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Subintimal placement of covered stent versus subintimal balloon angioplasty in the treatment of long-segment superficial femoral artery occlusion

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Abstract

BACKGROUND: Subintimal endovascular intervention has been used widely in the treatment of symptomatic superficial femoral artery (SFA) occlusion. The relative effectiveness of subintimal placement of a covered stent (CS) versus balloon-only subintimal angioplasty (SIA) remains uncertain.

METHODS: We performed a retrospective cohort study of consecutive patients with symptomatic SFA occlusions (>15 cm) who underwent subintimal endovascular intervention, either CS or SIA, in a single institution. Primary patency was the primary outcome. Secondary outcomes included complication rates, freedom from re-intervention, and limb salvage rates. Patency was ascertained with followup duplex or clinically.

RESULTS: We evaluated 57 patients in the SIA group and 31 patients in the CS group. At 1 year the SFA primary patency for the SIA and CS groups was 28% versus 75% ($P < .001$), whereas the primary assisted patency was 37% versus 84% ($P < .001$), respectively. Need for bypass was 13% versus 0% ($P = .05$) in the SIA and CS groups, respectively.

CONCLUSIONS: Placement of a covered stent improves patency after subintimal intervention for long SFA occlusion.

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Endovascular therapy has revolutionized the management algorithms of patients with peripheral arterial disease (PAD). Since its early description,[1] subintimal angioplasty (SIA) has been used extensively in the treatment of superficial artery (SFA) occlusion. In some centers,[2] SIA is today the procedure of choice even for more fit patients with severe PAD, and it is thought to be equivalent to open bypass with respect to short-term limb-salvage outcomes.[3]

The long-term results of SIA have been variable, with 1-year restenosis rates ranging from 25% to 80%.[4–6] Treatment failure has been associated with a number of factors including hypertension, diabetes, poor run-off, renal insufficiency, multiple segmental, long, or more distal lesions, and residual stenosis after intervention. Patients with long lesions (>15 cm) at the femoral–popliteal segment do not fare that well after endovascular intervention. More recently, however, placement of covered stent (CS) emerged as a more durable alternative to plain balloon angioplasty. A number of studies showed that better patency, ranging from 58% to 93% at 1 year, could be achieved when self-expanding nitinol stents covered with expanded polytetrafluoroeth-

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ylene (Viabahn Endoprosthesis; W.L. Gore, Flagstaff, AZ) were placed in the SFA.[7,8] In a prospective randomized trial,[9] CS placement in the SFA was as durable as femoral–popliteal bypass in the treatment of patients with claudication, rest pain, or tissue loss. Other randomized studies also have shown that placement of a CS is superior to plain balloon angioplasty for SFA occlusions less than 15 cm in length.[10,11]

We recently adopted a policy of primary stent graft placement for patients presenting with long (>15 cm) SFA occlusions. Given the paucity of published results after endovascular intervention for this type of SFA disease, we performed this study to compare outcomes between patients with long-segment SFA occlusion who were treated with either SIA only, or with SIA followed by CS placement.

Materials and Methods

By using an electronic medical record system, a retrospective review was performed of patients with disabling claudication or critical limb ischemia who underwent endovascular intervention as initial treatment from January 2006 to December 2008. SIA with selective use of bare metal stent placement was used during the first half of this time period, whereas routine CS placement has been performed since May 2007. This change in strategy was initiated after publications underscored the long-term durability of stent graft placement. Patient demographics, surgical reports, angiographic data, and follow-up information were reviewed. All patients had long-segment (>15 cm) SFA occlusion. Primary patency was the primary outcome, whereas complication rates, freedom from re-intervention, and limb salvage rates comprised secondary outcomes.

The procedures were performed in the operating room with high-quality fixed imaging equipment under local anesthesia or mild sedation using standard techniques for crossing chronic occlusions. Re-entry devices were not used. Technical success was defined as the creation of a subintimal channel bypassing the occlusion, with successful re-entry into the true lumen and subsequent angioplasty and/or stenting. Anterior and posterior tibial and peroneal arteries were the vessels counted when calculating run-off vessels. A vessel was thought to be patent if it was in continuity with the treated SFA without any stenotic (>30%) or occluded segments, and patent at least up to the ankle.

Stent grafts were used to cover the entire occluded segments and adjacent segments of high-grade stenosis. Genicular branches more than 3 mm in diameter were not covered. Flush SFA occlusions were treated with placement of a CS flush with the origin of the profunda femoris artery. We used oblique projections and adequate magnification to ensure optimal visualization and avoid compromise of the profunda take-off. Although Viabahn is a self-expanding stent, we found the deployment to be very accurate provided that the delivery system is stabilized adequately.

After the procedure, patients received clopidogrel for 6 weeks and aspirin for life, and typically were discharged home on the same day. Clinical follow-up evaluation took place at 2 weeks, 6 months, and 12 months after the procedure and included physical examination and measurement of ankle–brachial indexes (at 6 and 12 mo). Duplex examination of the subintimal channel and further follow-up evaluation were obtained at the discretion of the treating surgeon. Absence of flow indicated occlusion, systolic velocity of greater than 200 cm/s, and a ratio of greater than 2.5 indicated recurrent stenosis.

Patency of the treated vessel was defined as follows: (1) flow through the vessel shown by duplex ultrasonography, (2) maintenance of an ankle–brachial index greater than .15 higher than the baseline level before the procedure, (3) maintenance of a palpable pulse at the ankle that was absent before the procedure, and (4) continued resolution of symptoms. Statistical analysis was performed using the Fisher exact test to analyze categoric data, and the Student *t* test or the Wilcoxon rank-sum test for continuous data. Kaplan–Meier survival analysis and log-rank statistics were used to determine patency rates. Multivariate Cox regression analysis was used to determine predictors of primary patency. The level of statistical significance was set at an α value of .05.

Results

We identified 57 patients who had SIA and 31 patients who underwent CS placement. Age, sex, indications for intervention, and comorbid conditions are listed in Table 1. The mean outflow vessel number was 1.8 versus 2.0 (P = .08), and treated SFA length was 19 ± 4 cm versus 23 ± 5 cm (P = .003) in the SIA and CS groups, respectively. Coexisting iliac lesions were encountered and treated in 6 patients in the SIA group and 4 patients in the CS group (P = .73).

SIA was successful in recanalizing the SFA in 47 (82%) versus 27 (87%) (P = .76) in the group that had CS. Failure to re-enter the true lumen was the reason for failure in 12

Table 1 Demographics and patient characteristics

Risk factor	SIA, n (%)	CS, n (%)	*P* value
Sex			
Male	55 (96)	30 (96)	1.0
Female	2 (4)	1 (4)	1.0
Smoking	47 (82)	22 (70)	.06
HTN	35 (61)	22 (70)	.78
DM	28 (49)	18 (58)	.21
Hyperlipidemia	31 (54)	16 (52)	.62
Claudication	16 (28)	10 (32)	.21
Rest pain	28 (49)	15 (48)	.63
Tissue loss	13 (23)	6 (20)	.23
Number of outflow vessels	2	1.8	.08

HTN = hypertension; DM = diabetes mellitus.

cases, and failure to initiate the dissection plane accounted for failure in 2 more cases with flush SFA occlusion. In the SIA group 2 patients underwent selective stent placement in the mid- and proximal portion of the SFA owing to inadequate recanalization and remaining flow limiting stenosis after balloon angioplasty only. From the 10 technical failures in the SIA group 3 patients underwent open bypass for rest pain or tissue loss, whereas 2 patients opted to have primary amputation. Five more patients with claudication rejected open intervention and opted to continue on medical management only. One of the 4 patients who failed original recanalization in the CS group underwent a successful surgical revascularization for rest pain. The other 3 patients were claudicants and refused further intervention.

Periprocedural complications occurred in 2 patients in the SIA group versus 1 patient in the CS group ($P = .68$). In the angioplasty-only group 1 patient developed a small groin hematoma that did not require blood transfusion, whereas a second patient developed persistent groin pain that responded to analgesics and subsided over the course of 1 month. In the stent graft group 1 patient developed intraoperative popliteal artery thrombosis that responded to overnight thrombolysis. The 30-day mortality rate for both groups was 0%, whereas the 1-year mortality rate was 5.2% (n = 3) in the SIA group versus 3.2% (n = 1) in the CS group ($P = .5$). There were no stent fractures in the CS group or in the 2 patients in the SIA group who underwent placement of a bare metal stent.

The median follow-up period was 14 months (range, 7–22 mo) in the SIA group and 9 months (range, 3–17 mo) in the CS group ($P = .0005$). At 1 year the cumulative SFA primary patency for the SIA and CS groups was 28% versus 75% ($P < .001$), whereas the primary assisted patency was 37% versus 84% ($P < .001$), and the secondary patency was 56% versus 84% ($P = .01$), respectively. The Kaplan–Meier curves for primary, primary assisted, and secondary patency are shown in Fig. 1.

Re-intervention for restenosis of occlusion of the successfully treated site occurred in 14 patients in the SIA group and 3 patients in the CS group ($P = .15$). Reason for re-intervention included occlusion or stenosis with concomitant recurrence of symptoms. Progression of disease in the other sites such as iliac or tibial with worsening of symptoms necessitated intervention in 1 more patient in the SIA group and 4 more patients in the CS group, and the resulting total endovascular re-interven-

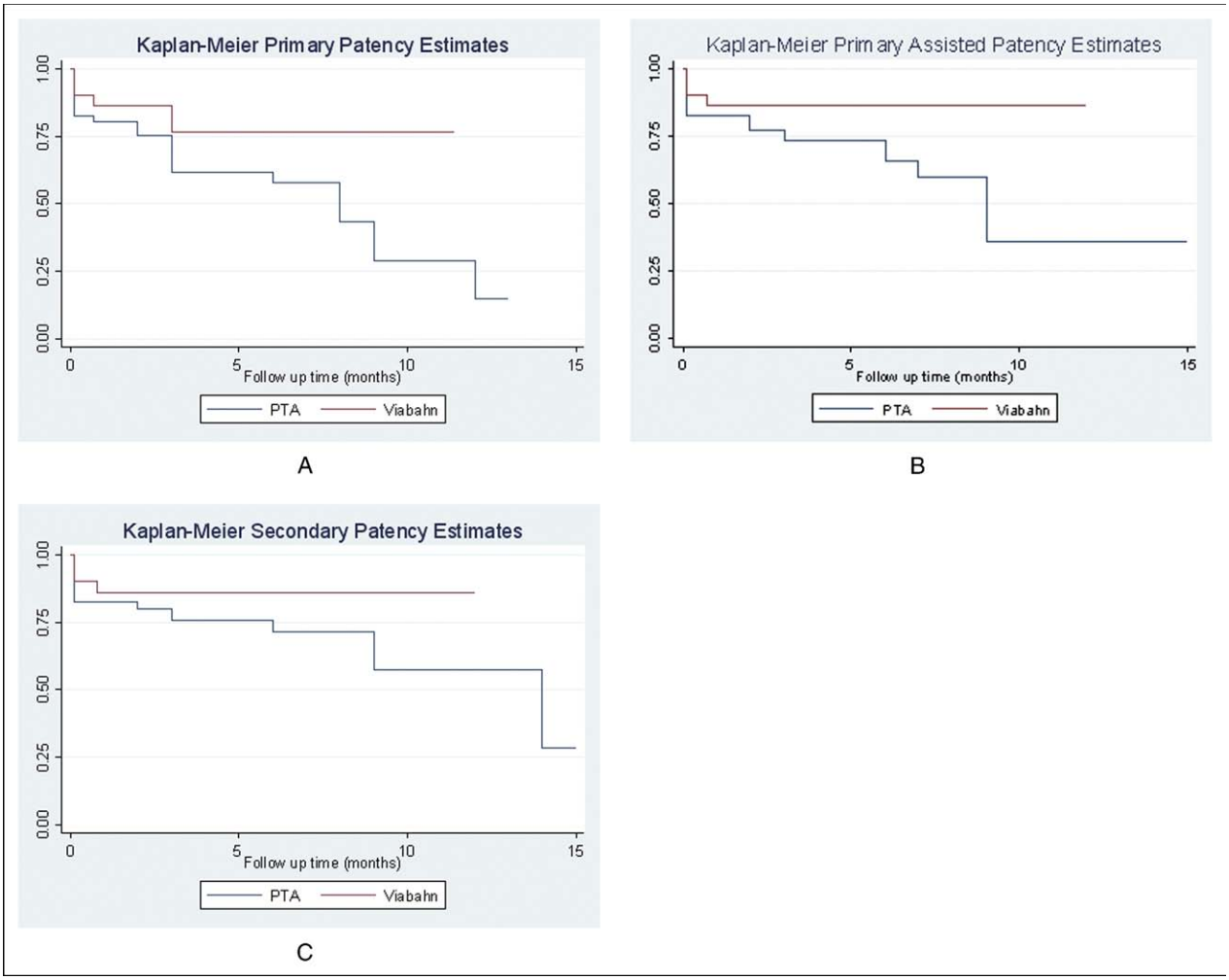

Figure 1 (A) Primary, (B) primary assisted, and (C) secondary 1-year patency in the 2 patient groups. PTA: percutaneous transluminal angioplasty

Table 2 Multivariate regression analysis for determinants of primary patency showed only correlation with the presence of diabetes

Variable	HR (95% CI)	*P* value
HTN	.56 (.08–3.66)	.5
Hyperlipidemia	4.78 (.51–12.21)	.17
DM	7.18 (1.45–18.05)	.03
Smoking	3.17 (.23–9.48)	.38
ESRD	5.15 (.53–19.48)	.12
Claudication	.1 (.003–4.02)	.23
Rest pain	.78 (.03–17.58)	.88
Tissue loss	2.93 (.2–24.91)	.21
Single vessel run-off	1.21 (.22–6.77)	.81

HTN = hypertension; DM = diabetes mellitus; ESRD = end-stage renal disease.

tion rates were 32% versus 25% ($P = .21$) for the SIA and CS groups, respectively.

Open bypass was necessary in 6 patients in the SIA group whose target vessel re-occluded after initial recanalization. None of the patients in the CS group underwent surgical intervention to relieve symptoms (10% vs 0%; $P = .05$). Indications for bypass included persistent nonhealing ulcer (n = 3), rest pain (n = 2), and claudication (n = 1). Major amputation was required in 3 patients in the SIA group and in none of the patients in the CS group ($P = .28$). Univariate analysis found only diabetes mellitus to be a significant risk factor for reduced primary patency and this correlation persisted when multivariate analysis was performed (Table 2).

Comments

Endovascular therapy has revolutionized the management of patients with PAD, and although current (Transatlantic Inter-society Consensus) TASC II guidelines[12] recommend traditional bypass surgery for patients with TASC C or D lesions, continuous improvement in technology and endovascular equipment has encouraged high-volume centers to now expand the endovascular indications to treat patients with these advanced lesions. Our study is notable because it showed that placement of a CS improved the short-term primary 1-year patency and decreased re-intervention and open surgical intervention in patients with long-segment SFA occlusion.

Balloon angioplasty alone traditionally has had better results when treating short stenoses compared with long occlusions, a fact that reflects on the TASC recommendations[13] for endovascular treatment of lower-extremity PAD. Substantial improvements in technology have occurred since then, and the newer TASC II guidelines[12] indicate that endovascular therapy can be considered for lesions up to 15 cm. The use of CS has improved the short-term patency in our series with SFA lesions longer than 15 cm. Other institutions also have reported improved patency when CS is used for a variety of lesion lengths. Fischer et al[14] reported primary and secondary patency rates of 57% and 80% after 3 years, respectively, and 45% and 69% after 5 years in their cohort of patients with various stages of PAD who underwent primary CS placement for SFA lesions that averaged 10.7 cm in length. Saxon et al[15] published long-term data on a group of patients with mean SFA lesions of 14.2 cm. Primary, primary assisted, and secondary vessel patency rates were 76%, 87%, and 93%, respectively, at 1 year and 55%, 67%, and 79%, respectively, at 4 years. In another study comparing CS with balloon angioplasty only in the treatment of SFA disease, Saxon et al[11] reported primary 1-year treated vessel patency of 65% versus 40% for the stent graft and angioplasty-only groups, respectively. These series suggest that placement of stent graft improves patency compared with either concurrent or historical controls. Our study is unique, however, in that CS were placed in the subintimal space, and covered the entire length of the occluded SFA. This is conceptually very important because it mechanically excludes a long segment of a heavily diseased vessel from the circulation and leaves only the proximal and distal landing zones prone to restenosis.

Data also now are being accumulated on the relative value of CS placement in the SFA compared with the traditional femoral–popliteal bypass with prosthetic material. Kedora et al[16] performed a randomized single-center study comparing open surgical reconstruction with stent-graft placement for long lesions. The primary patency at 12 months was 73.5% and 74.2%, whereas the secondary patency was 83.9% and 83.7% for the stent graft and the femoral–popliteal surgical groups, respectively. Re-intervention rates were similar between the groups. A recent update[9] from this cohort showed that the 2-year primary and secondary patency rates were 63% and 74% for the stent graft group, compared with 64% and 76% for the surgical femoral–popliteal group. These data underscore the notion that CS placement for SFA lesions is a durable option and can be considered even as an alternative to the open reconstruction with prosthetic graft.

A few technical points with regard to CS insertion are worth further discussion. Sizing becomes important before placing a CS in a small vessel such as the SFA. We typically do not oversize the stent. Angioplasty within the stent is performed after deployment at least up to the nominal pressure of the balloon. We avoid rigorous balloon dilatation of the native vessel adjacent to the landing area to minimize barotrauma that may result in increased intimal hyperplastic response. Our goal is to cover the entire length of the diseased SFA; in cases of very proximal lesions this may imply placement of the CS flush to the origin of the profunda femoris artery. More challenging is the situation arising when large collaterals reconstitute the popliteal artery at the re-entry point just adjacent to the diseased SFA. The

decision of whether or not to cover these collaterals is a complex one and needs to be individualized. Indication for the intervention, size, and number of collaterals; number of outflow vessels; and the disease burden at the re-entry point, all need to be considered before deploying a CS across the collateral vessels.

Failure to achieve recanalization of the SFA with endovascular means should leave the patients at baseline, and not preclude future open reconstruction. This implies that attention must be paid to not compromise the profunda, or the common femoral artery with balloon overdilatation at the proximal landing zone or careless wire manipulation. Similarly, the surgeon should be particularly thoughtful with regard to the re-entry point in the above-the-knee popliteal artery; if re-entry to the true lumen cannot be achieved easily, overextending the dissection to the distal popliteal may create significant issues with subsequent creation of a femoral to above-the-knee popliteal bypass and should be avoided. Finally, re-occlusion of a vessel that has been treated successfully leads to a predictable recurrence of symptoms. At that time an attempt for endovascular treatment is reasonable, although open reconstruction remains an equally good alternative.

Admittedly, there were several limitations in our study, which are related to its retrospective nature and the inherent issues of selection, interpretation, recall bias, and treatment bias. There was no treatment randomization; instead, data from consecutive patients were analyzed. In addition, the number of patients was small and as a result some of the clinical important differences did not reach statistical significance. Furthermore, the follow-up period was short and did not allow for statements on long-term durability. Another issue pertaining to follow-up evaluation is that not all the patients had confirmed patency with imaging studies. Finally, a cost analysis was not performed, and therefore the question of the higher upfront cost of a CS versus the long-term benefit as a result of the increased patency and lower chance for re-intervention remains.

In summary, patients with greater than 15-cm SFA occlusions showed improved primary patency after CS placement. Endovascular re-intervention and surgical reconstruction for recurrent SFA lesions were also more common in the SIA group. Primary placement of a CS is a promising endovascular modality in the treatment of SFA occlusive disease, although more long-term data are needed to ensure durability.

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