Infrainguinal vein graft stenosis: Cutting balloon angioplasty as the first-line treatment of choice

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Objective: **The optimal treatment for hemodynamically significant infrainguinal vein bypass graft stenosis is not known. This study compares three options as first choice for the revision of failing infrainguinal vein grafts: cutting balloon angioplasty (CBA), standard percutaneous transluminal balloon angioplasty (PTA), and open surgical revision (OS).**
Methods: **Infrainguinal vein bypass graft lesions treated in a single institution during a 12-year period were evaluated. Of these, 161 lesions in 124 infrainguinal bypasses (101 patients) were treated with OS (n = 42), PTA (n = 57), or CBA (n = 62). The initial indication for the bypass in these patients was limb salvage in 73% and claudication in 27%. The primary outcome of interest was the development of vein graft occlusion or significant stenosis (≥70%) as detected by surveillance duplex ultrasound scanning or arteriography some time after repair.**
Results: **The stenosis-free patency rates at 48 months for OS, CBA, and PTA were 74%, 62%, and 34%, respectively. PTA was associated with an increased risk of treatment failure compared with both OS (hazard ratio [HR], 3.9; $P < .0001$) and CBA (HR, 3.1; $P < .0001$). There was no significant difference between OS and CBA (HR, 1.3 for CBA vs OS, $P = .6$). Pseudoaneurysms developed in two CBA patients. One ruptured and required interposition graft, and one was monitored.**
Conclusion: **Cutting balloon angioplasty is a reasonable, initial treatment for infrainguinal vein graft stenosis in most patients. It is a safe, minimally invasive, outpatient procedure with patency rates that are comparable to OS and superior to PTA. (J Vasc Surg 2008;47:960-6.)**

Lower extremity bypass using autologous vein is an effective and widely accepted procedure for the treatment of lower extremity ischemia. However, infrainguinal vein grafts develop stenoses that threaten their patency in up to 20% of the cases.[1-3] The traditional treatment for a vein bypass graft stenosis is open surgical revision, and these reconstructions produce reasonable long-term patency rates.[1,4-6] In the endovascular era, there are competing options for the treatment of hemodynamically significant infrainguinal vein bypass graft stenosis that require comparison with open surgical revision.

Open repair of vein bypass grafts has drawbacks: additional conduit is required, dissection through scar tissue to achieve anastomosis with either an inflow or outflow artery may be necessary, and surgical wound healing may delay recovery. Although these operations are not typically associated with significant morbidity, a stay in the hospital is usually required. During the past 10 years, various studies have evaluated the possibility of endovascular intervention rather than open repair of failing vein grafts, with mixed results.[2,6-9] The benefit of endovascular intervention is that these revisions can be performed in a less invasive manner on an outpatient basis, but standard balloon angioplasty has not generally been durable.

From the Division of Vascular Therapy, Hawaii Permanente Medical Group.
Competition of interest: none.
Presented at the Twenty-second Annual Meeting of the Western Vascular Society, Kohala Coast, Hawaii, Sep 8-11, 2007.
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CME article
0741-5214/$34.00

doi:10.1016/j.jvs.2007.12.035

Cutting balloon angioplasty (CBA) is a more recent development and has been used in various situations where the results of standard balloon angioplasty have not been satisfactory.[10] Preliminary reports have suggested that CBA of vein graft stenosis is feasible and may be a reasonable treatment option.[11,12] In this study, we compared open surgery (OS), CBA, and percutaneous transluminal angioplasty (PTA) in the management of failing infrainguinal vein bypass grafts.

METHODS

This study compared the efficacy of OS, CBA, and PTA for the initial treatment of infrainguinal vein bypass graft stenosis. A retrospective review from a prospectively collected vascular database was conducted of all lower extremity infrainguinal vein bypass graft revisions at Kaiser Foundation Hospital in Honolulu between January 1995 and June 2007.

Study population. This study includes three distinct phases, during which the management of failing infrainguinal vein grafts was modified to reflect available treatment options. Between 1995 and 1998, graft repairs were performed using OS preferentially, with PTA reserved for patients who were at high risk for OS or in whom surgery could not be performed. These included patients with high medical comorbidities, lack of vein, and hostile anatomy for surgery. Between 1999 and 2002, patients were treated selectively with either OS or PTA according to the type of lesion. Focal stenoses, especially in the body of the graft, were treated with PTA. Longer lesions (extending >3 cm) were treated with OS. Since October 2002, PTA has been abandoned in favor of CBA, which we have performed as the first-line treatment. Open surgery has been reserved for those in whom endovascular intervention has failed and

those unable to have endovascular intervention, including patients with severe renal insufficiency, contrast allergy, and small vein diameter. A feasibility study of the use of CBA was performed that included our initial 8 cases.[12]

Bypass grafts were performed using reversed saphenous vein. Patent but failing grafts that were treated by surgical or endovascular means were included. Grafts revised after thrombectomy or thrombolysis, or both, were excluded. Demographic data, medical risk factors, and surgical and endovascular variables were analyzed. Data collected included the type of vein bypass, indications for bypass, inflow and outflow vessels, time to stenosis after the initial bypass procedure, location of vein graft stenosis, number of lesions, treatment modality, complications, and recurrent stenosis. Lesion length was not analyzed as a separate variable. Graft lesions were identified by the recurrence of ischemic symptoms, a change in findings at physical examination, or the use of infrainguinal vein graft duplex ultrasound (DUS) surveillance.

The standard surveillance protocol includes DUS mapping of the entire limb ≤6 weeks, at 6 months, and 12 months. If no lesions are present, surveillance is performed annually. If lesions are present and are not repaired, graft surveillance continues at an increased frequency of either every 3 months or every 6 months, depending on the discretion of the attending surgeon. The criteria for further investigation with arteriography were DUS scan findings of increased peak systolic velocity ≥300 cm/s, or a velocity ratio of 3:1, or evidence of low flow (graft velocity ≤25 cm/s). Most of the graft stenoses were detected during standard DUS surveillance. The same criteria were used to monitor the grafts after revision.

During the study period, 173 vein bypass graft revisions were performed. One of these had no follow-up data available, leaving 172 potential lesion treatments for analysis. Because we did not want to bias the results of the study by including multiple re-do procedures on a small number of recalcitrant lesions and because the aim of the study was to determine the optimal *initial* treatment modality for infrainguinal vein bypass graft lesions, all re-do procedures performed using the same treatment modality on the same lesion were excluded from the analysis a priori. We excluded a total of 11 re-do procedures performed on five lesions (including 7 re-do PTA, 3 re-do CBA, and 1 re-do OS), leaving 161 lesions for the analysis.

Stenoses treated a second time using a different modality were included in the analysis. For example, if a lesion was treated with PTA and then failed and was later treated with OS, both of these procedures were included in the analysis. Of the 161 procedures analyzed, 150 were first-time procedures and 11 were re-do procedures performed on a lesion using a different modality.

Technique of cutting balloon angioplasty. The technique of CBA of infrainguinal vein graft stenosis has been described.[12] Clopidogrel was administered before the procedure (75 mg/d) and continued for 1 month after the procedure. In most cases, the sheath tip was placed just proximal to the origin of the vein graft. Heparin was administered (75 to 100 U/kg) before guidewire passage across the lesion.

A 0.014-inch diameter guidewire, with directional catheter support, was used to enter the graft and cross the lesion using road mapping. The balloon is inflated slowly, over approximately 60 seconds, so the atherotomes are centered by the expanding balloon, thus creating cleavage planes in the sclerotic lesion that are separated from each other along the inner circumference of the graft. The cutting balloon diameter was sized to be larger than the residual lumen within the graft at the site of the stenosis but smaller than the final intended diameter of the graft.

After CBA, a standard angioplasty balloon sized to the intended diameter of the vein graft on a 0.014-inch diameter guidewire was advanced to the site of the lesion and balloon angioplasty was performed. The angioplasty balloon was brought to the intended profile of the vein graft over 30 to 60 seconds, but was not oversized, and inflation was maintained for a minimum of a minute and often for several minutes. Patients were routinely discharged on the day of the procedure.

Outcome assessment. The primary outcome studied was the time from revision to the detection of "treatment failure," defined as either (1) graft occlusion or (2) a ≥70% recurrent bypass graft stenosis at the site of the target lesion detected by either DUS imaging or contrast arteriography. Standard primary patency was also calculated using the graft as the unit of analysis to facilitate comparison of these results with those of other studies. Surveillance after CBA, PTA, and OS was performed in a similar manner and was the same as that performed for standard infrainguinal vein graft bypasses. A physical examination and DUS scan were performed routinely ≤6 weeks and at 6 months, 1 year, and annually after infrainguinal bypass graft revision.

Vein graft lesions were categorized by their location within the bypass graft. Contrast arteriography was performed when clinically indicated for bypass grafts with suspected hemodynamically significant stenosis or occlusion based on either the DUS scan or the physical examination, or both. Annual studies were performed for the lifetime of the patient or the graft.

Statistical analysis. Summary statistics were calculated, including means and standard deviations for continuous variables and proportions for categoric variables. Because more than one lesion per graft may have been treated (and oftentimes using different modalities), the estimates were performed using the lesion (and not the graft) as the unit of analysis. The proportion of lesions free from treatment failure was estimated using the Kaplan-Meier method, and survival curves were compared and tested for statistical significance using the log-rank test. Cox proportional hazards regression was used to identify risk factors for treatment failure and to assess the association of treatment modality with treatment failure while controlling for other study variables. Owing to possible dependence of treatment failure among lesions belonging to the same graft, robust standard errors were used to calculate *P* values and 95% confidence intervals (CI).[13] The data analysis was

Table I. Characteristics of patients, grafts, and vein graft lesions in the study population

Characteristics	*Value*
Patients, No.	101
Age, mean ± SD y	70.5 ± 10.4
Sex, male, No. (%)	58 (57.4)
Grafts, No.	124
Indication, No. (%)	
Limb salvage	91 (73.4)
Claudication	33 (26.6)
Proximal anastomosis, No. (%)	
CFA	94 (75.8)
SFA/PFA	11 (8.9)
POP	19 (15.3)
Distal anastomosis, No. (%)	
AK POP	27 (21.8)
BK POP	55 (44.4)
Tibial	21 (16.9)
Pedal	21 (16.9)
Treated lesions	161
Lesions per graft, mean No. (range)	1.2 (1–4)
Lesion location, No. (%)	
Proximal anastomosis	77 (47.8)
Body of graft	37 (22.0)
Distal anastomosis	47 (29.2)
Lesion treatment, No. (%)	
1st time treatment	150 (93.2)
2nd time, new modality	11 (6.8)
Time interval from graft placement to lesion appearance, No. (%)	
Early (<6 mon)	42 (26.1)
Intermediate (6-12 mon)	36 (22.4)
Late (≥12 mon)	83 (51.6)
Treatment modality, No. (%)	
Open surgery	42 (26.1)
Cutting balloon angioplasty	62 (38.5)
Standard PTA	57 (35.4)

AK, Above knee; *BK,* below knee; *CFA,* common femoral artery; *POP,* popliteal; *PTA,* percutaneous transluminal angioplasty; *PFA,* profunda femoral arteries; *SFA,* superficial femoral artery; *SD,* standard deviation.

performed using Stata 8.0 software (StataCorp LP, College Station, Tex).

RESULTS

A total of 161 infrainguinal vein bypass stenoses were treated in 124 bypass grafts in 101 patients. The characteristics of these lesions, grafts, and patients are summarized in Table I. The indication for bypass was limb salvage in 91 (73%) and claudication in 33 (27%). Among the 161 treated stenoses, 42 were treated with OS, 62 with CBA, and 57 with PTA. Of the 42 lesions treated with OS, 23 were treated with inflow jump grafts, nine with outflow jump grafts, and 10 with vein patches.

There were a total of 3736 lesion-months of follow-up, including a mean of 23.4 months (range, 1-102 months) per lesion treatment. The univariate analysis of study factors associated with treatment failure is reported in Table II. In the univariate analysis, factors associated ($P < .05$) with an increased risk of treatment failure included the treatment modality, the initial indication for graft placement, and the number of lesions per graft.

Table II. Univariate association of study variables with the risk of either lesion restenosis or graft occlusion in 161 lesions

Factor	*HR (95% CI)*	P
Age, per 10 years	1.2 (0.9-1.5)	.3
Sex, female vs male	1.2 (0.7-2.0)	.4
Indication, limb salvage vs claudication	3.4 (1.7-6.9)	.001
Proximal anastomosis		.9
CFA (ref)	1.0	
SFA/PFA	1.2 (0.6-2.3)	
POP	1.1 (0.6-2.0)	
Distal anastomosis		.9
AK POP (ref)	1.0	
BK POP	1.1 (0.6-2.1)	
Tibial	0.9 (0.4-2.2)	
Pedal	1.2 (0.5-2.3)	
Lesions per graft, ≥2 vs 1	1.9 (1.1-3.0)	.014
Lesion location		.8
Proximal anastomosis (ref)	1.0	
Body of graft	0.9 (0.5-1.7)	
Distal anastomosis	0.8 (0.5-1.4)	
Lesion revision, 2nd time vs 1st time	0.9 (0.4-2.0)	.9
Lesion timing		.6
Late, ≥12 mon (ref)	1.0	
Intermediate, 6-12 mon	1.0 (0.6-1.8)	
Early, <6 mon	1.3 (0.7-2.4)	
Treatment modality		<.0001
Open surgery (ref)	1.0	
Cutting balloon angioplasty	1.3 (0.6-2.8)	.6
Standard PTA	3.9 (1.8-8.4)	<.0001

AK, Above knee; *BK,* below knee; *CFA,* common femoral artery; *CI,* confidence interval; *HR,* hazard ratio; *POP,* popliteal; *PTA,* percutaneous transluminal angioplasty; *PFA,* profunda femoral arteries; *SFA,* superficial femoral artery; *SD,* standard deviation.

A statistically significant relationship was found between treatment modality and treatment failure ($P < .0001$). PTA was associated with a significantly increased risk of treatment failure compared with both OS (hazard ratio [HR], 3.9; $P < .0001$) and CBA (HR, 3.1; $P < .0001$). No statistically significant difference was found between OS and CBA, with a HR of 1.3 for CBA vs OS ($P = .6$). The association of treatment modality with the primary outcome was not substantially changed by exclusion of the 11 re-do procedures. There was no significant difference when CBA was compared with OS (HR, 1.3; 95% CI, 0.5-3.4; $P = .5$), but the difference was significant when PTA was compared with OS (HR, 4.5; 95% CI, 1.8-11.2; $P = .001$).

The Kaplan-Meier curves for stenosis-free patency are shown in Fig 1. At 24 months, the stenosis-free patency rates were OS, 80%; CBA, 75%; and PTA, 36%. At 48 months, the stenosis-free patency rates were OS, 74%; CBA, 62%; and PTA, 34%. Standard primary patency was also calculated using the graft as the unit of analysis (Table III). At 24 months, the primary patency rates were OS 83%; CBA, 81%; and PTA, 40%. Mean length of follow-up was 28.4 months for OS, 21.9 months for CBA, and 21.4 months for PTA.

Technical success was achieved in 100% with OS, 98% with CBA, and 98% with PTA. Major complications after

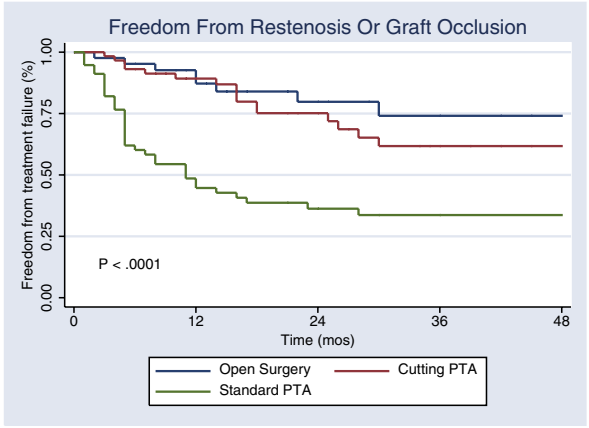

Fig 1. Comparison of treatment modalities. This graph represents freedom from occlusion or stenosis >70% after infrainguinal vein bypass graft revision using different treatment modalities. Curves were created using Kaplan-Meier method. Standard errors were less than 10% in all treatment groups to 48 months. *PTA,* percutaneous transluminal angioplasty.

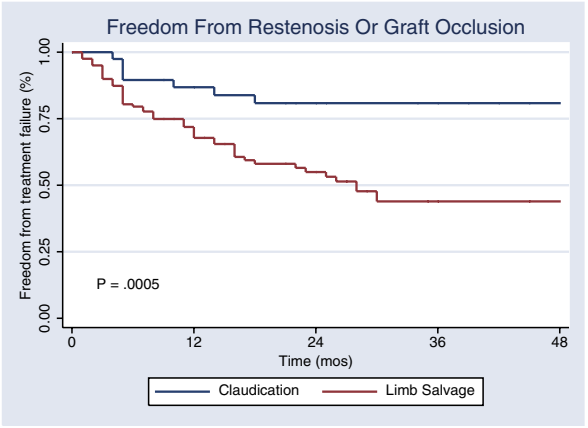

Fig 2. Comparison of indication for surgery. This graph represents freedom from occlusion or stenosis >70% after infrainguinal vein bypass graft revision in patients presenting with either limb salvage or claudication as the indication for bypass. Curves were created using Kaplan-Meier method. Standard errors were less than 10% in both groups to 48 months.

Table III. Analysis of primary patency rates[a] for open surgery, cutting balloon angioplasty, and standard percutaneous transluminal angioplasty

	Patency % (N)		
Follow-up period	*OS*	*CBA*	*PTA*
Primary patency (%) at			
0 months	100% (42)	98% (62)	98% (57)
6 months	95% (40)	90% (53)	62% (36)
1 year	90% (34)	88% (43)	47% (26)
2 years	83% (21)	81% (26)	40% (17)
3 years	77% (13)	67% (15)	37% (12)

CBA, cutting balloon angioplasty; *OS,* open surgery; *PTA,* percutaneous transluminal angioplasty.
[a]This analysis was performed with the graft as the unit of analysis (n = 124). For grafts with a history of multiple lesion treatments (n = 31), the first treatment (time of treatment and modality) were used as the index procedure to calculate patency rates. The primary patency rate of standard balloon angioplasty was significantly less ($P < .0001$, log-rank test) than the other two treatment modalities at ≥6 months.

Table IV. Stepwise Cox regression model (with backward selection) of factors associated with the risk of either lesion restenosis or graft occlusion in 161 lesions[a]

Factor	*HR (95% CI)*	P
Indication, limb salvage vs claudication	3.6 (1.7-7.6)	.001
Treatment modality		<.0001
Open surgery (ref)	1.0	
Cutting balloon angioplasty	1.6 (0.7-3.3)	.3
Standard PTA	4.3 (2.0-9.2)	<.0001

CI, Confidence interval; *HR,* hazard ratio; *PTA,* percutaneous transluminal angioplasty.
[a]Variables included in the initial model included (1) indication (limb salvage vs claudication, (2) lesions per graft (≥2 vs 1), and (3) treatment modality. Treatment modality and indication were retained in the model. There were no statistically significant ($P < .05$) interactions between these three variables.

OS included one myocardial infarction, one major hematoma, and one wound infection that prolonged the hospital stay (7%). Three significant complications were associated with CBA (5%). A delayed vein graft rupture occurred on postoperative day 5 necessitated urgent interposition vein grafting. A small pseudoaneurysm developed in a second patient that is still being monitored and has not required treatment. One access site hematoma required surgical drainage. After PTA, there were two major hematomas (5%) and one intraprocedural rupture requiring emergency graft replacement.

No patients died in this series. Overall, 11 instances of graft thrombosis occurred in the study, but there was no significant association between treatment modality and graft thrombosis. The association between treatment modality and outcome was driven primarily by recurrent stenosis and not by graft thrombosis. The likelihood of repeat stenosis or graft occlusion ≤1 year of treatment was 13% after OS, 11% after CBA, and 55% after PTA.

Lesions treated in grafts placed for limb salvage were associated with a 3.4-fold increase in the risk of treatment failure compared with lesions treated in grafts placed for claudication ($P = .001$). The Kaplan-Meier analysis of this relationship is shown in Fig 2. Lesions treated in grafts with ≥2 lesions had a 1.9-fold increase in the risk of treatment failure compared with lesions treated in grafts with solitary lesions ($P = .014$). A stepwise Cox regression model with backwards selection is shown in Table IV. Treatment modality, indication for surgery, and number of lesions per graft were entered into the initial model. After accounting for the effects of indication and treatment modality, the number of lesions per graft was no longer associated with treatment failure. Both initial indication for bypass and

Table V. Comparison of distribution of graft lesion location and timing of appearance of graft lesion in the three treatment groups

Variable	*PTA*	*CBA*	*OS*	P[a]
Location of treated lesion				.15
Proximal anastomosis	26	25	26	
Body of graft	11	19	7	
Distal anastomosis	20	18	9	
Age of lesion				.3
<6 months	19	13	10	
≥6 months	38	49	32	

[a]*P* values obtained using χ^2.

treatment modality remained in the model and were significantly associated with treatment failure. These results indicate that after controlling for other study variables, treatment modality retains a significant association with treatment failure and this association is predominantly accounted for by differences between both OS and CBA and PTA, but not between OS and CBA. Early appearance of the lesion after bypass (<6 months) and graft lesion location were not associated with treatment failure in the univariate analysis (Table II). No statistically significant association was found between the treatment modality and the lesion location or the time after bypass at which the lesion was treated (Table V).

DISCUSSION

The major limiting factor for long-term patency in vein bypass grafts is recurrent stenosis. Among the competing methods of repair of vein graft stenosis are OS, PTA, and CBA. Open surgery has been the gold standard for many years, but commits the patient to a re-do operation. PTA has been widely reported and studied and offers the advantage of a minimally invasive approach, but with limited applicability to selected lesions and marginal long-term durability. CBA has become available more recently and only feasibility studies have been performed.

The traditional treatment for a vein graft stenosis, identified in a patient with recurrent ischemia or with a significant finding by surveillance, is to proceed with OS. Assisted primary patency achieved by repairing a graft stenosis is generally better than the secondary patency that results when repair is performed after the graft has occluded.[14-16] The usual OS treatments include inflow or outflow jump grafts for anastomotic lesions, and patch angioplasty or interposition grafts for focal lesions within the body of the graft. Open surgical reconstruction provides reasonable long-term patency. Nguyen et al[1] demonstrated that OS of infrainguinal vein grafts resulted in a 5-year patency rate of 49% and a secondary patency rate of 80%. Landry et al[3] demonstrated an 87% assisted primary patency at 5 years after OS revision of vein bypass grafts. Sanchez et al[6] reported an 86% primary patency at 21 months, and Bandyk et al[17] found an 85% primary patency rate at 5 years after OS.

Open repair has significant drawbacks, however. An additional conduit is required. An inflow or outflow jump graft is often necessary because many of these lesions occur at anastomoses. This frequently requires sharp dissection through scar tissue to achieve anastomosis with either an inflow or outflow artery, which may also be diseased. These are not operations typically associated with significant morbidity, but regional or general anesthesia and a stay in the hospital are still required. Although results are good after OS, surveillance is still needed and some failures of OS require further repair.

The potential advantages of endovascular vs OS are fewer in the case of vein graft revision than in many other contemporary scenarios (eg, iliac angioplasty vs aortofemoral bypass), but there are compelling reasons to consider an endovascular option. Endovascular intervention for a failing infrainguinal bypass can be performed with local anesthesia on an outpatient basis. There are no wound healing or conduit issues. Certain medications, such as clopidogrel, do not need to be discontinued for the procedure. Endovascular intervention does not preclude the use of OS at some later time.

During the past decade, several clinical studies have evaluated the possibility of endovascular intervention rather than OS of failing vein grafts. Some series have suggested that PTA achieves results that are similar to OS:

- Avino et al[2] demonstrated that the stenosis-free patency rate at 2 years was the same for both OS and PTA (63%) when patients were carefully selected for an endovascular approach. Graft stenoses selected for PTA were focal, short (<2 cm), single lesions in grafts that were >3.5 mm in diameter and had been in place for >3 months.
- Nguyen et al[1] used PTA for focal, short (<1.5 cm) lesions in the body of the graft and achieved 48% patency at 5 years.
- Tong et al[18] used PTA to treat all-comers with vein graft stenosis, and this resulted in patencies of 54% at 3 years and 45% at 5 years.

Most studies, however, demonstrated that the failure rate for PTA was higher.

- Perler et al[7] reported an experience consisting of 24 cases of PTA with a 3-year primary patency of 22%.
- Whittemore et al[9] used PTA in 30 patients with 54 stenotic lesions, and the 5-year primary patency rate was 18%.
- Other findings included 42% patency at 21 months by Sanchez et al,[6] 39% patency at 1 year by Rua et al,[19] 36% patency at 1 year by Vikram et al,[20] and 39% patency at 2 years by Alexander and Katz.[8]

Most of the studies show that the success of PTA is less than that of OS. Although success is improved somewhat with very selective use of PTA, in most settings it is not durable enough to be used as a mainstay of treatment. The findings for OS and PTA in the present study are consistent with these earlier studies: OS was significantly better than PTA,

and the patencies after PTA were poor overall (45% at 1 year and 34% at 4 years).

Cutting balloon angioplasty was initially introduced for coronary applications because repeat coronary balloon angioplasty alone has not been very effective. Since the development of CBA several years ago, it has been used in a variety of applications where the results of standard balloon angioplasty have not been acceptable. The rationale for CBA is that sclerotic lesions are cut, rather than ripped. Predictable cleavage planes are created that can be stretched, thus potentially avoiding unnecessary injury to the intimal surface and erratic tearing of the stenosis.

Cutting balloon angioplasty for infrainguinal vein graft stenosis was reported by Engelke et al[11] in 2002. Kasirajan et al[12] reported results of a feasibility study in 2004: recurrence developed in only one patient of 19 at a mean of 11 months after CBA. More recent studies performed by Garvin and Reifsnyder[21] and Vikram et al[20] have demonstrated 6-month patencies of 48% and 80%, respectively, for CBA in failing infrainguinal vein grafts. Differences in the study populations and the manner in which CBA was used in these two studies probably explain the difference in results. However, these data suggest a need for longer-term results and for comparison with the current standard of open repair.

This study builds upon available data. Although previous studies reveal a wide range of patency rates for OS, CBA, and PTA, to our knowledge, these three treatment methods have not previously been directly compared in the same study. The results of OS in the present study (4-year patency of 74%) were within the published range of success for OS repair. The results of PTA in this study (4-year patency of 34%) were also comparable with previously published studies. This study provides long-term results of CBA for vein graft stenosis and comparative long-term data with established treatments. Our findings indicate that CBA is competitive with OS and superior to PTA.

The present study has several limitations. The treatment groups were not randomized, and the potential for treatment bias was present. The small cohort in each treatment group could mask trends that may have become apparent over time. The study was conducted during a period in which treatment protocols, techniques, and device availability changed substantially.

In addition, the longitudinal nature of the study may have introduced other unintended variables. There was an increased use of clopidogrel and an institution-wide improvement in the use of statins. These changes are partially controlled for by the fact that PTA was practiced most commonly in between the periods of primary OS and primary CBA.

Although the results of PTA were significantly different than the other two modalities, the difference between OS and CBA was not significant. The possibility remains that the results of PTA might have been somewhat improved if it had been used more regularly in the most recent period, but the basic mechanism and balloon mechanics are the same as in the earliest period. Whenever the results of PTA have been compared with either OS or CBA, they have almost always been substantially inferior.

Longer follow-up and larger treatment groups could eventually reveal that CBA is inferior to OS. However, the minimally invasive nature of CBA, along with the fact that it does not preclude later use of OS if needed, contributes to the concept that it is a reasonable initial treatment for vein graft stenosis. We believe that a specific technique for the use of cutting angioplasty is essential to avoid complications such as graft rupture and achieve acceptable long-term results. If CBA is the selected treatment, it should be performed as the initial treatment and not reserved only for poor angiographic results of PTA.

The initial cutting balloon diameter is undersized to the diameter of the graft but larger than the luminal diameter at the stenosis to assist in avoiding rupture of the graft. The cutting balloon is inflated slowly so that the atherotomes are well separated, which allows the creation of evenly spaced cleavage planes and avoids a deep incision in nondiseased vein wall. The vein is further enlarged with a standard balloon inflation that is sized to the intended diameter of the vein and is used to deliberately and gradually stretch the sclerotic lesion, rather than rip it.

CONCLUSION

Cutting balloon angioplasty is a reasonable initial treatment of choice for infrainguinal vein graft stenosis. It is a safe, minimally invasive outpatient procedure with patency rates that are comparable with open surgery and superior to standard balloon angioplasty. Treatment of vein graft stenosis with standard balloon angioplasty has been abandoned in our institution. Open surgery is reserved for patients with recurrent lesions after cutting balloon angioplasty, and for those in whom an endovascular intervention cannot be performed. Monitoring is required after cutting balloon angioplasty, as with any type of revision.

AUTHOR CONTRIBUTIONS

Conception and design: PS, MC, NN
Analysis and interpretation: MC, PS
Data collection: PS, MC
Writing the article: PS, MC, NN
Critical revision of the article: PS, MC
Final approval of the article: PS, MC, NN
Statistical analysis: MC
Obtained funding: Not applicable
Overall responsibility: PS

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Submitted Sep 21, 2007; accepted Dec 13, 2007.

DISCUSSION

Dr Kubaska III (Orange, Calif). Dr Schneider and his group have presented a retrospective study comparing long-term results of treating vein graft stenoses using cutting balloon angioplasty vs more traditional treatments of open surgical revision and standard balloon angioplasty. Cutting balloon angioplasty has been shown in this study to be superior to standard balloon angioplasty and to have comparable 4-year stenosis-free patency rates vs open surgical revision of 62% vs 74%, respectively. These findings indicate that cutting balloon angioplasty is competitive with open surgical revision in the initial treatment of infrainguinal vein graft stenosis.

The Achilles heel compromising long-term patency of infrainguinal vein bypass grafts is the development of stenoses from intimal hyperplasia at the anastomotic or mid-graft locations associated with vein valves. Using standard duplex imaging surveillance protocols, stenosis can be localized and scheduled for treatment prior to graft failure, thereby improving patency and longevity of the graft.

I have a few questions for the authors. With cutting balloon technology greatly changing over the period of the study, do you think that this may have influenced the technical success of these procedures and ultimately the long-term outcomes of the procedures?

Have you used other types of cutting balloons or scoring balloons prior to standard balloon angioplasty? At our institution, we have recently started using the AngioSculpt [AngioScore Inc, Fremont, Calif], a scoring balloon, to treat stenosis of infrainguinal cryopreserved vein grafts, which are known to be prone to recurrent stenosis with favorable results.

Did you find that lesions in the body of the graft which are usually associated with vein valves more or less difficult to treat than anastomotic lesions and why?

And finally, do you think with the addition of antiplatelet agents such as clopidogrel in conjunction with aspirin, the patency rates following percutaneous interventions have improved over the past decade? Could you comment on preprocedural administration of Plavix [Sanofi-Aventis, Bridgewater, NJ], duration of the antiplatelet therapy, and in cases where patients do not tolerate long-term antiplatelet drug administration?

I thank the program committee for the privilege of discussing this paper and the authors for sending me their manuscript well before the meeting for my review. Thank you.

Dr Schneider. Balloon angioplasty is definitely better now than it was in the mid to late '90s. Part of it is the equipment—the devices that we have available—and the other is the pharmacological manipulation that goes with it. However, vein graft lesions have not changed. My impression before we did this study was that balloon angioplasty gives you a great result about a third of the time and you cannot really figure out why. A third look great after balloon angioplasty and a third look like you didn't do anything and a third look like you ripped it. The nice thing about cutting is that the vein graft lesion is usually a focal lesion, which is nice for endo, and by cutting it first it gives you the ability to open it without ripping it.

So, well what about balloon angioplasty? Results of a very contemporary series might be better, and if it were, it would probably be because of statins and antiplatelet agents and other factors. Basic balloon mechanics have not changed. The results of balloon angioplasty for vein graft lesions in this series was right in line with many series that have been performed in the past 10 years. I do not think that we will go back to balloon angioplasty for vein graft lesions. The reason is that the additional risk of cutting angioplasty is low and because the cutting provides a coordinated cut whereas the angioplasty will always be a little bit random.

About scoring balloons—the thing I like about the scoring balloons is that you can get them in longer segments. This is a piece of metal sort of intertwined around the outside of the balloon. Maybe that will work nicely for diffuse tibial lesions, but we have not tried them in the vein graft stenoses.

The lesions in the body of the graft: It is not a huge number but we looked hard and really could not find a difference between the different locations of the lesions and how they responded.