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 reinstituted. 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). Sixty-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 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%.
operative repair. In the past, angiography was routinely directly attributable to the angiographic procedure. This resulting in prolonged hospital stays, and 1 patient re-

procedure had adverse events requiring operative interven-

tion, and 1 procedure resulted in graft occlusion. Two pro-
cedures had adverse events requiring operative interven-

plasty is associated with significant morbidity. Four pro-
cedures proved to be poor. In addition, we could not dem-

strate any location of graft stenosis that proved to

prising for longer lesions, adverse event–free rates of 60%

20% at 5 years have been achieved.11-13 However, opera-
tive therapy requires general or regional anesthesia and

days of hospitalization. In hopes of decreasing mor-

bidity 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 mo-
dality in the treatment of hemodynamically significant

vein graft stenoses. Early in our experience, arteriogra-

phy 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 se-

ries, 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 sig-

nificant recurrent stenosis or progressed to occlusion. Al-

though only 50% of failures following surgical repair oc-

curred 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 pro-

gram, 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 revi-

sion if certain selection criteria were used.18 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 angiop-

lasty proved to be poor. In addition, we could not dem-

onstrate any location of graft stenosis that proved to

respond more favorably to PTA.

This series demonstrates that vein graft angiop-

lasty is associated with significant morbidity. Four pro-
cedures had adverse events requiring operative interven-

tion, and 1 procedure resulted in graft occlusion. Two pa-

patients had life-threatening cardiac complications re-

sulting in prolonged hospital stays, and 1 patient re-

mains 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 sur-

gical revision. This required patients to undergo 2 inva-
sive procedures, with their additional morbidity. Re-

cently, duplex imaging has been successfully used as the
sole preoperative imaging modality in many patients be-

fore operation.19 The elimination of arteriography as an
obligatory step before surgical repair will lower the mor-
bidity of operative revision and make this treatment op-
tion even more attractive.

We conclude that angioplasty at best provides a tem-

orary solution to the problem of vein graft stenosis and
carries a significant morbidity. Although the initial suc-
cess rate of angioplasty is high, its long-term durability
does not appear to equal that of surgical revision. Al-

though PTA may be successfully used in patients with
limited life expectancy or prohibitive surgical risk, its rou-
tine use in treating these lesions cannot be recom-

mended. At present, surgical revision should be consid-
ered 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 75% diameter loss has been shown to prevent graft thrombosis, which is why routine graft surveillance has become a standard of care.

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 adequate. When all lesions were considered, the 3-year cumulative patency of 29% suggests that angioplasty is not a durable option. Furthermore, the significant morbidity in 8 patients would seem to doom this technique in grafts at risk.

These results are in keeping with the findings of others, and they confirm my own bias. But before we completely abandon angioplasty, it is important that we not overlook circumstances in which this technique might prove durable. Viewed from another perspective, 25% of patients had durable results from balloon angioplasty. The authors evaluated patient variables such as risk factors, coagulation status, graft source, and angioplasty site. But they did not comment on the specific characteristics of each lesion. We know, for example, that angioplasty has better long-term patency rates for stenoses that are less than 1 cm in length versus those that are longer, and for grafts that are larger than 3 cm compared with smaller grafts. Similarly, lesions that are associated with valve leaflets appear to be better suited to angioplasty.

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?

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 do a patch angioplasty or try to do anything different with the proximal anastomosis?

Dr Katz: Dr Valentine, we did not specifically evaluate outcome based on the length of stenosis. However, we did limit PTA to lesions of 3 cm or less in length. The majority of these lesions were quite short as evidenced by the mean stenosis length of 1.2 cm. All of the vein grafts in the study were at least 3 cm in diameter, so we did not have any small grafts undergoing PTA.

We did not really find any correlation between residual stenosis and recurrence rate. We used a 30% stenosis as our cutoff for angioplasty success since this is the standard accepted by interventional radiologists. However, most had a residual stenosis of 10% or less following PTA. The only case in which a stent was used was a case in which there was a vein graft rupture and the interventional radiologist placed a covered stent, which led to rapid graft occlusion.

The majority of the patients had been placed on warfarin for preexisting conditions such as atrial fibrillation. However, a few patients were placed on anticoagulation in the hopes of improving graft patency, so I really cannot eliminate a selection bias. At present, the only circumstance in which I could envision recommending a PTA would be in the rare patient with no autogenous conduit available for use in revision.

Dr DeBord, we believe the proximal stenoses were due to the fact that we employ reverse vein grafts exclusively. We have taken to using the technique described by the Oregon group of using a vein branch and incorporating that into the heel of the proximal anastomosis. This has reduced but not eliminated the problem.