Balloon angioplasty as a treatment of failing infrainguinal autologous vein bypass grafts

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Purpose: The purpose of this study was to evaluate the role of balloon angioplasty in the treatment of failing infrainguinal vein bypass (IVB) grafts.

Methods: A retrospective chart review of patients undergoing revision of a failing IVB graft by vascular surgeons at a tertiary care center from 1990 to 2001 was performed. Failing bypass grafts were identified by routine duplex scan surveillance and physical examination. The criteria for endovascular intervention varied on the basis of surgeon preferences and time period; factors considered when choosing balloon angioplasty included significant comorbidities that precluded operative intervention, the lack of adequate conduit for surgical revision, or poor accessibility of the stenotic lesion. Data recorded included demographic patient data, type of IVB graft, patency status, further procedures performed, and all complications and mortalities. Cumulative primary and assisted patency rates were calculated by using Kaplan-Meier life-table analysis.

Results: A total of 45 balloon angioplasties were performed in 36 patients. There were 36 angioplasties of vein bypass grafts, and additional balloon angioplasties were performed on nine of these patients. Locations of IVB grafts included femoropopliteal (13 patients), femorodistal (13), and popliteal to tibial (10). Initial success was achieved in 33 of 36 vein bypass grafts (91.7%). In these bypass grafts, the stenotic lesions were identified and treated at the proximal anastomosis (3 patients), mid-bypass graft (6 patients), and distal anastomosis (27 patients). Autogenous vein was used for all bypass grafts. Cumulative vein bypass graft (life-table analysis) primary patency rates (those free of occlusion or bypass graft threatening stenosis) were 74.2% at 6 months, 62.7% at 12 months, and 58.2% at 24 months. Repeat interventions included surgical thrombectomy with vein patch angioplasty or bypass graft revision, as well as repeat balloon angioplasty with or without thrombolysis. Cumulative assisted vein bypass graft patency rates (those free of occlusion or bypass graft threatening stenosis) were 87.0%, 83.2%, and 78.9% at 6, 12, and 24 months, respectively. Two patients (6%) developed thigh hematomas; no other procedure-related complications were noted, and there were no deaths in the perioperative period.

Conclusion: Balloon angioplasty of failing infrainguinal vein bypass grafts can be successfully performed with a low rate of complications. Acceptable short-term patency can be achieved. This procedure should be considered as an initial option in failing IVB grafts. (J Vasc Surg 2004;39:421-6.)

Maintaining the patency of infrainguinal vein bypass (IVB) grafts has long been a challenging task for vascular surgeons. Although the etiology of bypass graft failure has been well described, the mechanisms that result in bypass graft failure remain poorly defined. Improvements in duplex ultrasound scanning technology and increased surveillance of IVB grafts have allowed for the detection of a subset of these bypass grafts that are at risk for thrombosis. Considerable uncertainty still exists about the optimal management of these threatened bypass grafts. Increased experience with endovascular therapies has lead to the application of balloon angioplasty to the threatened bypass graft, but the efficacy of this treatment modality when compared with operative techniques, such as patch angioplasty, interposition graft, or replacement graft, remains unclear.

Three decades ago, Szilagyi et al first described the potential lesions that can result when saphenous vein bypass grafts are used as arterial conduits. Their use of angiography to evaluate vein bypass grafts revealed that a third developed anatomical defects that might lead to thrombosis. Attention has, therefore, turned to the identification of those bypass grafts with defects before thrombosis has occurred. Although intraoperative bypass graft angiography, and more recently intraoperative duplex scan evaluation, can be effective in identifying immediate technical problems and vein bypass graft defects that can be immediately corrected, most patients who develop bypass graft-threatening defects do so in the first 6 to 12 months after surgery. Routine surveillance angiography is impractical, and ankle-brachial index (ABI) has been shown to be somewhat unreliable in identifying all threatened bypass grafts. The refinement of duplex ultrasound scanning technology and surveillance techniques has enabled vein bypass grafts with hemodynamic abnormalities to be readily identified. Although the criteria used to define
threatened vein bypass grafts vary slightly, the use of color duplex scanning has been shown to accurately identify those bypass grafts that are at risk of thrombosis. Furthermore, cost analysis suggests that patients who undergo routine surveillance with duplex scans will incur less overall cost because of decreased rates of amputation.22

Once a threatened vein bypass graft has been identified, the surgeon must determine the best course of action to maintain patency. Options for intervention include balloon or patch angioplasty, interposition graft, or vein graft extension. This study evaluates the efficacy and safety of balloon angioplasty of threatened IVB grafts in our recent experience.

METHODS

A retrospective analysis of patients undergoing balloon angioplasty by a vascular surgeon after IVB graft placement was performed. The patients were identified by way of a medical record search using ICD-9 (International Classification of Diseases, 9th edition) codes. All charts were reviewed, and the following data were recorded: age, gender, weight, vascular risk factors (diabetes, hypertension, hyperlipidemia, and smoking), surgical history (including bypass graft types, dates, and locations), surveillance techniques and findings, postoperative procedures, date and site of balloon angioplasty, complications of balloon angioplasty, duration of follow-up, and bypass graft patency at time of follow-up. In addition, the method and outcome of any subsequent interventions were extracted from the medical records. Outcomes of procedural success, morbidity, and mortality, and postprocedural patency were all evaluated.

Infrainguinal vein bypass grafts were performed with a variety of methods, including reversed, in situ, and free nonreversed bypass grafts. Those bypass grafts that had been performed at our institution were performed by one of five board-certified vascular surgeons.

All IVB grafts were routinely followed with a color duplex scan surveillance protocol after surgery; this protocol included evaluation immediately after bypass graft, then at 3-month intervals for the first year, 6-month intervals for the second year, and then annually. In addition, any vein bypass grafts with abnormalities found on duplex scanning were studied more frequently at 3-month intervals. Duplex scanning was performed with the use of an Acuson 128 XP color duplex scanner (Acuson Corp, Mountain View, Calif) with either a 5- or 7.5-MHz linear array transducer. The entire bypass graft was imaged with each study. Threatened bypass grafts were defined as any bypass graft with an increase in peak systolic velocity (PSV) to three times the PSV in the rest of the bypass graft or an overall flow decrease throughout the bypass graft with PSV < 45 cm/sec. The decision to perform balloon angioplasty versus operative repair of these bypass grafts was made on an individual basis. Long-segment stenoses (≥2 cm), bypass grafts with multiple stenoses, and abnormalities detected throughout the length of the bypass graft were considered indications for surgical repair. Initially during the study period, balloon angioplasty was reserved for patients without adequate native vein for repair and for high-risk patients who were considered too great a surgical risk because of severe medical conditions. Later in the series, some surgeons preferred to use balloon angioplasty as an initial method, whereas others continued to select certain patients for endovascular intervention. Other than with those stenoses identified perioperatively, which were all treated surgically, the timing of stenosis after bypass graft was not a factor in determining the method of intervention. All balloon angioplasties reported in this series were performed in the operative suite by vascular surgeons trained in endovascular techniques. Antegrade ipsilateral puncture was the preferred technique, and balloon size was based on the angiographic appearance of the bypass graft. Overinflation and prolonged balloon inflation were not routinely used. Balloon angioplasties performed by radiologists in the interventional radiology suite were not included in this review because different angioplasty indications, techniques, and documentation were used by these clinicians. Angiograms were obtained either preoperatively or at the start of the balloon angioplasty procedure. The size of the balloon used for balloon angioplasty was based on the angiographic appearance of the vein bypass graft and stenotic lesion. All interventions were evaluated with completion angiograms. Technical success was defined as a less than 30% stenosis remaining on the completion angiogram. Vascular laboratory evaluation, including duplex scans, ankle-brachial indices, and pulse-volume recordings, were obtained prior to discharge. Restenoses were identified by using the same duplex scan criteria listed earlier. Postangioplasty routines varied on the basis of the patient’s overall medical status and related vascular disease; all patients were on aspirin daily.

Once all data had been collected, the primary and assisted bypass graft patency rates of threatened IVB grafts treated with balloon angioplasty were determined by using Kaplan-Meier life-table analysis. Morbidity and mortality rates were also calculated.

RESULTS

A total of 36 patients were identified who had undergone balloon angioplasty by a vascular surgeon for a threatened IVB graft. The patient population included 23 men and 13 women. The average age was 66.9 years (range, 38-87 years). Comorbidities included diabetes (66.7%), hypertension (75.8%), hypercholesterolemia (42.4%), and smoking (51.5%). The initial bypass graft operations on these patients included femoropopliteal bypass graft (36%), femorodistal bypass graft (36%), and popliteal to distal bypass graft (28%). These bypass grafts included 13 reversed greater saphenous vein bypass grafts, 6 in situ bypass grafts, 12 nonreversed greater saphenous vein bypass grafts, 3 composite bypass grafts, and 1 cryopreserved vein bypass graft. The data about one bypass graft were not available, as this bypass graft had been placed at an outside institution. The exact lengths of stenoses were not uniformly recorded;
however, we do not treat lesions >2 cm with balloon angioplasty.

A total of 45 balloon angioplasties were attempted in 36 patients, with interventions evenly spaced over the study period. There were 36 balloon angioplasties of the vein bypass grafts themselves, as well as 9 balloon angioplasties of other lesions on the same patients. Balloon angioplasties were performed on vein bypass grafts at the proximal anastomosis in 3 vein bypass grafts (8%), mid-bypass graft in 6 vein bypass grafts (17%), and the distal anastomosis in 27 vein bypass grafts (75%). Additionally, five patients underwent balloon angioplasty of the external iliac artery, and four patients underwent balloon angioplasty of distal native arteries. Three of the patients who underwent balloon angioplasty of the iliac lesions also had stent placement. With regard to the balloon angioplasties performed on the vein bypass grafts, initial technical success was achieved in 33 of 36 bypass grafts (91.7%). Reasons for failure at time of balloon angioplasty included persistent stenosis in one patient and preprocedural thrombosis of the threatened bypass graft in two patients. These patients subsequently underwent surgical thrombectomy and revision with either interposition vein graft (one patient) or extension vein graft (one patient). There were no major complications and no deaths during the first 30 days after balloon angioplasty. Minor complications consisted of two patients (4%) with thigh hematomas, one of which required surgical exploration and evacuation. These hematomas were the result of puncture site bleeding and did not represent vein bypass graft perforation or rupture.

A total of 33 vein bypass grafts were followed with routine duplex scan surveillance, with an average follow-up period of 26.8 months (longest, 138 months). One patient was lost to follow-up. A total of 12 bypass grafts progressed to occlusion, and 3 bypass grafts developed restenosis. Cumulative primary stenosis-free patency (Kaplan-Meier life-table analysis) rates were 74.2%, 62.7%, and 58.2% at 6, 12, and 24 months, respectively (Fig 1; Table I, online only). Of the 15 bypass grafts that restenosed or occluded, 11 events occurred within the first year after balloon angioplasty. The average time to restenosis or occlusion was 8.4 months after the initial procedure. A total of 7 patients underwent secondary intervention, with interventions including thrombectomy with vein patch angioplasty (1 patient), thrombectomy with vein graft extension (2 patients), and further balloon angioplasty (4 patients), with thrombolysis in 2 of these patients. Six of these revisions occurred within the first year. The resulting assisted stenosis-free patency rates (Kaplan-Meier life-table analysis) were 87.0%, 83.2%, and 78.9% at 6, 12, and 24 months, respectively (Fig 2; Table II, online only).

One patient went on to require an above-knee amputation after occlusion of the femoropopliteal bypass graft 2 months after a balloon angioplasty. No other major amputations were performed, and there were no deaths attributable to subsequent interventions for peripheral vascular disease.

Of those bypass grafts that restenosed or thrombosed after initially successful balloon angioplasty, 4 were femoropopliteal bypass grafts, 5 were femorodistal bypass grafts, and 6 were popliteal to distal bypass grafts. Of these patients, 2 had undergone balloon angioplasty of the proximal anastomosis, 3 had undergone balloon angioplasty of the mid-bypass graft, and 10 had balloon angioplasty at the distal anastomosis. Because of the small numbers involved in each of these groups, no statistical analysis was performed to evaluate the relative efficacy of balloon angioplasty in each individual type of bypass graft or location of stenosis.

DISCUSSION

The optimal treatment of a threatened vein bypass graft has sparked debate over the past several decades. Controversy remains about the definition of a threatened vein bypass graft and also the importance of the identified stenotic lesion. The purpose of this study, however, was not to answer the question of the efficacy of routine duplex scan surveillance, as the authors use this method on all IVB grafts. Our goal was to assess the outcome after balloon angioplasty of a stenotic vein bypass graft lesion.

To determine the importance of our results, we must first assess the historical success of the more traditional
surgical intervention. Nehler et al. published a large review of patients who had undergone surgical revision of a threatened IVB graft. Their revisions included inflow procedures (8%), patch angioplasties (7%), interposition vein grafts (53%), and vein graft extensions (25%). They demonstrated outstanding results, with cumulative patency rates of 99% at 1 year and 96% at 3 years, as well as limb salvage rates of 99% and 97% at one and three years, respectively. They accomplished these results with a morbidity rate of 13.6% and one mortality (1%). Individual morbidities included myocardial infarction (3.4%), renal insufficiency (1.7%), and congestive heart failure (1.7%). Those investigators emphasized the importance of using autogenous vein in the revision of these grafts. They used autogenous vein in most of their cases. With excellent results like those, it is unlikely that we can improve on patency and limb salvage rates. However, given these morbidity rates and the need for available vein, endovascular revision could play a significant role in those patients who are at higher anesthetic risk or who lack adequate vein for surgical revision.

In addition to this assessment of surgical success rates, several investigators have evaluated the efficacy of balloon angioplasty in the treatment of vein bypass graft stenoses. Tong et al. reported 90 balloon angioplasties performed on threatened IVB grafts with a cumulative stenosis-free patency rate of 55.8% at 6 months, 54% at 1 year, and 45% at 3 years. Those investigators noted a slightly improved patency rate in those patients treated for a primary versus recurrent stenosis. They reported no complications related to their balloon angioplasties. Favre et al. used balloon angioplasty for select short stenoses of IVB grafts with initial success rates similar to ours. They demonstrated a 91% initial success rate and cumulative patency rates at 1 and 2 years of 91% and 72%, respectively. Katz et al. demonstrated slightly worse patency results, with an 8% complication rate. They reported failure rates of 31% at 6 months, 55% at 1 year, and 63% at 2 years. These data together demonstrate that there are some threatened IVB grafts treated with balloon angioplasty that will go on to occlude; however, acceptable patency rates can be achieved with minimal morbidity. This is in concordance with our findings. Although all of the above studies evaluated either balloon angioplasty or surgical revision alone, there remains the question of whether one method is superior when compared directly.

Berkowitz et al. reviewed a total of 78 threatened IVB grafts treated over a 22-year period. They treated 81% with a balloon angioplasty versus 19% with a surgical revision, including patch angioplasty and short extension vein grafts. They reported a 61% 5-year patency rate in those patients treated with balloon angioplasty, compared with 29% of surgically treated IVB grafts. It should be noted, however, that some of their surgical group represented lesions previously treated with balloon angioplasty. In addition, their subset analysis indicated that those bypass grafts with stenoses in mid-bypass graft and at the distal anastomosis that were treated with balloon angioplasty, which represents most of the patients from our study, had a higher restenosis rate when compared with other lesions. Interestingly, whereas our data were limited to those patients with short stenotic lesions, those investigators were unable to demonstrate a difference in patency between lesions longer and shorter than 2 cm. More recently, Avino et al. reviewed various interventions on 144 vein graft stenoses. Their patient population included a large array of sites of bypass grafts, types of conduit, and types of intervention performed. Overall they determined no difference in 2-year patency rate between those bypass grafts treated surgically (55%) and those treated with balloon angioplasty (63%). The decision to perform one intervention versus the other was based on clinical and duplex scan criteria. Bandyk et al. had previously reported a large series of patients with threatened IVB grafts who had been treated by a variety of methods, including patch angioplasty, bypass graft extension, and balloon angioplasty. They found that those lesions treated with a surgical revision had a lower incidence of restenosis when compared with the patients treated with balloon angioplasty (1 of 33 versus 9 of 18). Those investigators were also able to demonstrate excellent bypass graft patency rates with secondary procedures for stenosis.
Unfortunately, those studies, along with our present study, are difficult to compare. Multiple variations in the treatment protocols exist, including different duplex scan criteria to define a treatable stenosis, different inclusion criteria for surgical versus endovascular repair, and different surgical and endovascular techniques. In addition, the treated lesions are difficult to compare directly, varying in length, location, and severity. For instance, most lesions treated in our patients were at the distal anastomosis site. This fact might have lead to slightly decreased patency rates when compared with other reports that included more lesions from other parts of the bypass graft. These lesions also represent a group that would likely require more extensive surgical revision with an extension bypass graft. In addition, in the presence of nonhealing ulcers or wounds in the skin overlying the stenotic lesion, endovascular methods offer an appealing alternative to surgery. Also, we do not generally perform endovascular interventions on vessels with diffuse disease or on long lesions (>2 cm). These variable factors likely contribute to the wide spectrum of patency rates reported in the studies above. The variation in protocols makes comparing all of the available data difficult at best. Other difficulties arise from the relatively small number of patients studied in most series. Given those numbers, conclusions are difficult to draw. Indeed, none of our numbers were sufficient to warrant subgroup analysis. From the standpoint of improved patency, however, no strong trends were noted that would indicate that one lesion site would be better treated with balloon angioplasty.

A concerning finding in our data was a surprisingly large number of vein bypass grafts that had occluded. Given the frequent surveillance with duplex scans, we would have expected to identify more restenoses than occlusions. On further review, we found that several patients did not present for follow-up duplex scanning examination as scheduled. Specifically, one patient went for 1 year without evaluation after initially undergoing duplex scan studies at 3 and 6 months. In another patient, the 3-month evaluation was missed, and the patient subsequently presented with a thrombosed graft. Finally, one patient stopped presenting for studies after 6 months of postoperative evaluation and then presented with a thrombosed graft in just less than 1 year after the bypass graft. The specific reasons for missed follow-up appointments could not be readily obtained. Furthermore, some patients who were high risk for surgery or poor candidates for further intervention were no longer followed with an eye toward further intervention. Also, some patients occluded early after balloon angioplasty. Finally, some patients who had healed their foot wounds no longer required further revascularization. Despite the number of thrombosed bypass grafts, we were able to demonstrate good assisted patency rates by using a combination of endovascular and surgical secondary interventions.

The three patients who could not undergo balloon angioplasty at the time of planned intervention should also be noted. In one case, the balloon angioplasty was inadequate to achieve angiographic resolution of the stenosis. In the other two cases in whom balloon angioplasty could not be performed, thrombosis occurred in the interim between diagnosis of the stenotic lesion and treatment. This result underlines the importance of responding to threatened bypass grafts quickly and decisively. Both of these patients underwent successful surgical revision of their bypass grafts.

In summary, our data suggest several conclusions and add to the growing understanding of the role of endovascular interventions for threatened IVB grafts. Specifically, balloon angioplasty can be performed on threatened IVB grafts with a low rate of morbidity and mortality. Initial success and short-term patency of threatened vein bypass grafts is acceptable. Given these findings, balloon angioplasty represents an option for the initial correction of well-selected lesions in threatened IVB grafts, such as lesions that could require extensive dissection and those arising in high-risk patients. Further evaluation with well-controlled, prospective studies should project more light on this difficult clinical problem. Continued surveillance is imperative to define patients with recurrent stenoses after balloon angioplasty procedures; in addition, more intensive surveillance, initially at 1-month intervals, might be warranted after these interventions.

REFERENCES


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