvasive criteria for intervention for restenosis?

2. Do you have any thoughts regarding the potential for radiation to help prevent restenosis, and what were your antiplatelet and anticoagulation regimens in these patients?

3. In three patients the procedure was unsuccessful because of the inability to pass a guidewire through the area of residual distal plaque. Did you consider an attempt to pass the guidewire retrograde from the popliteal approach, and is there any potential for disobliterating a short segment or midfemoral stenosis or occlusion with these techniques mentioned through a posterior popliteal approach, thus saving the groin for a later bypass procedure?

I would like to thank the society for the opportunity of reviewing this paper and the privilege of the floor.

Thank you.

Dr. David Rosenthal. Thanks, Stan. In the study protocol, the patients were followed up with postoperative duplex ultrasound at 3, 6, and 12 months and 6 months thereafter. We followed peak systolic velocities as you mentioned; some did indeed return towards baseline with vessel remodeling. More important, I believe, is the necessity to follow a restenotic lesion that progresses. If this occurred, we treated these lesions aggressively, and the patient underwent a percutaneous balloon or stent angioplasty procedure.

Your second question related to postoperative antiplatelet or anticoagulant regimens. The patients in this study were placed on antiplatelet agents—aspirin, Plavix, or Ticlid at the surgeon’s discretion—but not anticoagulants. Your question about radiation is intriguing. As you are aware, the interventional cardiologists are treating restenosed coronary arteries after angioplasty with a variety of beta and gamma radiation sources labeled onto a variety of catheters, balloons, and stents in the hope of inhibiting intimal hyperplasia. I have been involved with research in this area, labeling beta radiation emitting isotopes onto various backbone structures such as polypropylene, and I can tell you beta radiation inhibits intimal hyperplasia. This may prove to be a useful adjunct in remote endarterectomy and is something to look into.

Your last question, Stan, had to do with the popliteal approach to cross difficult plaque end points and the benefit of leaving the inguinal region virgin. If you are speaking about a percutaneous popliteal approach in order to pass a guide wire across distal plaque, this is not unreasonable. Dr. Galland’s group in England reported just such a technique in the European Journal of Vascular and Endovascular Surgery in 1996. They recommended this technique when they could not pass a guidewire after a remote endarterectomy from the femoral approach. They passed a guidewire under ultrasound surveillance through the popliteal approach in order to stent or balloon distal plaque.

I don’t think I would do a remote endarterectomy through a posterior popliteal incision, as it is more morbid than a simple cutdown over the femoral artery. Technically though you could do this procedure through a posterior popliteal approach for a midfemoral lesion. Interesting idea.

Dr. John A. Mannick (Boston, Mass). David, I enjoyed the paper. I have felt for a long time that there is a role for femoral endarterectomy, particularly in individuals who do not have suffi-
cient length of usable vein for a bypass graft, and I have had a modest personal experience with closed endarterectomy using the vibrating loop that the Zimmer Company produced some years back. We found, as you did, that there was a very high incidence of restenosis in the endarterectomized segment, but it always occurred early, and, as a surprise to us anyway, it responded very well to balloon angioplasty, which produced a very durable long-term result. Have you seen any late failures at the 2- and 3-year level when you have gone through your angioplasty procedure? Are these people as we have found relatively immune for stenosis for a long period of time, very much like an autogenous bypass? Again, I enjoyed the paper very much.

Dr Rosenthal. Thanks, John. Inherent in what you are saying is that when we have to intervene early (eg, within 2 years) we are describing an intimal hyperplastic lesion. These restenoses are more amenable to balloon or stent angioplasty than atherosclerosis and yield a more durable result. We did have late failures, but I cannot honestly tell you what caused the endarterectomies to fail. My guess is that the late failures occurred at the outflow tract, but I don’t have sufficient data to prove this.

Dr Mark Jackson (Dallas, Tex). What was the status of the limbs in the patients who occluded their SFA? Did you have any patients who developed any limb-threatening ischemia with either grade 2 or grade 3 ischemia?

Dr Rosenthal. As you saw from the indications for the procedure slide, I believe 52 of these patients were claudicants. An anecdotal finding of interest was that after a remote endarterectomy, at arteriography, we frequently see an exuberant collateral network that has reopened along the SFA. When the SFAs occlude at the outflow tract, you can see a portion of the artery remaining patent through geniculate collaterals. are maintained with this procedure. In general, when the patients occluded their arteries, they did not develop limb-threatening ischemia; they developed the same symptom they had before remote endarterectomy. One patient in the series had an amputation. This was a diabetic, renal failure patient who had a patent SFA at the time of amputation for gangrene of the foot that we could not salvage.

Do you recall that spiral-looking covered stent that I showed Mark? That was conceived by Tom Fogarty and is an intriguing concept as the stent will give the artery structural support, yet will not compromise the collaterals’ vessels. Time will tell if Fogarty is right once again, but my money is on him.

Dr George Meier (Norfolk, Va). David, I enjoyed that presentation very much. What I want to ask relates to where we are going with this. I have recently had a couple of conversations with Dr Moll relative to this topic, and he feels very strongly that relining the SFA is essential to long-term outcomes. I wondered, based on your experience, what your current position is relative to relining.

Dr Rosenthal. I think Franz Moll is right; however, you have a two-edged sword. The relining of the endarterectomized SFA with, for example, a PTFE stent-graft, may compromise your collateral vessels opened at endarterectomy, versus simply “tacking” plaque at the outflow tract with a stent and leaving the collaterals patent. The SFA is a different vessel from a high-octane, high-flow iliac artery, which, after balloon/stent angioplasty, will remain open. As vascular surgeons, we know better than anybody that the SFA is a low-flow, low-pressure system that angulates in a postero-medial plane as it goes toward the popliteal fossa. The SFA is unique among peripheral arteries, and I believe some form of supported conduit along the endarterectomized SFA will yield the best long-term results. Our colleagues in Europe are really the leaders in this area, and they are already evaluating various conduits.