Failed superficial femoral artery intervention for advanced infrainguinal occlusive disease has a significant negative impact on limb salvage

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Objective: **Endovascular treatment of superficial femoral artery (SFA) lesions is a well-established practice. The repercussions of failed SFA interventions are unclear. Our goal was to review the efficacy of SFA stenting and define negative effects of its failure.**

Methods: **A retrospective chart review was conducted from January 2007 to January 2010 that identified 42 limbs in 39 patients that underwent SFA stenting. Follow-up ankle-brachial index and a duplex ultrasound scan was performed at routine intervals.**

Results: **Mean patient age was 68 years (range, 43-88 years); there were 22 men (56%) and 17 women (44%). Intervention indication was claudication in 15 patients (36%), rest pain in seven patients (17%), and tissue loss in 19 patients (45%). There were 15 patients (36%) with TransAtlantic Inter-Society Consensus (TASC) A, nine patients (21%) with TASC B, five patients (12%) with TASC C, and 13 patients (31%) with TASC D lesions. The majority of lesions intervened on were the first attempt at revascularization. Three stents (7.7%) occluded within 30 days. One-year primary, primary-assisted, and secondary patency rates were 24%, 44%, and 51%, respectively. Limb salvage was 93% during follow-up. Seventeen interventions failed (40%) at 1 year. Of these, seven patients (41%) developed claudication, seven patients (41%) developed ischemic rest pain, and three patients (18%) were asymptomatic. During follow-up, three patients (7.7%) required bypass and three patients (7.7%) major amputation, one after failed bypass. All limbs requiring bypass or amputation had TASC C/D lesions. Thirty-day and 1-year mortality was 2.6% and 10.3%, respectively.**

Conclusions: **Interventions performed for TASC C/D lesions are more likely to fail and more likely to lead to bypass or amputation. Interventions performed for TASC C/D lesions that fail have a negative impact on limb salvage. This should be considered when performing stenting of advanced SFA lesions. (J Vasc Surg 2012;56:106-12.)**

The most advanced form of lower extremity atherosclerotic disease, critical limb ischemia (CLI), has significant morbidity and mortality for many aging Americans. CLI, defined as chronic ischemic rest pain, ulcers, or gangrene, has challenged vascular specialists for decades.[1]

Traditionally, the mainstay treatment strategy for limb revascularization in this patient population has been open surgical bypass. However, since the advent of balloon angioplasty 30 years ago,[2] there has been a large increase in endovascular treatment (balloon angioplasty and stenting) of lower extremity atherosclerotic disease.

In the article by Goodney et al,[3] they have shown that in the past decade, there has been a threefold increase in endovascular treatment of lower extremity atherosclerotic disease with a simultaneous 42% decrease in open surgical bypass. The TransAtlantic Inter-Societal Consensus (TASC) reported recommendations both in 2000 and 2007. Lesions defined as TASC A should undergo endovascular treatment as the first-line therapy, whereas lesions defined as TASC D should undergo traditional open surgical bypass. It was unclear what the ideal treatment strategy is for TASC B and C lesions, but the consensus was that most TASC B lesions underwent endovascular treatment, and most TASC C lesions underwent open surgical bypass.[4]

With the increasing number of endovascular procedures being performed, many authors recommend an aggressive endovascular approach to the treatment of advanced infrainguinal lesions (TASC C/D). Multiple studies[5,6] have shown acceptable patency rates for endovascular treatment of advanced infrainguinal lesions with minimal periprocedural complications.

Opponents to endovascular treatment of these advanced lesions argue that the effects of a failed infrainguinal intervention can negatively impact further revascularization and limb salvage.[7] However, a paucity of data exist defining the negative effects of a failed infrainguinal intervention. The purpose of this study was to determine the negative effects of a failed superficial femoral artery (SFA) intervention.

METHODS

After institutional review board approval, the electronic medical records of all patients undergoing angioplasty and stenting of the superficial femoral and popliteal arteries at a

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Table I. Stent types with use of frequency

Stent type	*Number of patients (n = 74) (%)*
Atrium ICAST stent	2 (2.7)
Cordis SMART stent	62 (83.7)
Edwards Life Science Lifestent	4 (5.4)
Atrium ICAST stent	6 (8.1)

Table II. Patient comorbidities and risk factors

Risk factors	*Number of patients (n = 39)*	*Percentage*
Coronary artery disease	19	49
Myocardial infarction	9	23
Hypertension	36	92
Diabetes	19	49
Hypercholesterolemia	29	74
End-stage renal disease	6	15
Warfarin anticoagulation	5	11
Smoking history	30	77

single institution during a 36-month period were reviewed. Using Current Procedure Terminology (CPT) codes 37205, 75962, and 35474, patients were selected that underwent stenting of SFA lesions alone. Stent placement occurred when a residual stenosis (ie, >30%) was found after balloon angioplasty or when a lesion was determined on angiogram to not be amenable to balloon angioplasty alone. No stents were primarily placed after a complication of balloon angioplasty (ie, dissection). Patients undergoing angioplasty alone or angioplasty or stenting of concomitant popliteal or tibial lesions were excluded. Only patients undergoing stenting of the SFA were included in this study.

Interventions were performed or supervised by five vascular surgeons. SFA lesions were classified according to the second TASC II classification and determined by the treating surgeon. Patient gender, demographics, presence of comorbidities, body mass index, history of end-stage renal disease, history of smoking, and use of anticoagulation therapy were recorded. Indications for intervention, location, length, severity of arterial lesions, type and size of stent deployed, and quality of distal runoff were noted. Runoff at the tibial level was determined by the number of vessels patent (zero, one, two, or three). Distal vessel runoff was determined by angiographic evaluation and evaluation of dictated operative reports. Complications including access site hematoma, clinical myocardial infarction, amputations, and death were recorded.

Type and number of secondary interventions were noted. The type of stent was chosen on the basis of surgeon preference (Table I). All patients received a bolus of 150 to 300 mg of clopidogrel postintervention and were maintained on 75 mg of clopidogrel for at least 30 days postintervention. All patients were systemically heparinized with 80 units/kg of heparin before angioplasty and stenting. Activated clotting time levels were not routinely checked. Initial procedural success occurred when the treated arterial segment had <30% stenosis remaining.

Patients received duplex scans and arterial-brachial indices every 3 months for the first year. Loss of primary patency was considered to have occurred with vessel occlusion or when a hemodynamically significant stenosis was detected on duplex scanning. We considered a 50% stenosis to be present when a peak systolic velocity was greater than 200 and a 2:1 velocity ratio was seen across the lesion.

SFA interventions requiring repeat angioplasty or stenting of previously occluded or stenotic SFA stents to maintain patency were recorded. Stent occlusions requiring stent thrombectomy were also noted and considered to be secondarily patent. Stent thrombectomy was accomplished by performing percutaneous mechanical thrombectomy with use of an initial pulse-spray technique and use of the Angiojet DVX catheter system (Medrad, Inc, Pittsburgh, Pa). After thrombectomy, tissue plasminogen activator infusion was continued for 24 hours, or a subsequent balloon angioplasty with possible stent placement was performed for residual stenosis (>30%). Primary, primary-assisted, and secondary patency rates were recorded throughout the duration of the study period and used as outcome measures when plotting survival curves.

RESULTS

Between January 2007 and January 2010, 500 diagnostic angiograms and balloon angioplasties were performed. Forty-two endovascular stenting procedures of SFA lesions were performed in 39 patients. Nine patients, with nine compromising stents, were lost to follow-up at 1 year but were included in the study. Twenty-two patients were men (56%) and 17 were women (44%). Mean patient age was 68 years (range, 43-88 years). Patient's comorbidities are listed in Table II. Of the 42 stents placed, 19 (45%) were placed for tissue loss, 15 (36%) for claudication, and seven (17%) for rest pain. Technical success rate was 100%. At 1-year, follow-up was available for 34 limbs with a mean of 14.9 months (range, 1-42 months).

Superficial femoral arterial segments treated were the only lesions included in this study. Thirty-two of 42 limbs had "good" (ie, >two distal vessels) distal vessel runoff scores. Fifteen lesions were classified as TASC A (36%), nine were TASC B (21%), five were TASC C (12%), and 13 were TASC D (31%).

Overall primary patency, primary-assisted, and secondary patency rates at 1 year were 24%, 44%, and 51%, respectively (Fig 1). Primary, primary-assisted, and secondary patency rates at 1 year for TASC A lesions were 47%, 66%, and 72%, respectively; for TASC B, 13%, 33%, and 33%, respectively; for TASC C, 40%, 40%, and 40%, respectively; and for TASC D, 0%, 32%, and 46%, respectively (Fig 2). When stratifying for patients who have had at least 1-year follow-up and more, primary, primary-assisted, and secondary patency rates increase to 34%, 54%, and 63%, respectively. Limb salvage was 93% during follow-up. SE

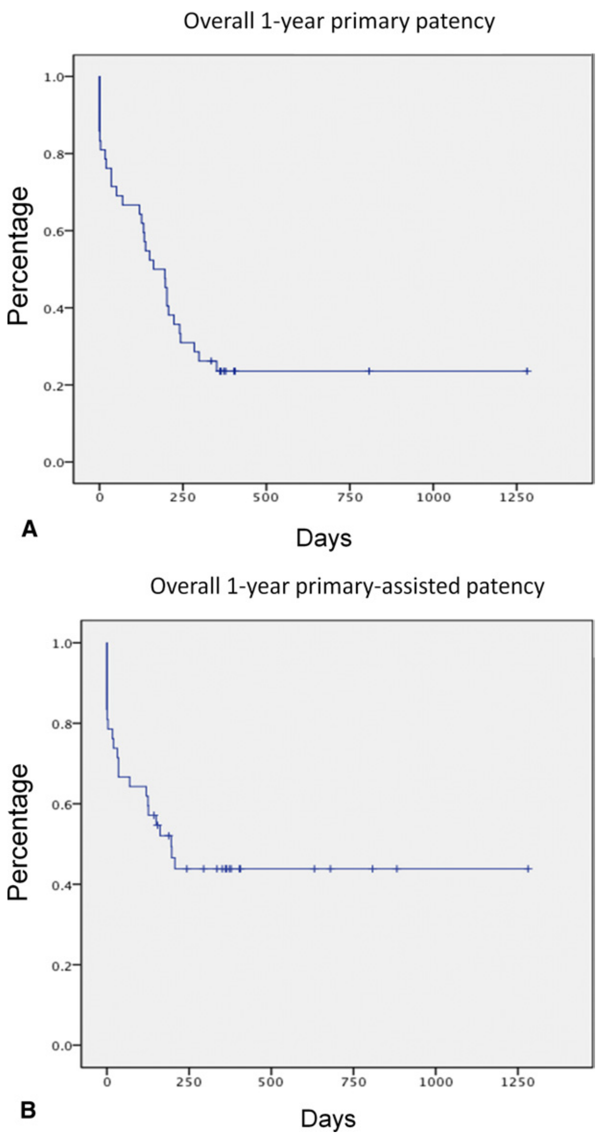

Fig 1. A, Overall 1-year primary patency. **B,** Overall 1-year primary-assisted patency.

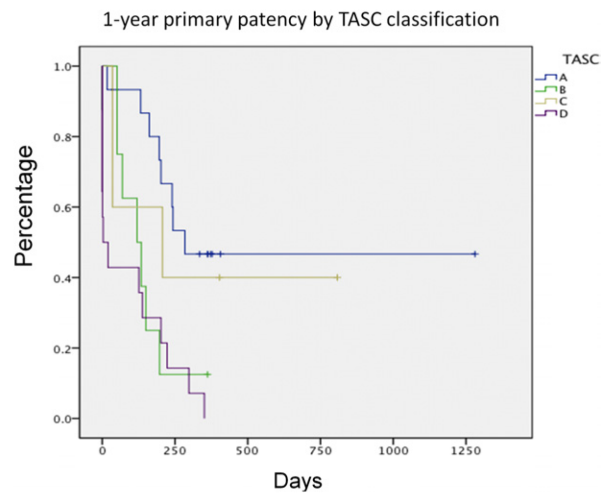

Fig 2. One-year primary patency by TransAtlantic Inter-Society Consensus (*TASC*) classification.

Table III. Risk factors: univariate analysis

Variable	*Hazard ratio (95% confidence interval)*	P *value*
Hypercholesterolemia	4.5 (0.851-24.00)	.077
Smoking history	6.088 (1.001-37.028)	.050
Diabetes	3.012 (0.681-13.329)	.146
Hypertension	0.287 (0.020-4.048)	.355

for calculated Kaplan-Meier patency curves was <10% at 12-month follow-up. In univariate analysis, history of hypercholesterolemia and smoking had a negative impact on primary patency (Table III).

Seventeen interventions failed (40%) at 1 year. Of the 17 failed interventions, nine stent failures were due to significant stenosis and eight were due to occlusions. Of the nine stent failures due to stenosis, six were due to intrastent stenosis and three were due to native arterial stenosis. SFA failure was evenly distributed among TASC classifications, with five classified as TASC A, four as TASC B, three as TASC C, and five as TASC D. Of the 17 failed SFA interventions, at the time of stent failure, symptoms were the following: seven (41%) had claudication, seven (41%) had ischemic rest pain, and three (18%) remained asymptomatic. Of the seven failed SFA interventions, only one progressed from claudication symptoms preprocedure to developing ischemic rest pain after stent failure. Thirty-day and 1-year mortality was 2.6% and 10.3%, respectively.

During follow-up, of the 17 failed SFA interventions, three went on to open bypass for limb salvage and three went on to major amputation (one after a failed bypass). The six limbs requiring either bypass or major amputation were TASC C or D lesions (Table IV). Of the patients that required amputation, one patient underwent stenting for chronic total occlusion of the SFA with tissue loss. Patency was lost and multiple percutaneous reinterventions failed. An open bypass was performed that failed and the patient underwent a below-the-knee amputation (BKA). The second patient underwent bilateral SFA stenting for gangrene. Patency of both stents was lost within 30 days and the patient subsequently underwent bilateral amputation for severe wet gangrene.

Of the patients requiring open bypass for limb salvage, one patient underwent stenting for chronic total occlusion of SFA with rest pain, primary patency was lost within 30 days, subsequent graft thrombolysis failed, and the patient underwent open bypass for CLI. A second patient underwent SFA stenting for nonhealing burn wounds that failed within 3 days without an attempt at revascularization. This patient underwent open bypass in order to

Table IV. Outcomes of failed SFA intervention by TASC classification

Event	*TASC A (n = 15)*	*TASC B (n = 9)*	*TASC C (n = 5)*	*TASC D (n = 13)*
Stent failure	5	4	3	5
Loss of runoff vessels	0	0	0	2
Open revascularization	0	0	1	2
Major amputation	0	0	2	1

SFA, Superficial femoral artery; *TASC,* TransAtlantic Inter-Society Consensus.

heal his wounds. A third patient with a previous iliofemoral bypass underwent SFA stenting for persistent foot ulceration. Patency was lost and, after multiple failed percutaneous reinterventions, open bypass was performed for CLI.

Distal vessel runoff was only affected in two failed SFA interventions. This change did not alter the bypass options for one patient. However, in the second patient, the bypass performed for CLI subsequently failed and the patient underwent a BKA.

Based on this experience, it seems that interventions performed for TASC C and D lesions are more likely to fail and more likely to lead to bypass for limb salvage or amputation, and, therefore, have a negative impact on limb salvage.

DISCUSSION

Peripheral arterial disease, which affects 8 to 10 million Americans in the United States, continues to contribute a significant morbidity and mortality to patients with vascular problems.[8] Progression of disease from stable claudication to CLI may occur and necessitates a comprehensive care plan for these patients. Treatment strategies range from medical therapy with risk factor reduction to endovascular therapy to open surgical bypass. Recent advances in endovascular technology and skill has sparked interest in endovascular treatment of advanced infrainguinal occlusive disease.[9] With improvement in nitinol stents and utilization of the subintimal technique, many authors advocate endovascular treatment of many advanced TASC D type femoropopliteal lesions.[5] Reported 1- and 2-year patency rates rival those for open surgical bypass. Baril et al,[5] in their review of 79 TASC D limbs treated with endovascular stenting, showed 1-year primary and primary-assisted patency rates of 52.5% and 88.4%, respectively.

Few randomized prospective trials exist comparing the efficacy of endovascular treatment with stenting vs open surgical bypass for SFA lesions. McQuade et al[10] reported long-term primary patency rates of endovascular-treated lesions similar to those of surgical bypass-treated lesions. In their study, primary patency in the stent graft group was 72%, 63%, 63%, and 59% at 12, 24, 36, and 48 months, respectively, compared to the surgical bypass group with 12, 24, 36, and 48 months of primary patency rates of 76%, 63%, 63%, and 58%, respectively. However, these studies fail to look at the affect of a failed SFA intervention on limb salvage.

A recent retrospective review by Gur et al[7] examined their 5-year experience with endovascular treatment of SFA lesions. In their report, they found that lesions classified as TASC C or D were more likely to fail with occlusion, lose runoff vessels, and can alter the site of subsequent open operation than their TASC A or B counterparts. The authors concluded that a failed SFA intervention in advanced infrainguinal occlusive disease may negatively impact later attempts at revascularization.

In our study, SFA stenting performed for TASC C or D lesions was more likely to fail and more likely to lead to bypass or amputation when compared to TASC A or B lesions. When an SFA intervention failed with stent occlusion in TASC C or D lesions, they were more likely to undergo major amputation. None of the patients in our study that had TASC A or B lesions that had loss of patency required any further intervention. Patients that were intervened for claudication, despite having a hemodynamically significant stenosis or occlusion, were more likely to either be asymptomatic or have tolerable claudication and not require a bypass or amputation, whereas patients intervened for CLI that had a failed SFA intervention were more likely to lead to multiple attempts at open revascularization and major amputation.

The higher amputation rate seen in our study in more advanced TASC C/D lesions compared to TASC A/B lesions may just represent the extent of disease. Several authors[7,11] have found that failed SFA interventions in advanced TASC C/D lesions effect subsequent distal bypass procedures. When performing endovascular stenting of advanced TASC C/D lesions with use of angioplasty in the subintimal plane, loss of collateral circulation can occur. Without this circulation in place, if stent failure occurs, patients may progress to more advanced clinical disease. Furthermore, with the lack of collateral circulation in place, there is a theoretic risk of stent thrombosis propagating to runoff vessels and effecting limb salvage.

In our series, six patients with failed SFA interventions went on to undergo major amputation or bypass. Four patients required open surgical bypass; one of them failed and required a BKA. Of the three remaining bypasses, two of them required further secondary balloon angioplasty for anastomotic stenosis and one of them required an open surgical revision. None of the amputations occurred in the face of patent stents. Overall limb salvage was 93%. None of our patients with a failed SFA intervention crossed over to a more advanced TASC classification. Only one patient with a TASC D classification who underwent endovascular stenting for claudication that failed progressed to rest pain with no tissue loss. This patient refused any further intervention. Similar to findings in the bypass vs angioplasty in severe ischemia of the leg (BASIL) trial,[11] four of the six failed SFA interventions had significant negative impact on patency of bypass grafts and limb salvage. It seems that the stenting first with no consequence adage can be detrimental to both limb salvage and to further attempts at revascularization.

We conclude that patients with advanced infrainguinal occlusive disease with CLI (TASC C/D lesions) would likely benefit from open surgical bypass over endovascular stenting. However, many of these patients are not appropriate surgical candidates and endovascular therapy is the only option. These patients present a difficult treatment dilemma for vascular surgeons. Based on our study, patients with CLI that undergo a failed percutaneous SFA intervention have a higher likelihood of amputation. Furthermore, stent thrombosis may have a negative impact on bypass patency. The higher amputation rates seen in patients with TASC C or D lesions compared to TASC A or B lesions again may just represent extension of disease. Randomized control trials comparing stenting vs open bypass in advanced TASC C and D lesions with limb salvage as the primary outcome would shed some light on the subject. Patients with advanced TASC C or D lesions that undergo stenting for claudication are more likely to fail than their TASC A or B counterparts, but a failed SFA intervention in these patients does not necessarily lead to amputation or bypass. Based on this experience, patients with lifestyle-limiting claudication with TASC C and D lesions that are appropriate surgical candidates and have adequate autogenous vein available should undergo open surgical bypass as opposed to endovascular therapy.

AUTHOR CONTRIBUTIONS

Conception and design: OA, BA, RM, PH, RH
Analysis and interpretation: OA, BA, RM, MK, RH
Data collection: OA, BA, RM, MK, AG, RH
Writing the article: OA, BA, RM, RH
Critical revision of the article: OA, BA, RM, RH, PH, AG
Final approval of the article: OA, BA, RM, RH
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Overall responsibility: OA

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DISCUSSION

Dr Peter Rossi (*Milwaukee, Wisc*). Thank you, Dr Al-Nouri, for the nice presentation. I would like to thank the program committee for giving me the opportunity to review this and thank Dr Al-Nouri for getting me the article several weeks ago. The article is a nice summary of isolated superficial femoral artery stenting for infrainguinal disease, and, despite the small number of patients in the series and the small number of limbs, I think it does give us some valuable insights. The 93% overall limb salvage rate in your article is laudable. It is interesting, though, that 31% of the cases that were done here were for TASC D lesions and 36% overall were done for claudication. When I examined the data and just sat down with a calculator, if I eliminated the claudication patients, the actual limb salvage rate for patients with chronic limb ischemia was down to 77%, and that's pretty comparable to previously published articles for redo infrainguinal bypass procedures. I'm a little bit curious. Could you comment on that? I have four overall questions regarding your manuscript. One, in your results in the manuscript, you mentioned that there were "500 lower extremity angioplasty and diagnostic angiogram procedures," so if I take it that you stented 42 of these, that gives you a 92% rate of isolated percutaneous transluminal angioplasty and you only stented about 8%. I'm wondering what your criteria were for actually placing stents and whether the fact that you stented a lesion meant that it was a higher-risk lesion and perhaps more likely to fail. Our group has previously shown that the number of patent runoff vessels is directly proportional to the rate of success of these procedures. You mentioned in your manuscript that you had an average of 2.1 patent tibial vessels in your procedures here, and I'm wondering if you examined the patency of the runoff in terms of the success of the intervention. The third question is about your medical management. You did mention that the patients were on aspirin and Plavix, or one of the two. I'm curious as to whether you put these patients on statins or how involved you get in the medical management. There are certainly data that suggest improved patency and better outcomes with patients who are on statins and angiotensin-converting enzyme (ACE) inhibitors. I don't know if you're involved with that. Probably my only concern with the manuscript is that you do make the statement that the failure of these procedures for TASC C and D lesions leads to a decrease in limb salvage, and I'm not really sure that you showed that. The reason I say that is that they are moving on to having open revascularization, and at that point, your limb salvage rate is still very similar to previously published data for redo procedures. So I don't know if it's really that the failure of the procedure leads to a problem or if it just indicates more severe disease and they have to go on to another procedure, like they might traditionally have to. Thanks for allowing me to review this. I look forward to your responses.

Dr Omar Al-Nouri. Thank you, Dr Rossi. With regard to your first question, when you break it down, if you take away the claudication patients who were intervened on and you look at just the critical limb ischemia, the limb salvage is pretty comparable to open bypass. However, when SFA interventions fail, I think several recent studies have shown that it might not have an absolute effect on negative limb salvage, but it does change the distal target bypass, and that might decrease the patency of the open revascularization and make the bypass more difficult subsequently when you do have a failed SFA intervention, which could lead to decreased limb salvage. When we looked at the numbers for our patients, we used several CPT codes, and the 500 angioplasties that we looked at, those were not only just balloon angioplasty/stenting, but that included iliac interventions as well as diagnostic angiograms. So it was a large amount of data to go through to find just those 42 limbs. I think you're right, we specifically looked at patients that just underwent SFA stenting, we excluded patients that underwent only balloon angioplasty, thus, we're selecting out for these more advanced lesions and maybe setting it up for potentially having a failure. I'm sorry, the third and fourth questions? I apologize.

Dr Rossi. One was about medical management as far as using statins or ACE inhibitors, and the other was about the assumption that the failed percutaneous intervention leads to more difficult procedures for limb salvage.

Dr Al-Nouri. For the medical management, we have always put those patients on 30 days of Plavix postoperatively. We are pretty involved in the statin therapy with the medical doctors as well, so we do place the patients on statins if they were not on statins before and they have an indication to be on statin therapy. We talked about excellent vessel runoff, good vessel runoff, or poor vessel runoff, with a score of 3, 2, and 1, respectively, but did not break the patients down into these categories to see if they have a better patency rate the higher the runoff score is. We are still accruing data from the Veteran Affairs; once we have a more substantial number of patients, we will definitely look at patency rates broken down by runoff score.

Dr Karl Illig (*Rochester, NY*). I have good news and bad news for you. The good news is that your article was very well presented and your data were very clear, and I thank you very much for that. The bad news is that I have to pile on a little bit with regard to the prior discussant's fourth question. I don't think you have really answered what you have set out to ask. Rather, you've really sort of just reaffirmed the definitions of TASC C and D lesions. In other words, your results really are no more than the definitions of TASC C and D. The question you're trying to answer is if you initially approach a patient using endovascular techniques, do you burn your bridges; are you making things worse? A way of answering this would be to take your stented patients and blindly determine what a surgical bypass would have entailed, and then, when those who fail do so, compare what they end up requiring. If a patient would have required bypass to the popliteal level originally and then after a failed stent requires a pedal bypass, you've burned your bridges. Be careful about saying that just because some patients went on to amputation that you're doing anything good or bad – that is the natural history of this disease, and you cannot say that you have changed anything without some sort of control group.

Dr Al-Nouri. No, it's a very good question. We are also looking at our open bypass experience within the same time period. The idea when we set out looking at our SFA experience was how can we tie this in exactly with a failed SFA intervention? Does it burn our bridge in terms of the distal target that they might have? So it's one thing we are going to look at, as well as compare and look at the open bypass surgery and see, in this patient who failed and subsequently went on to have an open bypass, if it was the patency rate as opposed to someone who did not fail initially and see if those are comparable or not.

Dr Illig. Because your number is so small, for this article you could really very easily figure out what their bypass would have been and then what their bypass ended up being afterward.

Dr Al-Nouri. Yes.

Dr Philip Goodney (*Lebanon, NH*). That was nicely presented. I just wondered if you had calculated amputation-free survival curves or major adverse limb event curves. They would help to put into context some of the discussions that you've had with those who have come up to talk about your article. Patency is dependent upon how long a patient lives, of course, and you put a lot of stents into some very sick patients, and that might affect the overall limb salvage rate, just because a patient might not live long enough to get their amputation. Similarly, limb-specific outcome measures, such as the major adverse limb events, which is one of the Society for Vascular Surgery objective performance goals that we'll use to compare these results to open surgery, might effectively contribute to your study. I wonder if you have that information, and if you don't, will you put it in your manuscript?

Dr Al-Nouri. I don't have that information on hand right now. We're still looking at it. But we are looking at the amputation-free survival and it probably will be in the manuscript. You know, looking at amputation-free survival, that number might not be as significant as patency, and that's kind of why we wanted to specifically look at patency, because we did have a significant percentage of patients (36%) who were claudicants. Those patients should survive. So, amputation-free survival might not be the best indicator in patients with critical limb ischemia.

INVITED COMMENTARY

Ruth L. Bush, MD, MPH, *Temple, Tex*

The utilization of lower extremity endovascular interventions for the treatment of both claudication and critical limb ischemia has dramatically increased in the last decade. Part of this increase may be accounted for because of technological advances and part may be due to more aggressive treatment of patients considered high medical risk who would have previously been precluded from more traditional open bypass procedures. Dr Al-Nouri and colleagues have provided a detailed analysis of their institutional experience with endovascular interventions in the superficial femoral artery. Despite the small size of the study group and the cohort heterogeneity, their results have produced some important treatment options and essential patient messages that can be used by the peripheral interventionalist.