Balloon angioplasty for revision of failing lower extremity bypass grafts

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Objective: **The aim of this study was to evaluate the efficacy and safety of balloon angioplasty as the primary method of intervention in patients with color duplex ultrasound documented failing bypass grafts and to determine factors that may affect the patency of lower extremity bypass grafts revised by percutaneous transluminal angioplasty (PTA).**

Methods: **All consecutive patients who underwent lower extremity bypass grafts from January 2009 to December 2013 were enrolled in a graft surveillance program. Patients identified as having failing grafts underwent arteriography to confirm the diagnosis with a view to concomitant treatment of the lesion using balloon angioplasty. Procedural success was defined as <30% residual stenosis. Treatment failure was defined as target lesion restenosis or graft occlusion. Descriptive and life-table analyses were performed.**

Results: **PTA was used to revise 96 failing grafts in 90 patients. Mean age was 65.8 years (range, 50-88 years), 64% were male, and 66% were symptomatic. Mean follow-up was 18.5 months (range, 3-24 months). Twenty-four grafts (25%) underwent repeat angioplasty for restenosis. Grafts with multiple lesions ($P = .009$) and grafts aged <6 months from the index operation ($P = .004$) were the only graft-related variables that showed a significant effect on the longevity of the endovascular revision. The PTA-revised grafts had primary, assisted primary, and secondary patency rates of 56.9%, 83.2%, and 90%, respectively, at 2 years.**

Conclusions: **Primary balloon angioplasty of failing lower extremity bypass grafts, notwithstanding the higher restenosis rate and the need for reintervention, appears to be safe and is associated with acceptable early and medium-term patency rates. Grafts with multiple lesions and those revised ≤6 months of the index operation showed a significant association with the need for a second revision at the same site. (J Vasc Surg 2015;62:93-100.)**

Maintaining the patency of bypass grafts has been a challenging task for vascular surgeons for decades.[1] Despite improved surgical techniques and careful postoperative surveillance, bypass grafts continue to fail, often with severe consequences for the affected patient.[2] Although technical problems, poor patient or procedure selection, hypercoagulable states, and progression of atherosclerosis have all been reported to lead to graft thrombosis,[3] most bypass graft failures are ascribed to intimal hyperplasia, which occurs in the midterm period (2 to 24 months).[4]

Graft surveillance is worthwhile to prevent graft thrombosis and enhance patency rates.[5-9] If graft thrombosis occurs, subsequent graft revision and patency rates are markedly inferior compared with when a failing, but patent, graft is treated.[10] Attention has, therefore, turned to the identification of those bypass grafts with defects before thrombosis has occurred.[1] Accumulating data have validated the utility of color duplex ultrasound (CDU) scanning to detect hemodynamically significant abnormalities of infrainguinal arterial bypass grafts,[8,11-13] the rationale being that correction of stenotic lesions is likely to improve graft patency and reduce the risk of amputation.[14-16]

Considerable uncertainty still exists about the optimal management of these threatened bypass grafts once they are identified.[17] Determining the utility of any treatment for failing grafts is made difficult by the variety of treatment options, the frequent multiplicity of lesions, and specific lesion characteristics, including length, location, and temporal development after graft implantation.[18]

Traditional operative techniques, such as patch angioplasty, interposition, or jump graft, remain the gold standard for the management of failing grafts. However, these techniques require the availability of an additional autogenous conduit and carry the risk of morbidity and mortality associated with reoperation.[16] Increased experience with the application of balloon angioplasty in the management of occlusive lesions of the iliac, femoral, renal, and mesenteric arteries has led to the introduction of this technique for the management of failing bypass grafts. However, the efficacy of this treatment modality, first described by Alpert et al,[19] remains unclear.[1,17,20-23]

The aim of this study was to report our experience on the efficacy and safety of balloon angioplasty as the primary method of intervention in patients with CDU-documented failing bypass grafts and to determine factors that may affect the patency of percutaneous transluminal angioplasty (PTA)-revised lower extremity bypass grafts and the subsequent need for multiple revisions.

METHODS

This study was approved by the Assiut University Institutional Review Board. From January 2009 to December

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2013, all consecutive patients who underwent lower extremity bypass graft procedures using autogenous, prosthetic, or composite grafts were enrolled in a graft surveillance program. This included patient history and physical examination, ankle-brachial index determination, and CDU scanning before the initial hospital discharge, at 6 weeks, every 3 months for the first year, and then every 6 months thereafter. Selected patients were examined more frequently, every 6 to 8 weeks, because of changes in the limb clinical status or to monitor any bypass graft with subcritical flow abnormalities detected by CDU scanning.

The CDU examination was performed by two experienced vascular technologists using GE LOGIQ-P6 duplex ultrasound system (GE Healthcare, Buckinghamshire, United Kingdom) using a 3.4-10.8 MHz linear-array transducer. The CDU scanning protocol included the assessment of the entire graft and the native inflow and outflow vessels based on velocity, waveforms, and color flow characteristics. At the sites of duplex-detected stenosis, the peak systolic velocity (PSV) and PSV ratio across the stenosis were calculated. Criteria for identifying a graft that was at risk included any or all of a focal PSV within the graft or in the inflow or outflow vessels >300 cm/s, a PSV ratio across the stenosis of >3.5, uniformly low PSV <45 cm/s throughout the entire graft, an interval decrease in the ankle-brachial index of >0.15, or a significant change in clinical status.

Patients identified as having significant stenosis were brought to the angiography suite, after obtaining an informed consent, where they underwent arteriography to confirm the diagnosis with a view to concomitant treatment of the lesion. Only simple balloon angioplasty procedures were performed for graft lesions, and other endovascular techniques, such as cutting balloon angioplasty and atherectomy, were not used.

A retrograde/contralateral femoral access was often preferred because it offers a comfortable working length from the arterial entry site to the origin of the bypass graft and allows treatment of lesions in the inflow vessels. Brachial access was used in patients with femorofemoral and axillofemoral bypass grafts. Angioplasty balloon size and length were chosen according to the angiographic appearance of the bypass graft and the lesion. Because the hyperplastic lesions tend to be quite firm, high-pressure balloons with extended inflation times were frequently required to fully efface these lesions.

All interventions were evaluated with completion angiograms. Technical success was defined as <30% stenosis remaining on the completion angiogram. All patients were given aspirin indefinitely and clopidogrel for a minimum of 30 days after the procedure. After a successful intervention, all patients re-entered the graft surveillance program at the starting point. Restenosis was identified by using the same CDU criteria listed earlier. Balloon angioplasty was repeated for all patients who developed recurrent failing bypass grafts.

Patient characteristics, demographic data, and cardiovascular risk factors were recorded. Specific characteristics related to the original graft procedure were also delineated, including bypass configuration, conduit type, and inflow and outflow vessels. Also recorded were patient presentation, duplex ultrasound scan results that detected the failing grafts, number of lesions per graft, and bypass age at time of intervention. The study excluded grafts with technical complications requiring early revision (≤30 days) and grafts revised after thrombectomy or thrombolysis.

With the full understanding that all the grafts studied had lost primary patency, reporting standards established by the Society for Vascular Surgery/International Society for Cardiovascular Surgery were used. Graft patency was calculated starting from the time of the angioplasty procedure. Primary patency was defined as freedom from all-cause graft failure inclusive of lesion recurrence and graft occlusion, assisted primary patency was defined as freedom from graft occlusion, regardless of the need for additional intervention to maintain patency, and secondary patency was defined as restoration of graft patency after occlusion.

Statistical analysis was performed using SPSS 17.0 software (SPSS Inc, Chicago, Ill), and MedCalc 13.3 software (MedCalc Software, Ostend, Belgium). Descriptive statistics were used, with continuous variables expressed as mean ± standard deviation and categoric data expressed as percentages. Univariate analysis was performed with the χ^2 for categoric variables. Survival data, including primary graft patency and assisted primary graft patency were determined using Kaplan-Meier life-table analysis. A value of $P < .05$ was considered significant for all analyses.

RESULTS

Between January 2009 and December 2013, 384 patients underwent 398 lower extremity bypass graft procedures. These grafts were monitored for a mean of 23.3 ± 9.4 months (range, 2-36 months). During the follow-up period, 302 bypass grafts did not require intervention to maintain graft patency, whereas 90 patients with 96 grafts (24%) had undergone balloon angioplasty for a threatened bypass graft, and those comprise our study group.

Patients were predominantly men (64%) and were a mean age of 65.8 ± 8.4 years (range, 50-88 years). Comorbidities included diabetes (81%), smoking (74%), hypertension (49%), and hypercholesterolemia (39%). Also, 42% of patients had a history of symptomatic coronary artery disease, and 29% had a history of cerebrovascular disease (Table I).

The initial bypass graft operations in these patients included femoropopliteal bypass graft (51%), femorodistal bypass graft (22%), popliteal-to-distal bypass graft (15%), femorofemoral bypass graft (6%), iliofemoral bypass graft (3%), and axillofemoral bypass graft (3%). Conduits used were reversed great saphenous vein grafts, either ipsilateral or contralateral (72%), polytetrafluoroethylene grafts (20%), and polytetrafluoroethylene grafts/vein composite grafts (8%). The proximal anastomosis was from the common femoral artery in 51 grafts (53%), from the superficial femoral artery in 25 (26%), and from the popliteal artery in