Subintimal angioplasty: Our experience in the treatment of 506 infrainguinal arterial occlusions

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Objective: The treatment of patients with chronic arterial occlusions involving the superficial femoral artery has changed significantly with the incorporation of subintimal angioplasty (SIA) into vascular surgery practice. To more clearly define technical feasibility, patency, and clinical outcomes of SIA, we reviewed our cumulative experience.

Methods: A retrospective review of all patients who underwent SIA of arterial occlusions originating in the superficial femoral artery was performed. Patient history, demographics, procedural details, and follow-up information were collected and analyzed. Patency, limb salvage, sustained improvement in claudication, freedom from surgical bypass, and survival were determined by Kaplan-Meier analysis.

Results: From December, 2002, through July, 2006, 506 infrainguinal SIA procedures were performed in 472 patients with chronic arterial occlusion involving the superficial femoral artery. The mean age of patients treated was 69.4 ± 11.9 years and the indication for intervention was critical limb ischemia in 63% of limbs (n = 317) and disabling claudication in 37% (n = 189). Forty-seven percent of limbs (n = 237) had isolated SFA occlusions, 40% (n = 205) had femoropopliteal occlusions, and 13% of limbs had occlusions beginning in the SFA and extending into the tibial arteries (n = 64). Technical success was achieved in 87% of procedures. Following successful SIA, the mean ankle-brachial index increased by 54%, from 0.50 ± 0.16 to 0.77 ± 0.23 (P < .0001). Median follow-up was 12.4 months (0-48 months) and 30-day mortality was 0.8%. Primary patency at 12 and 36 months was 45% (SE 3.0%) and 25% (SE 3.6%) respectively. Secondary patency was 76% (SE 2.6%) and 50% (SE 4.8%) at 12 and 36 months. Factors associated with reduced primary patency included femorotibial occlusions (HR 1.57, CI 1.05-2.36) and the presence of critical limb ischemia (HR 1.39, CI 1.02-1.89). Limb salvage in patients with critical limb ischemia was 75% (SE 5.9%) at 36 months. Freedom from surgical bypass in patients with either critical limb ischemia or disabling claudication was 77% (SE 4.1%) at 36 months.

Conclusion: SIA is an effective percutaneous technique for the revascularization of patients with lower extremity chronic arterial occlusions involving the superficial femoral artery. The procedure is successfully performed in all segments of the lower extremity with minimal morbidity or mortality. Rates of limb salvage and improvement in claudication are similar to those achieved by open surgical bypass, while modest reductions in limb salvage and primary patency are experienced in limbs with femorotibial occlusions. (J Vasc Surg 2008;48:878-84.)

Subintimal angioplasty (SIA), a percutaneous method of lower extremity revascularization devised for the treatment of arterial occlusions, is increasingly being utilized in the United States. Discovered and initially popularized in the United Kingdom, SIA has been used effectively in the treatment of patients with critical limb ischemia as well as disabling claudication, reports of which are now present in both American and European literature.

The majority of these reports have provided short-term and mid-term outcomes in patients undergoing SIA for critical limb ischemia, while fewer reports of patients treated for disabling claudication exist. Most studies have included relatively small numbers of patients, resulting in limited statistical power to determine the types of patients and lesions best treated with SIA. With this in mind, we reviewed our collective experience using SIA as primary therapy for patients with disabling claudication or critical limb ischemia due to arterial occlusions originating in the superficial femoral artery (SFA).

METHODS AND MATERIALS

A retrospective review of all patients who underwent SIA from December 1, 2002 through July 31, 2006 was performed. Early in our use of SIA, patients treated were those with impending limb loss who were at prohibitive operative risk. As examples of limb salvage became numerous and the safety of SIA became apparent, the procedure was incorporated into first-line therapy for patients with extensive arterial occlusions who were facing open bypass if not for SIA. The vast majority of patients treated in this review were treated as part of a SIA-first approach to long segment occlusions not amenable to transluminal balloon angioplasty. SIA was not used in the treatment of patients with acute arterial occlusion or in patients with stenoses alone. Patients treated for isolated iliac, popliteal, or tibial artery occlusions were excluded from the study population. Patient demographics, clinic notes, non-invasive vascular studies, angiographic findings, and procedural reports were reviewed following approval by the Institutional Review Board.
Arterial occlusions ranged from those limited to the SFA to those extending through the popliteal artery into one or more tibial arteries. The vast majority of procedures were performed in an angiographic suite while the remaining procedures were performed in an operating room with non-fixed fluoroscopy if deep sedation, general anesthesia, or simultaneous open surgical procedures were required. Retrograde contralateral common femoral arterial puncture was the preferred means of angiographic access. Following angiography and identification of an infragenual arterial occlusion, patients were systemically heparinized. Lesions were typically approached by placement of a sheath over the aortic bifurcation and in proximity to the occlusion. A soft, angled, hydrophilic 0.035-inch guidewire in combination with a 4 French angled hydrophilic catheter (Glidecath, Terumo Medical Corporation, Somerset, New Jersey) were most commonly used to perform the subintimal dissection. The subintimal plane was entered by formation of a loop at the end of the guidewire and advancing it, along with the catheter, across the occluded arterial segment. Indicators of subintimal dissection included characteristic resistance to wire advancement, a broad helical path taken by the wire during advancement, the guidewire loop assuming the width of the native vessel, and a subtle release of wire resistance with true lumen re-entry near the distal extent of arterial occlusion. Occlusions crossed with the straight tip of a soft guidewire were considered transluminal recanalizations and excluded from this review. After confirmation of catheter re-entry into the true lumen, balloon angioplasty was used to dilate the subintimal channel. Balloons measuring 5-6 mm were typically used in the SFA, 4-5 mm balloons were typically used in the popliteal artery, and 2.5-3 mm balloons were selected for tibial angioplasty. Inflations were held for 60-120 seconds. Stents were selectively deployed within the channel to further open segments of suboptimal angioplasty, defined as residual stenosis >30%. This was most commonly required in regions of heavy calcification and at subintimal entry and re-entry points. Technical success consisted of the creation of a subintimal channel around the occlusion, successful re-entry into the true lumen, and balloon angioplasty establishing forward flow through the new lumen.

Following the procedure, patients received clopidogrel for a minimum of one month and aspirin indefinitely. Clinical follow-up at one month, three months, and six to twelve months following the procedure was routine and included physical examination and measurement of ankle-brachial indices. Duplex examination of the subintimal channel and further follow-up were obtained at the discretion of the surgeon. All additional endovascular procedures (balloon angioplasty, stenting, redo SIA, mechanical thrombolysis) to maintain or restore patency of the subintimal channel were recorded, as were all open surgical revisions, bypasses, major amputations, and deaths that occurred through December 31, 2006.

Patency of SIA was defined by at least one of the following criteria: flow through the vessel demonstrated by angiography or duplex ultrasound, maintenance of an ankle-brachial index >0.10 above the pre-procedure value,9 or maintenance of a palpable pedal pulse that was absent prior to the procedure in a patient asymptomatic following the procedure. All percutaneous reinterventions on the SIA were recorded for calculation of primary-assisted and secondary patency, as previously defined.9 Any limbs requiring open revascularization during the follow-up period were recorded and considered an endpoint of SIA patency. Symptomatic improvement in patients with critical limb ischemia was defined as the resolution of rest pain or healing of ulcers and gangrenous wounds following debridement or minor amputation. Symptomatic improvement in patients with claudication was defined as improvement in walking distance, as determined through follow-up visits. Continuous data is expressed as mean ± standard deviation and compared using Student’s t-test. P < .05 was considered statistically significant. Patency, limb salvage, symptomatic improvement, freedom from surgical bypass, and survival were determined using Kaplan-Meier survival analysis and compared by log-rank testing. Multivariate analysis was performed using Cox proportional hazards regression. Data is presented based upon technical successes of SIA to facilitate comparability of results between studies at a time when the rate of technical success remains variable10,11 and alters outcome data when analyzed on an intention-to-treat basis.

RESULTS

Subintimal angioplasty was performed in 506 limbs (472 patients) for infragenual arterial occlusions originating in the SFA between December 1, 2002 and July 31, 2006. Each procedure was performed by one of 14 board-certified vascular surgeons. The median number of procedures performed per surgeon was 34 (range, 6 to 62). Subintimal angioplasty was used more frequently as the study period progressed. In 2003, the first full year of study, 33 procedures were performed, while in 2005, 191 procedures were performed.

Patient demographics are presented in Table I. The indication for intervention was critical limb ischemia in 63% of limbs (n = 317) and disabling claudication in the remaining 37% of limbs (n = 189). Forty-seven percent of limbs (n = 237) had isolated SFA occlusions, 40% (n = 205) had femoropopliteal occlusions, and 13% of limbs (n = 64) had occlusions beginning in the SFA and extending into the tibial arteries. Lesion lengths were not consistently recorded at the time of procedure, however, the vast majority of lesions treated were either TransAtlantic Inter-Society Consensus (TASC) C or D (TASC I classification).

Subintimal angioplasty was performed in each limb when the arterial occlusion was not amenable to transluminal revascularization. The procedure was technically successful in 87% of attempts (n = 439). Technical success, based upon the extent of the occlusion treated, ranged from 84% in isolated SFA occlusions to 89% in cases of occlusion extending into the popliteal and tibial arteries (P = .45). Failure to re-enter the true lumen accounted for 73% (n = 49) of the 67 unsuccessful cases. Failure to enter the subintimal plane (n = 6), inability to cross the lesion
Table I. Patient demographics and risk factors for peripheral arterial disease

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>472</td>
<td></td>
</tr>
<tr>
<td>Limbs</td>
<td>506</td>
<td></td>
</tr>
<tr>
<td>Mean age, years</td>
<td>69.4 ± 11.9</td>
<td></td>
</tr>
<tr>
<td>Range, years</td>
<td>37-99</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>284</td>
<td>56.1</td>
</tr>
<tr>
<td>Indication</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>317</td>
<td>62.7</td>
</tr>
<tr>
<td>Rest pain</td>
<td>131</td>
<td>25.9</td>
</tr>
<tr>
<td>Ulceration</td>
<td>127</td>
<td>25.1</td>
</tr>
<tr>
<td>Gangrene</td>
<td>59</td>
<td>11.7</td>
</tr>
<tr>
<td>Claudication</td>
<td>189</td>
<td>37.3</td>
</tr>
<tr>
<td>Risk Factors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>361</td>
<td>71.9</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>276</td>
<td>54.5</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>247</td>
<td>48.8</td>
</tr>
<tr>
<td>Tobacco use</td>
<td>237</td>
<td>47.3</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>190</td>
<td>37.8</td>
</tr>
<tr>
<td>Previous infrapopliteal bypass</td>
<td>113</td>
<td>22.4</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>62</td>
<td>12.3</td>
</tr>
</tbody>
</table>

(n = 6), and failure to establish forward flow through the subintimal channel following angioplasty (n = 6) accounted for the remainder of unsuccessful attempts. In these 67 patients, 27 underwent subsequent surgical bypass procedures, 12 underwent primary major amputation, and nine patients died without further intervention. The remaining 19 patients had no further intervention by our surgeons.

Adjunctive procedures were utilized in the treatment of 5.3% of limbs (n = 27). These included open common femoral endarterectomy (n = 16), open common femoral artery exposure to facilitate SIA (n = 2), femoral-femoral bypass (n = 1), laser atherectomy (n = 2), and use of endoluminal re-entry devices (n = 6). Bare metal stents were deployed in 20.3% (n = 89) of successful SIA procedures. In these procedures, a mean of 1.6 ± 0.8 stents were used with a mean total stent length of 99.1 ± 71.3 mm. Complications occurred in 5.5% of procedures (n = 28), and included 15 arterial perforations (3.0%), none of which resulted in hemorrhage, four femoral artery pseudoaneurysms (0.8%), four episodes of distal embolization (0.8%), two arteriovenous fistulas (0.4%), one groin soft-tissue infection (0.2%), one groin hematoma (0.2%), one retroperitoneal hematoma (0.2%), and one common femoral artery intimal flap (0.2%). Only the common femoral artery intimal flap required open surgical intervention for correction. The remaining complications were treated conservatively (n = 21) or by percutaneous means alone (n = 6). Femoral pseudoaneurysms were treated by duplex-directed thrombin injection as appropriate and distal emboli were recovered with aspiration catheters.

The median follow-up was 12.4 months (range, 0 to 48 months). In limbs successfully treated with SIA, 308 limbs (70%) had pre-procedural ankle-brachial indices (ABI) measured. The remaining 30% of limbs (n = 198) presented with tissue loss and were taken directly for angiography and intervention or had ABI that could not be located. Forty-three percent of limbs (n = 189) had ABI measured up to one month before and up to one month after the procedure. In these limbs with paired pre- and post-SIA measurements, the mean increase in ABI was 0.27 (SE 0.16), from 0.50 ± 0.16 to 0.77 ± 0.23 (P < .0001). Primary patency was 45% (SE 3.0%), 30% (SE 3.3%), and 25% (SE 3.6%) at 12, 24, and 36 months, respectively (Fig. 1). Primary-assisted patency was 61% (SE 3.0%), 42% (SE 3.6%), and 38% (SE 3.9%) at these intervals, while secondary patency was 76% (SE 2.6%), 57% (SE 3.7%), and 50% (SE 4.8%). Subsequent endovascular procedures were required to maintain or restore patency in 122 limbs (28%).

When patency of SIA was further analyzed based upon the distal extent of arterial occlusion, reductions in patency were observed for each more distal segment of occlusion (Fig. 2). At 36 months, primary patency was 31% (SE 6.6%) in 200 limbs with isolated SFA occlusion, 20% (SE 5.2%) for 182 femoropopliteal occlusions, and 16% (SE 6.9%) for 57 limbs with femorotibial occlusions. Primary patency of femorotibial SIA was significantly lower than for femoropopliteal (P = .05) or isolated femoral SIA (P = .005). Secondary patency at 36 months was 54% (SE 8.5%) for femoral SIA, 48% (SE 7.1%) for femoropopliteal SIA, and 43% (SE 11.2%) for limbs requiring femorotibial SIA (Fig. 2). These differences did not reach statistical significance (P = .08).

Multiple factors that may affect primary patency were examined by univariate analysis (Table II). The presence of diabetes, female gender, critical limb ischemia, and tibial vessel re-entry were each associated with reduction in primary patency. In multivariate analysis, however, only femer.
Surgical bypass was performed in 49 of 439 limbs (11.2%) at a mean of 8.5 ± 8.2 months following SIA. Sixty-three percent of bypasses (31 of 49) were performed in critically ischemic limbs. By Kaplan-Meier analysis, freedom from surgical bypass was 77% (SE 4.1%) at three years. There were no patients for whom SIA was believed to have altered the level of surgical bypass.

Major amputation (above-knee or below-knee) was required in 31 of 439 limbs (7.1%) at a mean of 8.2 ± 10.1 months. Limb salvage in 265 limbs treated for CLI was achieved in 88% (SE 2.5%) of limbs at 12 months, 81% (SE 3.9%) of limbs at 24 months, and 75% (SE 5.9%) of limbs at 36 months. Only one amputation was performed in a patient who presented with disabling claudication. This occurred 35 months following femoropopliteal SIA in a patient who progressed to gangrene of the foot secondary to worsening tibial vessel disease. Prior to amputation, a femorotibial bypass and a popliteal-tibial bypass had been performed in the preceding two years, each of which failed following progression of disease. Limb salvage was further analyzed by extent of occlusion (Fig. 3). At 36 months, limb salvage was 88% (SE 4.1%) in limbs with isolated SFA occlusions, 68% (SE 11.1%) in limbs with femoropopliteal occlusions, and 64% (SE 11.0%) in limbs with femororotal occlusions. In comparison to isolated SFA occlusions, limb salvage for femorotibial occlusions was significantly reduced (P = .02).

There were 174 limbs treated for disabling claudication with SIA. Claudication was improved or eliminated in 96.8% of limbs three months following the procedure. Sustained improvement in walking distance was attained in 90% (SE 2.7%) of limbs at 12 months, 76% (SE 4.7%) of limbs at 24 months, and 67% (SE 7.5%) of limbs at 36 months. No differences in outcomes were found between limbs with isolated femoral versus femoropopliteal occlusions (P = .45). The small number of femorotibial procedures for claudication (n = 8) precluded meaningful statistical comparison.

There were four deaths (0.8%) within 30 days of the procedure, none of which were attributed to the vascular intervention. A total of 64 patients (14%) died during the study period, 56 of whom had critical limb ischemia. By Kaplan-Meier analysis, three-year survival in patients with disabling claudication was 84% (SE 6.8%) (Fig. 4). In patients with critical limb ischemia, three-year survival was 55% (SE 7.8%).

**Fig 2.** Primary patency of subintimal angioplasty by extent of occlusion. At 36 months, primary patency in limbs with isolated superficial femoral artery (SFA) occlusion was 31% (SE 6.6%). In limbs with femoropopliteal occlusion, primary patency was 20% (SE 5.2%), and in limbs with femororotal occlusion, primary patency was 16% (SE 6.9). Primary patency in limbs with femoropopliteal occlusion was significantly reduced in comparison to limbs with isolated SFA occlusion (P = .005) or femororotal occlusion (P = .05). Standard errors are <.10% for all data points.

**Table II.** Univariate analysis of factors potentially associated with reduced primary patency of subintimal angioplasty

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>HR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tobacco use</td>
<td>0.92</td>
<td>0.68-1.22</td>
<td>.55</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.95</td>
<td>0.69-1.30</td>
<td>.72</td>
</tr>
<tr>
<td>Stent use</td>
<td>0.96</td>
<td>0.69-1.33</td>
<td>.79</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>1.33</td>
<td>1.01-1.82</td>
<td>.04</td>
</tr>
<tr>
<td>Female gender</td>
<td>1.35</td>
<td>1.02-1.85</td>
<td>.03</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>1.58</td>
<td>1.18-2.10</td>
<td>.002</td>
</tr>
<tr>
<td>Femororotal occlusion</td>
<td>1.66</td>
<td>1.16-2.99</td>
<td>.01</td>
</tr>
</tbody>
</table>

HR, hazard ratio; CI, confidence interval.

**Table III.** Multivariate analysis of factors associated with reduced primary patency of subintimal angioplasty

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>b</th>
<th>SE</th>
<th>HR</th>
<th>95% CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femororotal occlusion</td>
<td>0.45</td>
<td>0.21</td>
<td>1.57</td>
<td>1.05-2.36</td>
<td>.03</td>
</tr>
<tr>
<td>Critical limb ischemia</td>
<td>0.33</td>
<td>0.16</td>
<td>1.39</td>
<td>1.02-1.89</td>
<td>.04</td>
</tr>
<tr>
<td>Female gender</td>
<td>0.27</td>
<td>0.15</td>
<td>1.31</td>
<td>0.98-1.75</td>
<td>.07</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.25</td>
<td>0.15</td>
<td>1.28</td>
<td>0.95-1.73</td>
<td>.11</td>
</tr>
</tbody>
</table>

b, beta; SE, standard error; HR, hazard ratio; CI, confidence interval.

Stent use was not associated with improved patency (HR = 0.96). Primary patency at three years in patients requiring stent placement was 28% compared with 24% in those who did not (P = .59). Secondary patency at three years was 45% in patients receiving stents and 51% in patients who did not (P = .47).
DISCUSSION

The role of SIA in the care of patients with peripheral arterial disease is gradually emerging as numerous centers now report their experience with the technique.12-17 What began as a salvage technique for patients facing amputation without surgical options has now become a valuable tool in the endovascular arsenal of surgeons treating increasingly complex arterial occlusions.

In this report, the largest review of SIA published to date, we provide new data on the patency and clinical outcomes of patients treated with SIA for arterial occlusions originating in the SFA. In all patients, primary patency of SIA was 45% at one year and 25% at three years. During this period, 28% of patients required percutaneous reintervention to maintain or restore patency of the subintimal channel. This resulted in secondary patency of 76% at one year and 50% at three years. These results are comparable to prior reports of SIA,2,6,8,14,17,18 and are also comparable to published results of prosthetic bypass patency at five years ranging from 39% to 77% for above-knee bypass, to 25% for tibial bypass.19-22 Secondary patency of SIA appears to be inferior to that of historical saphenous vein bypass results, which have been reported in many earlier studies to be between 74% and 85%.19,21,23-25 However, our results approach vein bypass outcomes recently reported in the PREVENT III trial that evaluated one-year outcomes in 1404 similarly co-morbid patients with critical limb ischemia.26 In this study, conducted between 2001 and 2003, primary, primary-assisted, and secondary patency at one year were 61%, 77%, and 80%. These results are not surprising, as many patients with TASC Class A, B, and even C lesions – lesions once treated with surgical bypass – are now treated percutaneously per TASC and TASC II guidelines.27,28 The remaining population of patients, largely those with TASC C and D lesions, are by definition, those with the most extensive disease.

Despite the modest overall patency of SIA, clinical outcomes in patients with either disabling claudication or critical limb ischemia were clearly better than patency data would predict, and are similar to those achieved by surgical bypass.26,29 In our patients, limb salvage in patients with CLI was 75% at three years and 67% of patients with disabling claudication reported improvement or resolution of symptoms at three years. Overall, only 23% of patients treated with SIA required surgical bypass during the study period. There are several possible explanations for the modest discrepancy between patency data and clinical outcomes. First, patency was determined by strict objective assessment only. Long-term follow-up evaluations of patients doing well and “clinically” patent but without objective evidence of such were not considered in Kaplan-Meier calculations of patency. As a result, the actual patency may have been compromised by the lack of uniform ABI and arterial duplex assessment in the post-procedure period. Comparison of “clinical patency” with limb salvage may have yielded more similar results. Second, successful SIA enabled wound healing and healing of minor lower extremity amputations, after which loss of SIA patency may not have lead to recurrence of symptoms. Third, SIA may have provided time for patients to develop additional collateral circulation, reducing or eliminating recurrence of symptoms in some patients whose SIA later failed. Finally, survival of patients with critical limb ischemia in this series was only 55% at three years. Due to the impact of multiple medical co-morbidities present within this portion of our study population, many who experience SIA failure do not

![Fig 3. Limb salvage by extent of arterial occlusion. At 36 months, limb salvage was 88% (SE 4.1%), 68% (SE 11.1%), and 64% (SE 11.0%) for limbs with isolated SFA, femoropopliteal, and femorotibial occlusion, respectively. In comparison to limbs with isolated SFA occlusion, limb salvage in extremities with femorotibial occlusion was significantly reduced (P = .02). Fine dotted line denotes SE > 10%.](image1)

![Fig 4. Survival in 472 patients with disabling claudication or critical limb ischemia (CLI) secondary to infrainguinal arterial occlusion involving the superficial femoral artery. At three years, survival was 84% (SE 6.8%) in patients with claudication and 55% (SE 7.8%) in those with CLI (P < .0001). Standard errors are <10% for all data points.](image2)
live long enough to develop tissue loss necessitating surgical bypass or amputation.

There are several unique findings of this study. The first is that SFA occlusions extending into the popliteal or tibial arteries do not negatively impact technical success. When analyzed by extent of occlusion, there were no differences in rates of technical success. In addition, there was limited use of re-entry devices during the study period, as they have only recently become available. Increased use of such devices will likely improve rates of technical success for SIA based upon early reported experience with these devices.

The second unique finding is that the primary patency of SIA and limb salvage is impacted by the distal extent of arterial occlusion. Over half of the limbs treated in this study presented with occlusions originating in the SFA that continued into either the popliteal or tibial arteries. Patients treated with SIA for femorotibial occlusions experienced significant reductions in primary patency. This difference was less pronounced in examination of secondary patency, but the trend persisted. Limb salvage at three years was likewise reduced in patients with femorotibial occlusions. Similarly, Lazaris et al have reported on 46 patients with critical limb ischemia and various levels of infrainguinal arterial disease treated with SIA and found length of occlusion to be an independent predictor of reduced patency.

However, the individual arterial segments involved were varied among these patients and is a potentially confounding factor when calculating the importance of length.

The third important finding is that selective stenting of portions of the subintimal channel not well expanded by angioplasty alone results in equivalent patency to those patients who receive successful SIA alone. There were no significant differences in primary or secondary patency between patients who required stent placement and those who did not. Treiman et al reported SIA results utilizing a primary stent placement approach in 29 patients with critical limb ischemia. While primary patency was 85% at one year, patency fell to 18% at three years and 9% at four years. Although recent reports of intraluminal SFA angioplasty have demonstrated an early benefit to primary stenting, we do not believe these results can be readily applied to subintimal revascularization. Instead, we believe that selective stent placement for suboptimal angioplasty is a reasonable approach and likely improves patency in those patients requiring it, resulting in nearly equivalent outcomes at three years.

As SIA provided similar limb salvage in our patients with critical limb ischemia and durable relief from claudication, with less morbidity and mortality than reported for open bypass, the role of SIA in the care of patients with peripheral vascular disease is now more clearly defined within the authors’ practice. A SIA-first approach has been adopted for nearly all patients presenting with symptomatic occlusions involving the SFA. Patients almost unanimously prefer this approach when percutaneous and open surgical options are discussed prior to angiography, and as SIA does not preclude future bypass surgery, this option is preserved for the minority of patients who might later require it. More importantly, SIA offers a less morbid means of revascularization to many patients, who by virtue of their medical co-morbidities are either poor surgical candidates or are at prohibitive surgical risk.

There are several limitations to the present study. First, it is a retrospective review of a large vascular surgery practice conducted at multiple sites. The use of periprocedural and follow-up non-invasive testing was less frequent than would be expected in a prospective trial. Second, the review consists of a heterogeneous population of infrainguinal arterial occlusions. While it would have been more concise to study occlusions limited to the SFA, we found that over half of our patients with occlusions originating in the SFA had extension of the occlusion into either the popliteal or tibial artery. To maintain some uniformity, however, isolated popliteal and tibial artery occlusions were excluded, and thus our results should not be construed as those for popliteal or tibial artery SIA. Finally, clinical endpoints including relief from claudication and freedom from surgical bypass were used to provide additional insight into patient outcomes, yet each is susceptible to surgeon bias.

CONCLUSION

Subintimal angioplasty is a valuable tool in the armamentarium of endovascular surgeons treating lower extremity arterial occlusions originating in the SFA. Limb salvage and improvement in claudication are excellent at three years, sparing most patients the need for surgical bypass during this time. As with surgical bypass, minor reductions in patency and limb salvage are seen with extension of intervention into the tibial arteries. However, the percutaneous nature of SIA makes it an appealing first-line therapy for many patients with SFA occlusion, and an especially valuable technique for the revascularization of patients who are either hesitant to undergo bypass surgery or are at high surgical risk.

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AUTHOR CONTRIBUTIONS

Conception and design: ES, AB, RL, JB, GM, JP
Analysis and interpretation: ES, GM, JP
Data collection: ES, AB, RL, JB
Writing the article: ES
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REFERENCES


