Subintimal Angioplasty with the Aid of a Re-entry Device for TASC C and D Lesions of the SFA

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Abstract  Aim: The aim of this prospective study was to assess the clinical effectiveness and related midterm patency of subintimal angioplasty (SAP) in patients suffering from critical limb ischaemia (CLI) in a single tertiary care university centre. The secondary aim was to evaluate the safety and clinical effectiveness of using a re-entry device when re-canalisation by SAP was unsuccessful.

Methods: From January 2005 to December 2007, consecutive patients suffering from CLI (Rutherford clinical categories: 4–6) were treated with SAP. All patients included in the study had occluded SFA (TASC C and D) and underwent clinical and ultrasound follow-up examinations at day 30 and at 3, 6, 9 and 12 months, and then yearly. A re-entry device (Outback, Cordis Corporation, Miami Lakes, Florida, USA in all cases) was only used when re-canalisation by simple SAP was unsuccessful, and stenting was used when residual stenosis was >30% or there was a flow-limiting dissection. Factors that could modify the outcome were analysed.

Results: In this study, 145 patients were treated, with a technical success rate of 83.5% (121 of 145) for simple SAP. Stenting was performed in 43% (n = 62) of successful SAP procedures. No death occurred in the perioperative period, while the 30-day mortality was 4.8% (7 of 145). The re-entry device (Outback) was used in 24 cases (16.5%). The technical success of the re-entry device was 79% (19 of 24), with a 90% success rate of stent placement at the site of re-entry. Complications occurred in 6.2% of all procedures (n = 9) (three arterial perforations (2.1%), three distal embolisations (2.1%), two femoral artery pseudo-aneurysms (1.4%) and one arterio-venous fistula (0.7%)). Factors capable of independently affecting the patency were renal insufficiency (p = 0.03), current smoking (p = 0.01) and diabetes (p = 0.04). The primary patency at 1 and 3 years was 70% and 34% and the secondary patency at 1 and 3 years was 77% and 43%, respectively. At the same time intervals, the limb-salvage rate was 88% and 49%.
Subintimal angioplasty (SAP) is a minimally invasive percutaneous technique for the re-canalisation of occluded iliac and infrap-inguinal arteries. It is usually performed under local anaesthesia and is based on the creation of a subintimal channel by endoluminal dissection and angioplasty. This technique has been used increasingly since it was first described by Bolia in 1987 and has been proposed as an alternative to lower limb bypass procedures in critical limb ischaemia (CLI). Re-entry devices have recently been introduced to facilitate the procedure of re-canalisation. In addition, failed SAP does not preclude the possibility of surgical revascularisation.

The aim of the present study was to assess the clinical effectiveness of Subintimal Angioplasty (SAP) and its midterm patency in SFA-occluded TransAtlantic Inter-Society Consensus (TASC) C and D lesions (>15 cm) in patients with CLI who were treated in a single tertiary care university centre. The secondary aim was to evaluate the safety and clinical effectiveness of the use of a re-entry device when re-canalisation by simple SAP was unsuccessful.

Methods

Patient selection

From January 2005 to December 2007, consecutive patients suffering from CLI (Rutherford clinical categories: 4–6) presenting with long-occluded SFAs/SFAs with long occlusions (TASC C and D — occlusions > 15 cm) were treated with SAP. This treatment was previously reserved for patients who were not candidates for surgery due to their poor state of health (see Table 1) or for anatomical reasons (previous ipsilateral bypass, an inadequate greater saphe nous vein or a leg ulcer preventing distal graft implantation). After limb salvage became common and safe, this technique was introduced as a first-line treatment in patients with CLI and SFA occlusions longer than 15 cm. The number of procedures performed by each operator prior to inclusion in this study was at least 30 successful SAPs. SAP has never been used in patients with acute arterial occlusion.

All patients underwent clinical examination, ABI (ankle—brachial index) measurement and ultrasound examination before treatment. The angiography was performed at the same time as the procedure in order to map the femoropopliteal lesions accurately and thus optimise the revascularisation strategy. All patients were treated by a vascular surgeon in an operating theatre equipped with a portable fluoroscopy unit (GE-OEC 9800; GE Medical Systems, Salt Lake City, UT, USA). Lesions were defined by angiography according to the TASC II classification. Run-off vessels were defined as the number of patent crural vessels after the procedure in continuation with the femoropopliteal segment. Demographic, clinical and intra-operative variables were entered into a specific database by the operating team (see Table 2). Data were collected in a computerised database and was analysed prospectively.

Definitions and end points

Primary technical success was defined as continuous arterial patency to the popliteal artery without any obvious flow-limiting lesions (absence of a stenosis > 50%). Clinical outcomes, primary patency, secondary patency and complications following SAP were reported according to the ‘Recommended standards for reports’ by Rutherford et al.7 The patency rate was based on a colour-flow ultrasound scan. A change in ABI of at least 0.10 was accepted as evidence of haemodynamic improvement (and a change of less than 0.10 was deemed to be a haemodynamic failure). In patients in whom the ABI could not be measured accurately (e.g., patients with diabetes and rigid calcified arteries) it was substituted by the toe pressure (which is usually unaffected by such conditions) or any measurable pressure distal to the re-vascularisation. Early mortality (<30 days) was reported. Limb salvage was defined as no amputation proximal to the metatarsal.

Endovascular procedure

Anterograde ipsilateral percutaneous femoral access was preferred when at least 5 cm of a patent proximal segment of SFA was evident at ultrasonography. A contralateral approach via a cross-over long sheath was used in the presence of either SFA occlusion in its origin, high femoral bifurcation (documented by ultrasound) or obesity. We were able to check the correct localisation of the CFA puncture and reduce the risk of retroperitoneal bleeding using micro-puncture sets and contrast injections under fluoroscopy.

Table 1 Definition of poor health status.

<table>
<thead>
<tr>
<th>Poor cardiac status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Unstable angina,</td>
</tr>
<tr>
<td>2. Symptomatic or poorly controlled ectopy/arrhythmia,</td>
</tr>
<tr>
<td>3. Poorly compensated or recurrent congestive heart failure,</td>
</tr>
<tr>
<td>4. Ejection fraction less than 25%,</td>
</tr>
<tr>
<td>5. Myocardial infarction within 6 months.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Poor pulmonary status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. FEV1 less than 1.2 L or less than 35% of predicted,</td>
</tr>
<tr>
<td>2. Supplemental oxygen use medically necessary,</td>
</tr>
<tr>
<td>3. Pulmonary hypertension.</td>
</tr>
</tbody>
</table>

FEV: forced expiratory volume, L: litre.
Calcification was included when it was $>50\%$ of the total length of the occlusion at intra-operative angiography. Stenting was performed only when residual stenosis was $>30\%$ or there was a flow-limiting dissection. The needle of the Outback catheter was advanced into the subintimal space under fluoroscopic guidance. Following successful advancement of a 0.014$^{\text{\textdegree}}$ guidewire from the subintimal space into the true lumen, a 4-F angiographic catheter was used to replace a 0.035$^{\text{\textdegree}}$ guidewire. The rest of the procedure was similar to a normal endovascular treatment/repair procedure.

All patients were pre-treated with acetylsalicylic acid at a mean dosage of 125 mg $\text{d}^{-1}$ and with clopidogrel or ticlopidine at a mean dosage of 75 mg $\text{d}^{-1}$ or 500 mg $\text{d}^{-1}$, respectively, for at least 4–5 days prior to admission. Weight-adjusted (70 U kg $\text{d}^{-1}$) heparin was administered and repeated as necessary to maintain an activated clotting time of 225–250 s throughout the procedure. Clopidogrel (75 mg $\text{d}^{-1}$) or ticlopidine (500 mg $\text{d}^{-1}$) was continued for at least 30 days (double anti-platelet therapy) after the interventional procedure (haemoglobin and white blood count were checked for 7–10 days after the percutaneous intervention). Mono anti-platelet therapy (aspirin, clopidogrel or ticlopidine) was continued indefinitely.

### Follow-up protocol

All patients underwent ipsilateral angiography on completion of the endovascular procedure.

An ultrasound examination was performed within 48 h of SAP and repeated at day 30 and 3, 6, 9 and 12 months, and then yearly. The clinical status of the patients and ABI index were evaluated at the same intervals, except in patients with huge ulceration in the leg or calcified arteries, in whom ABI index was substituted by toe pressure measurement. The ultrasound examination measured the patency of the treated artery and any evidence of internal thrombus. All examinations were performed in the same vascular laboratory, using the same ultrasound machines (Ultramark IU-22 and HDI 3500 ATL-Philips, Eindhoven, Holland). The B-mode imaging frequency was 7 MHz, and the pulsed-wave Doppler frequency 4 MHz. An insonation angle of 60$^{\text{\textdegree}}$ was used, with angle correction where necessary (40$^{\text{\textdegree}}$–60$^{\text{\textdegree}}$). We attempted to maintain the

### Table 2

Demographic, clinical and intra-operative variables.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limbs</td>
<td>145</td>
<td>100</td>
</tr>
<tr>
<td>Mean age ± SD</td>
<td>71.4 ± 5.5</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>64–93</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>93</td>
<td>64</td>
</tr>
</tbody>
</table>

**Indications**

- Critical limb ischaemia: 145 (100)
- Rutherford class IV: 76 (52)
- Rutherford class V: 48 (34)
- Rutherford class VI: 21 (14)

**Risk factors**

- Hypertension: 104 (72)
- CAD: 78 (54)
- CHF: 71 (49)
- COPD: 68 (47)
- Diabetes mellitus (100% type II): 74 (51)
- Tobacco use$^a$
  - None or none for last 10 years: 56 (39)
  - None current, but smoked in last 10 years: 19 (13)
  - Current (<abstinence): 52 (36)
    - <1 year: 17 (12)
    - >1 year: 35 (25)
    - >1 pack/day: 18 (12)
- Hypertension: 33 (23)
- Previous ipsilateral bypass (AK fem-pop): 17 (15) (12)
- Renal insufficiency: 48 (33)
- ASA classification
  - I: 0 (0)
  - II: 16 (11)
  - III: 106 (73)
  - IV: 23 (16)

**Intra-operative variables**

- Stenosis
- Occlusion: 145 (100)
- TASC C (mean length ± SD) cm: 64 (44) (17.12 ± 1.42)
- TASC D (mean length ± SD) cm: 81 (56) (22.46 ± 1.78)
- Calcification$^a$
  - 69 (47)
- Number of run-off vessels
  - 1: 89 (61)
  - 2: 44 (30)
  - 3: 12 (9)
- Stented patients: 79 (54)
- S.M.A.R.T. Control: 33 (22)
- Luminexx: 15 (19)
- LifeStent FlexStar: 31 (39)
- Ankle–brachial index (mean ± SD)
  - Pre-operative: 0.36 ± 0.08 (0.24–0.60)
  - Post-operative: 0.57 ± 0.21 (0.26–0.93)

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
</table>

**SD:** standard deviation, **CAD:** coronary artery disease, **CHF:** congestive heart disease, **COPD:** chronic obstructive pulmonary disease, **ASA:** American Society of Anesthesiology, **AK:** above the knee.

$^a$ Calcification was included when it was $>50\%$ of the total length of the occlusion at intra-operative angiography.
insonation of 60° all the time in order to standardise the study methodology. The mean length of follow-up was 595 days (range: 30–1234 days).

### Statistical analysis

The data are expressed as mean and standard deviation (SD) or as median and interquartile range (IQR), depending on the type of distribution. Kaplan–Meier curves were used to calculate the primary and secondary patency rates of angioplastied vessels on an intention-to-treat basis. Factors that could modify the outcome were analysed (sex, age (>80 years old), hypertension, diabetes, hyperlipaemia, renal insufficiency, ASA > II, current smoking, stenting, use of Outback, pre-operative Rutherford class, TASC C vs. TASC D). Of all the risk factors examined, those that showed a significant effect on patency were included in a Cox multivariate model. A \( p \) value < 0.05 was considered significant.

#### Table 3  Clinical outcome.7

<table>
<thead>
<tr>
<th></th>
<th>1 Month n (%)</th>
<th>6 Months n (%)</th>
<th>1 Year n (%)</th>
<th>2 Years n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>+3</td>
<td>–</td>
<td>1 (0.7%)</td>
<td>4 (3.5%)</td>
<td>7 (8%)</td>
</tr>
<tr>
<td>+2</td>
<td>45 (31%)</td>
<td>41 (28.3%)</td>
<td>37 (25.5%)</td>
<td>34 (26%)</td>
</tr>
<tr>
<td>+1</td>
<td>37 (25.5%)</td>
<td>41 (28.3%)</td>
<td>41 (31%)</td>
<td>34 (26%)</td>
</tr>
<tr>
<td>0</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
</tr>
<tr>
<td>–1</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
<td>37 (25.5%)</td>
</tr>
<tr>
<td>–2 [minor amputation]</td>
<td>6 (4.2%)</td>
<td>2 (1.5%)</td>
<td>1 (0.7%)</td>
<td>1 (0.7%)</td>
</tr>
<tr>
<td>–3 [major amputation]</td>
<td>8 (5.5%)</td>
<td>11 (8.4%)</td>
<td>13 (11.5%)</td>
<td>13 (11.5%)</td>
</tr>
<tr>
<td>Deceased patients</td>
<td>7 (4.8%)</td>
<td>5 (3.5%)</td>
<td>3 (2.3%)</td>
<td>3 (2.3%)</td>
</tr>
<tr>
<td>Lost to follow-up</td>
<td>0</td>
<td>2 (1.5%)</td>
<td>3 (2.3%)</td>
<td>3 (2.3%)</td>
</tr>
<tr>
<td>Patients studied</td>
<td>145</td>
<td>131</td>
<td>113</td>
<td>87</td>
</tr>
</tbody>
</table>

In cases in which ABI could not be measured accurately, an index based on toe pressure was used. Patients with major amputations were excluded from this analysis.

ABI: ankle–brachial index; * Categories referred to the Rutherford clinical classification.

+3 = **Markedly improved**: no ischaemic symptoms and any foot lesions completely healed; ABI essentially ”normalized” (increased to more than 0.90).

+2 = **Moderately improved**: no open foot lesions; still symptomatic but only with exercise and improved by at least one category; ABI not normalized but increased by more than 0.10.

+1 = **Minimally improved**: greater than 0.10 increase in ABI but no categorical improvement or vice versa (i.e. upward categorical shift without an increase in ABI of more than 0.10).

0 = **No change**: no categorical shift and less than 0.10 change in ABI.

–1 = **Mildly worse**: no categorical shift but ABI decreased more than 0.10, or downward categorical shift with ABI decrease less than 0.10.

–2 = **Moderately worse**: one category worse or minor amputation.

–3 = **Markedly worse**: more than one category worse or major amputations.
SPSS for Windows Version 13.0 (SPSS Inc., Chicago, IL, USA, www.spss.com) was used for all statistical analyses.

**Results**

During the study period 145 patients with SFA occlusions of more than 15 cm in length (TASC C and D lesions) were treated using an SAP technique (see flow diagram: Fig. 1). In the same period 71 other similar SFA lesions were treated by surgery (n = 27), hybrid procedures (n = 48) or by medical therapy alone (n = 5). Patient demographics are presented in Table 2, which shows that the patients included in this study had many associated co-morbidities and high ASA classification values. The TASC C lesions were 64 (44%; 17.12 ± 1.42 cm) and the TASC D lesions were 81 (56%; 22.46 ± 1.78 cm).

No intra-operative deaths occurred. The mortality rate was 4.8% (7 of 145) at 30 days, due to myocardial infarction (n = 4) or congestive heart failure (n = 3).

The technical success rate for SAP was 83.5% (121 of 145). Specifically, the technical success based on the extent of the SFA occlusion ranged from 86.3% in TASC C cases to 81% in TASC D cases (p = 0.34).

Regarding the use of a re-entry device, the technical success rate was 79% (19 of 24). The five cases of unsuccessful re-canulation with the use of a re-entry device were due to either calcified arteries or failure to establish direct flow through the subintimal channel and the true lumen, due to elastic recoil (see Fig. 1).

'Spot' stenting (bare metal stent; mean 4.7 ± 0.8 (range 3–6) cm) was used in 43% (n = 62) of successful SAP procedures (see Table 2). Of the procedures using a re-entry device, 17 out of 19 (90%) patients received at least one stent at the site of re-entry. Selective stenting was used in 33 (42%) cases of flow-limiting dissection, 39 (49%) of residual stenosis >30% and 7 (9%) with both of the aforementioned conditions. The stents used were: the S.M.A.R.T Control stent (n = 33; Cordis/Johnson & Johnson, Miami Lakes, FL, USA), the Luminexx stent (n = 15; C.R. Bard Inc., Murray Hill, NJ, USA) and the LifeStent FlexStar stent (n = 31; Edwards Lifesciences, Irvine, CA, USA) (see Table 2). We used these stents because of their high flexibility, particularly needed in the transition zone of the SFA to the popliteal artery.

Of the five failures after either a simple SAP or a re-entry device procedure, two cases were immediately converted...
to open surgery and the other three to a hybrid revascularisation.

Complications occurred in 6.2% of all procedures ($n = 9$) and included three arterial perforations (2.1%), two femoral artery pseudo-aneurysms (1.4%) (one of which resulted in a retroperitoneal haematoma), three episodes of distal embolisation (2.1%) and one arterio-venous fistula (0.7%).

Only the retroperitoneal haematoma required an urgent open surgical intervention for correction. The cases of arterial perforation required a long balloon inflation (one case) or a surgical bypass (two cases — below-the-knee vein bypass). Distal embolisation was remedied using aspiration catheters or the ‘push and park’ technique.$^{12}$ No surgical embolectomy was required following SAP.

The clinical outcomes at 1, 6, 12 and 24 months are shown in Table 3. The ABI index was not properly evaluable in only 12 (8%) patients during the entire follow-up period. Table 3 shows that the clinical benefits of SAP were slightly better in the first 6 months of follow-up following the procedure and subsequently the percentage of patients who were improving or stable remained constant.

The Kaplan–Meier curve and life table analysis of re-intervention during the entire follow-up period are shown in Table 2. The re-interventions performed were either percutaneous transluminal angioplasty (PTA) in failing SAP (PTA + stenting in selected cases) or bypass surgery in failed SAP (the vein was used whenever possible). The Kaplan–Meier curve and life table analysis for re-intervention are shown in Fig. 2. The Kaplan–Meier curves and life table analysis of the overall primary and secondary patency are reported in Figs. 3. The primary patency and secondary patency were 70% and 77% at 1 year follow-up; 53% and 61% at 2 years and 34% and 43% at 3 years. Figs. 4 and 5 show (respectively) Kaplan–Meier curves and life table analysis of patency for selective SAP + stenting vs. SAP + no selective stenting procedures, and for SAP + re-entry device vs. SAP + no re-entry device. The use of an Outback device and selective stenting did not affect the patency in a statistically significant way (see Table 4).

The limb salvage was 88%, 76% and 49% at 1, 2 and 3 years respectively (see Kaplan–Meier curve and life table analysis in Fig. 6).

All amputation cases had infected gangrene of the forefoot or, in the majority of cases, the entire foot and the
The distal part of the leg, leading to an above-the-knee amputation. The factors that independently affected patency were renal insufficiency ($p < 0.03$), current smoking ($p < 0.01$) and diabetes ($p < 0.04$) (see Table 4).

Discussion

SAP is a minimally invasive technique that is well tolerated by most patients and requires a modest amount of equipment. The advantages of a percutaneous interventional procedure over bypass surgery are avoidance of the complications of general anaesthesia, making an incision in an ischaemic leg and healing complications as well as less systemic stress (local anaesthesia) and faster recovery and ambulation.

Moreover, a re-do procedure might be more readily repeated than surgery, with the possibility of offering future surgical intervention if needed. The procedure needs to be performed by an experienced team composed of trained operators. Our team is composed of vascular surgeons, who were included in this study on the condition that they had completed a learning curve of at least 30 successful SAP procedures. In our centre we try to use a standardised approach: a brief (SAP) procedure of 30–40 min and use of a re-entry device is advised when accessing the true lumen is difficult, so as not to dissect the popliteal artery or threaten the supragenicular collaterals. If the procedure cannot be concluded safely, we continue the intervention surgically or use a hybrid approach. The presence of a vascular surgeon in the team is important as, in the case of a failed SAP, the first intervention should not preclude the possibility of further surgical re-vascularisation.

In a recent systematic article regarding SAP, Met et al. showed that this technique can play an important role in the treatment of peripheral arterial disease and can be considered as a ‘temporary bypass’ to provide wound healing and limb salvage, especially in the case of critical limb ischaemia. In our experience the association of SAP with a re-entry device has guaranteed good midterm results in patients suffering from CLI. This study has reported TASC C and D treatment. Although the TASC documents recommend that TASC D lesions be treated with open surgical reconstruction, the technical success of SAP in our patients did not differ significantly between the two TASC groups in our study.

![Figure 3](image-url)
Furthermore, our patients could be classified as a group at high risk for surgery. In fact, coronary artery disease (CAD) and Congestive heart disease (CHF) accounted for 54% and 49% of all patients respectively, while an ASA classification of equal to or more than III was present in 89% of the overall study population.

For these seriously ill patients, a mini-invasive treatment was chosen as the first-line treatment in order to avoid major surgical stress.

According to reports in many articles, SAP has lower patency rates than surgery\textsuperscript{1,4,14} and for the time being, bypass treatment remains ‘the gold standard’ for critical limb ischaemia\textsuperscript{16,17} although there are no comparative studies between SAP and surgery. In randomised trials such as BASIL\textsuperscript{18} few patients seemed to be eligible for randomisation due to their local anatomy, and many tended to prefer a minimally invasive treatment. Moreover, infrainguinal bypass surgery is demanding on resources and costly.

In our centre, the mean cost of a surgical procedure is about 28% higher than that of an interventional procedure (SAP plus selective stenting): surgery has a mean cost of 6800 Euros compared to a mean cost of 4900 Euros for an endovascular approach. The adjunctive cost of a re-entry device balances the costs of the two different procedures (SAP $+$ a re-entry device vs. bypass surgery). Moreover, an adjunctive stent increases the cost by another 400–600 Euros.

Our one- and two-year primary and secondary patency results were similar to those reported in other endovascular

\begin{figure}
\centering
\includegraphics[width=\textwidth]{Figure4.png}
\caption{Kaplan–Meier curve and life table analysis for primary patency (SAP vs. SAP $+$ selective stenting). Primary patency of 145 SFA occlusions treated with subintimal angioplasty (SAP) or SAP $+$ selective stenting.}
\end{figure}
studies, which presented overall patency rates for SAP at 12 months ranging from 53% to 90%. In a recent review of 506 infra-inguinal arterial occlusions, Scott et al. reported primary patency of 45% and 25% at 12 and 36 months respectively, while secondary patency was 76% and 50% at the same time intervals.

In our experience we did not observe much difference between primary and secondary patency. A possible explanation could lie in the difference in the signs shown by patients (both claudication and CLI) and the different levels of lesions in the leg (femoral, popliteal and tibial districts).

Primary technical failure is the inability to re-enter the true lumen. The Outback device (Cordis Corporation, Miami Lakes, FL, USA) was used in this study. The Outback re-entry device was voluntarily removed from the market between August 2008 and January 2009 (and has since been re-introduced) because of a higher-than-expected incidence of the piercing needle failing to retract safely, as described in an FDA report. However, in our experience the technical success of the device was satisfactory. The five failures we faced were due either to calcified arteries or failure of the angioplasty catheter to establish forward flow through the subintimal channel. We observed only 1 case of arterial perforation that required a staged surgical bypass. No technical problems due to the device itself were registered in our database.
With regard to the possible factors that might affect the patency rate of SAP, we found that diabetes, renal insufficiency and current smoking were the most important. Reekers and Bolia reported that arterial calcification was predictive of technical failure. Antusevas et al. reported that calcification of the SFA influenced technical success but did not affect primary-assisted patency, while distal run-off vessels, occlusion length and smoking were not significantly associated with primary or primary-assisted patency.

London et al. found that run-off vessels, smoking and occlusion length were independent risk factors for re-occlusion. Lazaris et al. recently described a clinical study of 51 infra-inguinal SAP procedures in 46 patients suffering from CLI. The 12-month patency in patients with more than one run-off vessel was 81%, compared to 25% in patients with only one run-off vessel. Regarding the length of occluded SFA, the risk of re-occlusion was 1.02 for every centimetre of occlusion. Comparable results for percutaneous trans-luminal infra-inguinal angioplasty have also been reported by other investigators.

Our patients were treated with double anti-platelet therapy for a month postoperatively and subsequently with mono anti-platelet therapy, continued indefinitely. Yilmaz et al. reported that the use of the anticoagulant warfarin may significantly improve the patency of an SAP procedure, although overall patency rates are still lower than those reported for bypass surgery.

<table>
<thead>
<tr>
<th>Risk factors</th>
<th>B</th>
<th>SE</th>
<th>Wald</th>
<th>df</th>
<th>p Value</th>
<th>Exp(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male gender</td>
<td>0.31</td>
<td>0.26</td>
<td>1.41</td>
<td>1</td>
<td>0.23</td>
<td>1.36</td>
</tr>
<tr>
<td>Age (&gt;80 years old)</td>
<td>0.04</td>
<td>0.02</td>
<td>3.68</td>
<td>1</td>
<td>0.06</td>
<td>1.04</td>
</tr>
<tr>
<td>Hypertension</td>
<td>–0.19</td>
<td>0.27</td>
<td>0.47</td>
<td>1</td>
<td>0.49</td>
<td>0.63</td>
</tr>
<tr>
<td>Diabetes</td>
<td>–0.60</td>
<td>0.30</td>
<td>4.14</td>
<td>1</td>
<td>0.04</td>
<td>0.55</td>
</tr>
<tr>
<td>Hyperlipaemia</td>
<td>–0.27</td>
<td>0.30</td>
<td>0.81</td>
<td>1</td>
<td>0.37</td>
<td>0.76</td>
</tr>
<tr>
<td>Renal insufficiency</td>
<td>0.64</td>
<td>0.29</td>
<td>4.71</td>
<td>1</td>
<td>0.03</td>
<td>1.89</td>
</tr>
<tr>
<td>ASA &gt; II</td>
<td>0.39</td>
<td>0.28</td>
<td>1.87</td>
<td>1</td>
<td>0.17</td>
<td>1.47</td>
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<td>0.12</td>
<td>6.62</td>
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<td>0.01</td>
<td>1.37</td>
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<td>Stenting</td>
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<td>0.25</td>
<td>0.01</td>
<td>1</td>
<td>0.94</td>
<td>1.02</td>
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<td>Use of Outback</td>
<td>–0.67</td>
<td>0.39</td>
<td>3.01</td>
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<td>0.08</td>
<td>0.51</td>
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<tr>
<td>Rutherford class 4</td>
<td>–0.31</td>
<td>0.35</td>
<td>0.77</td>
<td>1</td>
<td>0.38</td>
<td>0.47</td>
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<td>Rutherford class 5</td>
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<td>TASC C</td>
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<td>0.80</td>
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<td>TASC D</td>
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<td>0.04</td>
<td>1</td>
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<td>0.81</td>
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Figure 6  Kaplan-Meier curve and life table analysis for limb salvage. Limb salvage of 145 SFA occlusions treated with subintimal angioplasty.
In our experience, we found it useful to carefully apply spot-stenting in the case of either residual stenosis > 30% or a flow-limiting dissection. We tried to avoid covering long lesions with multiple stents. It could be argued that a more extensive use of stents can improve technical success on a long-term basis, although Treiman et al. demonstrated that routinely placing stents across the entire re-canalised segment could contribute to a high rate of late failure. In contrast, selective stent use after SAP can provide excellent late limb salvage, as reported by Schmieder et al. Our limb-salvage rate was similar to those reported in the TASC II document and the cases of failing/failed SAPs identified during the follow-up period were probably due to the combination of endovascular re-do and surgical bypass.

Another key point for successful midterm results after an endovascular procedure is an appropriate follow-up protocol. We agree with the strategy of Florenes et al. who attributed their excellent results to the fact that all the patients were placed in a duplex surveillance programme and any significant stenosis was treated with PTA or, in selected cases, with PTA + stenting. If an occlusion occurred and the patient had persistent CLI, bypass surgery was performed (vein grafting was used whenever possible).

Although this study is prospective, it does not scrutinise all the variables that may have influenced the outcome of the SAP procedure (e.g., calcification and run-off vessel number, as analysed by other authors). The analysis lacks the statistical power to effectively differentiate the relative importance of several other variables that occurred at a low frequency in the SAP plus re-entry device group. Moreover, this study was not controlled and randomised and the centre’s first approach to endovascular therapy for such SFA lesions is probably an important bias as well.

Conclusions

In the experience at our centre, subintimal angioplasty with the aid of a re-entry device for TASC C and D lesions of the SFA seems to be safe and clinically effective in patients suffering from CLI. Patency was affected independently by diabetes, renal insufficiency and current smoking in our study. Further follow-up and more data are necessary to confirm these findings.

Conflict of Interest

There is no financial arrangement or other relationship that could be construed as a conflict of interest.

References


