The Efficacy of Percutaneous Transluminal Angioplasty in the Treatment of Infrainguinal Vein Bypass Graft Stenosis

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Hypothesis: Percutaneous angioplasty would provide a durable alternative to surgical revision in the treatment of infrainguinal vein graft stenosis.

Design: Outcome analysis of the results of percutaneous angioplasty of infrainguinal vein graft stenosis.

Setting: Academic vascular surgical practice in a university-affiliated community hospital.

Participants: All patients undergoing percutaneous intervention for infrainguinal vein graft stenosis from January 1, 1995, to May 31, 2002, were enrolled in the study.

Interventions: Lower extremity arterial reconstruction was performed by one of us. Proximal and distal sites of graft placement were identified, as well as the conduit used. Percutaneous angioplasty was performed on grafts by 1 of 4 interventional radiologists. Criteria for intervention and the anatomic location of intervention were noted. Morbidity from percutaneous intervention was also determined.

Main Outcome Measures: Success and durability of percutaneous angioplasty were determined by clinical follow-up, duplex surveillance, and arteriography. Failure was defined as duplex ultrasonographic or arteriographic documentation of stenosis of $75\%$ or greater. Kaplan-Meier life table analysis was applied to all grafts in the study.

Results: Ninety-four patients with 101 grafts were included in the study. Nearly 35$\%$ of angioplasties had failed at 6 months, 53.6$\%$ had failed at 12 months, 60.6$\%$ had failed at 24 months, and 75.1$\%$ had failed at 36 months. Comorbid disease, use of anticoagulant medications, criteria for intervention, or anatomic location of percutaneous intervention did not affect patency. Eight angioplasties ($7.9\%$) were associated with significant complications.

Conclusions: Percutaneous angioplasty does not provide a durable solution to the problem of infrainguinal vein graft stenosis. Because of the high rate of complications, its routine use cannot be advocated.

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ARTERIAL DISEASE of the lower extremity has been estimated to affect up to 10$\%$ of the adult population and may lead to significant morbidity if left untreated. Autogenous vein bypass grafting has proved to be an effective and durable method of treating infrainguinal occlusive disease. Unfortunately, vein bypass grafts have a definite attrition rate over time. Repeat revascularization following graft occlusion often requires complex and difficult reconstructive techniques to achieve limb salvage. It was postulated and later proved that patent but hemodynamically failing grafts could be salvaged if intervention was performed before graft occlusion.

The advent of postoperative surveillance by duplex ultrasonography has allowed lesions in vein bypasses to be identified and treated before graft occlusion. Many studies have demonstrated the efficacy and long-term success of surgical repair in the treatment of infrainguinal vein bypass graft stenoses. The use of percutaneous transluminal angioplasty (PTA) in the treatment of these lesions has been more controversial. Little consensus has been reached regarding the durability of this procedure, and few studies have documented the morbidity associated with its use. In our institution, PTA was used as the primary method of intervention in autogenous bypass grafts with documented stenoses. This study summarizes our experience with this treatment modality.
The records of all patients undergoing PTA of vein bypass graft stenoses at Huntington Memorial Hospital between January 1, 1995, and May 31, 2002, were reviewed. All grafts underwent duplex ultrasonography within 1 month of operation. Grafts were then enrolled in a routine surveillance program and were scanned every 3 months for the first year and every 6 months thereafter. A hemodynamically significant stenosis was said to be present when a flow velocity of 300 cm/s was found within a graft or there was a velocity ratio above and below a stenosis of 3.5 or greater. All patients identified as having a hemodynamically significant stenosis less than 3.0 cm in length in a conduit greater than 3.0 cm in diameter were considered candidates for angioplasty. Following PTA, routine graft surveillance protocols were reinstated. Patients undergoing repeat angioplasty were excluded from the study.

All vein grafts were performed in a reversed fashion by 1 of 2 vascular surgeons. Angioplasties were performed by 1 of 4 interventional radiologists. Balloon catheters were inflated to 8 to 12 atm of pressure during PTA. Angioplasties were considered to be successful if a less than 30% residual stenosis remained following PTA. Angioplasties were considered to have failed when flow velocities of greater than 300 cm/s or velocity ratios of 3.5 or greater were detected at the site of previous PTA or when grafts were found to be occluded (failure was defined as duplex ultrasonographic or arteriographic documentation of stenosis of 75% or greater). Vein grafts that had failed angioplasty but remained patent were treated by open surgical revision or repeat PTA at the discretion of the treating vascular surgeon.

Patient demographics, type of conduit used, site of graft implantation, and length and location of the vein graft stenosis were recorded. Morbidity and mortality following PTA was also documented. Time to first failure following angioplasty was calculated using Kaplan-Meier life table analysis. Comparisons between groups were made using the log-rank method. Statistical significance was assumed at $P<.05$.

**RESULTS**

During 7½ years, 94 patients underwent 101 angioplasties as the primary treatment for autogenous vein bypass graft stenoses. Fifty-two of the patients were female and 42 were male (age range, 50-92 years; mean, 66 years). Fifty-five patients had hypertension, 54 smoked more than 20 cigarettes per day, and 41 were under treatment for diabetes mellitus. Before PTA, 41 patients were receiving antiplatelet agents, and 29 were being treated with warfarin sodium for preexisting medical conditions.

Slightly more than 76% of the angioplasties were performed on great saphenous veins, 18.8% on cephalic veins, 3.1% on basilic veins, and 1.9% on small saphenous veins. Seventy-six (75.2%) grafts originated from the common femoral artery, 20 (19.8%) from the superficial femoral artery, 3 (3%) from the deep femoral artery, and 2 (2%) from the popliteal artery. Seventy (69.3%) grafts terminated in the popliteal artery and 31 (30.7%) in the tibial vessels. The length of graft stenoses ranged from 0.5 to 3.0 cm (mean, 1.2 cm). Fifty-five graft stenoses undergoing PTA were located at the proximal anastomosis, 17 stenoses were at the distal anastomosis, and 15 stenoses were located in the body of the graft. Fourteen angioplasties were performed at multiple graft sites. Time from graft implantation to PTA ranged from 1 to 73 months (mean, 9.6 months).

Ninety-six percent of the angioplasties were initially successful. Graft follow-up ranged from 1 to 57 months (mean, 23 months). Nearly 35% of the angioplasties had failed at 6 months, 53.6% had failed at 12 months, 60.6% had failed at 24 months, and 75.1% had failed at 36 months (Table). Sex ($P=.31$), smoking history ($P=.27$), hypertension ($P=.65$), diabetes mellitus ($P=.42$), or the use of anticoagulant medications ($P=.08$) did not affect the failure rate. The site of angioplasty ($P=.68$), number of angioplasties performed ($P=.52$), or the type of conduit ($P=.98$) did not affect the durability of PTA. At 36 months, the failure rate of angioplasty was 72.2% at the proximal anastomosis, 84.6% at the distal anastomosis, and 67.8% for mid graft PTA ($P>.68$ for all). During the study, 30 (29.7%) grafts were discovered to be hemodynamically failing but patent, and 29 (28.7%) grafts had progressed to occlusion. Of the failing grafts, 16 were salvaged by surgical revision and 14 by repeat PTA. The primary assisted patency for grafts in this series at 36 months was 41%.

Eight angioplasties (7.9%) resulted in serious complications. Two patients developed pseudoaneurysms following PTA. One was successfully treated with thrombin injection and the other required operation. Two patients experienced thromboembolic events requiring surgical intervention. Pulmonary edema with subsequent myocardial infarction occurred in 2 patients. One patient had a graft rupture ultimately resulting in graft occlusion, and 1 patient developed contrast-induced nephropathy requiring permanent hemodialysis. There were no deaths within 30 days of angioplasty.

**COMMENT**

Infrainguinal vein bypass grafting is one of the most frequently performed vascular procedures. In the 1970s, it was postulated and later proved that vein graft stenoses may account for a large proportion of bypass failures. The advent of duplex surveillance allowed for the identification of hemodynamically failing but patent bypass grafts and has improved 5-year graft patency by 10% to

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It has been estimated that 15% to 30% of vein grafts develop significant stenoses requiring revision. Ideally, the form of revision performed should have minimal morbidity and provide a durable result.

Typically, vein graft stenoses are focal and result from myointimal hyperplasia. The site of stenosis is related to the type of bypass constructed. Stenosis at the proximal anastomosis is most frequent in grafts performed in a reversed fashion, while distal lesions are most often seen with in situ bypass grafting. Intragraft lesions are seen in all types of reconstructions and may be most frequent when autogenous conduits other than saphenous vein are used. Traditionally, vein graft stenoses have been treated with surgery. Using techniques of patch angioplasty for lesions of 1 cm or less and interposition grafting for longer lesions, adverse event-free rates of 60% to 80% at 5 years have been achieved. However, operative therapy requires general or regional anesthesia and several days of hospitalization. In hopes of decreasing morbidity and minimizing hospital stay, PTA of vein graft stenoses has been suggested as an alternative to surgical repair.

For several years, we used PTA as the primary modality in the treatment of hemodynamically significant vein graft stenoses. Early in our experience, arteriography was routinely used to confirm the presence of graft stenoses identified by duplex scanning, and angioplasty at the time of the diagnostic study was considered to be a reasonable alternative to surgical revision. In our series, early response to PTA was excellent, with a success rate of 96%. However, at 36 months, 75.2% of the grafts undergoing PTA had developed a hemodynamically significant recurrent stenosis or progressed to occlusion. Although only 50% of failures following surgical repair occurred at the site of revision, all of the angioplasty failures in our series found before graft occlusion were at the site of previous PTA. Even with a rigorous surveillance program, half of the adverse events in our series were graft thrombosis.

Previous authors have postulated that angioplasty would prove to be a durable alternative to surgical revision if certain selection criteria were used. Lesions found in adequate-caliber bypass grafts and stenoses less than 3 cm in length were believed by some authors to be ideal candidates for PTA. All of the patients in our study met these standards, yet the long-term durability of angioplasty proved to be poor. In addition, we could not demonstrate any location of graft stenosis that proved to respond more favorably to PTA.

This series demonstrates that vein graft angioplasty is associated with significant morbidity. Four procedures had adverse events requiring operative intervention, and 1 procedure resulted in graft occlusion. Two patients had life-threatening cardiac complications resulting in prolonged hospital stays, and 1 patient remains on hemodialysis following an episode of contrast-induced nephropathy. Each of these complications was directly attributable to the angiographic procedure. This morbidity would rival and perhaps exceed that seen in operative repair. In the past, angiography was routinely used to confirm the presence of graft stenosis before surgical revision. This required patients to undergo 2 invasive procedures, with their additional morbidity. Recently, duplex imaging has been successfully used as the sole preoperative imaging modality in many patients before operation. The elimination of arteriography as an obligatory step before surgical repair will lower the morbidity of operative revision and make this treatment option even more attractive.

We conclude that angioplasty at best provides a temporary solution to the problem of vein graft stenosis and carries a significant morbidity. Although the initial success rate of angioplasty is high, its long-term durability does not appear to equal that of surgical revision. Although PTA may be successfully used in patients with limited life expectancy or prohibitive surgical risk, its routine use in treating these lesions cannot be recommended. At present, surgical revision should be considered the treatment of choice for vein bypass graft stenosis.

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Rawson James Valentine, MD, Dallas, Tex: Autologous vein bypass grafts are prone to develop intrinsic lesions after being placed in the arterial circulation. Regardless of whether they are reversed, transposed, or left in situ, between 20% and 30% of grafts develop stenoses within the first postoperative year. Timely correction of a stenosis measuring 79% diameter loss has been shown to prevent graft thrombosis, which is why routine graft surveillance has become a standard of care.

DISCUSSION

The authors are to be congratulated for an excellent vein graft surveillance program in which they detected 94 patients with grafts at risk. The lesions discovered in this study certainly warranted repair. The main issue is how to repair them. You have just heard that percutaneous balloon angioplasty is appropriate in the treatment of graft and anastomotic lesions responsible for failing vein bypasses? Am J Surg. 1994; 168:97-101.

Dr Katz: Do you envision recommending a PTA would be in the rare patient with a lesion for example, a lesion less than 10 mm vs a longer lesion, and for short lesions in the larger grafts? Second, your definition of initial success of a residual stenosis less than 30% may have been too liberal. Were patients more likely to have a recurrent stenosis if they had any residual lesion at all, and were stents used in these patients? Third, patients who received warfarin after the first operation tended to have a worse patency rate after angioplasty. Were these patients put on warfarin because of inadequate grafts and therefore preselected for a worse outcome? Finally, can you imagine a scenario in which you would recommend angioplasty in these circumstances?

James R. DeBord, MD, Peoria, Ill: This paper deals with a problem that I face on a weekly basis, it seems. I was interested to notice that 55% of your stenoses that you felt needed treatment were at the proximal anastomosis. Is this because you do all of your grafts with a reverse vein and therefore have the smallest end of the vein at the proximal anastomosis? If the vein there is small and having now seen how that leads to a high degree of stenosis in your cases, have you changed your technique? Do you patch angioplasty or try to do anything different with the proximal anastomosis?

I have 4 questions for the authors. First, have you had the opportunity to examine outcome based on the length of the lesion—for example, a lesion less than 10 mm vs a longer lesion, and for short lesions in the larger grafts? Second, your definition of initial success of a residual stenosis less than 30% may have been too liberal. Were patients more likely to have a recurrent stenosis if they had any residual lesion at all, and were stents used in these patients? Third, patients who received warfarin after the first operation tended to have a worse patency rate after angioplasty. Were these patients put on warfarin because of inadequate grafts and therefore preselected for a worse outcome? Finally, can you imagine a scenario in which you would recommend angioplasty in these circumstances?