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Drug-coated balloon angioplasty for the treatment of edge stenosis after self-expanding covered stent placement for superficial femoral artery occlusive disease

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Abstract

Background: Edge stenoses are the predominant limitation of self-expanding covered stent treatment of superficial femoral artery (SFA) occlusive disease, necessitating reinterventions. Angioplasty of an edge stenosis is associated with a high recurrence rate. Drug-coated balloon (DCB) treatment of edge stenoses might improve outcomes by decreasing the incidence of restenosis.

Purpose: The aim of this study was to evaluate the outcomes of using a DCB for the treatment of edge stenoses after self-expanding covered stent placement for SFA occlusive disease.

Method: We performed a retrospective analysis of patients treated with a DCB for edge stenoses after self-expanding covered stent placement. The primary endpoint was primary patency at one year. The secondary endpoints included procedure-related complications, secondary patency, and freedom from target lesion revascularization (TLR).

Results: A total of 21 patients with 28 edge stenoses were included. The time from primary treatment to treatment of the edge stenosis was 19 months (interquartile range (IQR) 8; 52 months). Primary patency and assisted primary patency at one year were 66.7% with a secondary patency of 90.9%. Freedom from TLR was 86.1%, and freedom from clinically driven TLR was 89.4%. Four patients presented with a hemodynamically significant restenosis, and three of those patients had an occlusion. Median time to failure was six months (IQR 3.5; 7.0 months), and median time to occlusion was four months (IQR 3.0; 6.0 months).

Conclusion: The treatment of edge stenoses using a DCB is associated with a safe one-year outcome; however, this has to be confirmed in larger prospective studies. The continuous surveillance of patients is indicated.

Keywords

Drug-coated balloon, drug-eluting balloon, edge stenosis, Viabahn endoprosthesis, self-expanding covered stent, superficial femoral artery, peripheral artery disease

Introduction

Endovascular treatment for occlusive lesions in the superficial femoral artery (SFA) is increasingly applied, and an endovascular-first strategy should be considered in patients with lesions <25 cm, according to the guidelines of the European Society of Vascular Surgery.[1] Over the years, self-expanding bare nitinol stents seem to have comparable patency rates, more favorable restenosis rates, and improved clinical outcomes when compared to plain balloon angioplasty (PBA) in

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moderate to extensive SFA lesions.[2,3] Results, however, are limited by the occurrence of in-stent restenosis (ISR) and stent fractures, which occur more in longer lesions.[4–6] Self-expanding covered stents, known as the polytetrafluoroethylene-covered nitinol stents (Viabahn, W.L. Gore and associates, Flagstaff, AZ, USA) and designed to prevent tissue in-growth through the stent struts, were introduced to reduce the incidence of ISR. Randomized trials showed an improved patency of self-expanding covered stents over bare metal stents in long SFA lesions[7] and comparable patency rates compared to an above-the-knee femoropopliteal bypass.[8–10] Patency rates of self-expanding covered stents are mainly limited by the occurrence of edge stenosis at the distal and/or proximal ends of the stent.[11] Due to reduced flow and subsequent thrombus formation, an edge stenosis may eventually cause thrombosis.[12,13] The optimal treatment for edge stenosis is yet unknown. A retrospective study showed that treatment of an edge stenosis with PBA resulted in a 45% rate of restenosis and/or occlusion after one year.[11] An extension of the self-expanding covered stent yielded better results with regard to the secondary patency but, in turn, had higher costs and presented the risk of covering collaterals in the popliteal artery in the case of a distal edge stenosis.

Drug-based technology has been introduced as alternative treatment modality for atherosclerotic lesions. The concept of drug-coated balloons (DCBs) and drug-eluting stents is based on paclitaxel, a neoplastic drug that inhibits neointimal proliferation, and could therefore also be promising in the treatment and prevention of recurrent edge stenosis. There are several randomized controlled trials that showed the superiority of DCBs over PBA in complex femoropopliteal lesions.[14–17] Other single-arm studies using DCBs for the treatment of ISR showed promising patency rates and clinical outcomes.[18–21] Recently, a retrospective analysis showed that adjunctive treatment with a DCB before self-expanding covered stent placement reduced the incidence of edge stenosis and target lesion revascularization (TLR) and improved the primary patency rate up to 24 months of follow-up.[22] Although these results are promising, data regarding DCB treatment of edge stenosis after treatment of SFA occlusive disease with a self-expanding covered stent are still lacking. The aim of this study was to evaluate the outcomes of using a DCB for the treatment of edge stenosis after self-expanding covered stent placement for SFA occlusive disease.

Method

The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. The study was approved by the Medical Ethics Committee of Nijmegen (CMO 2013–222) and the local Institutional Review Board of each participating center.

Study design

The aim of this study was to evaluate the outcomes of using a DCB for the treatment of edge stenoses after self-expanding covered stent placement for SFA occlusive disease. The hypothesis was tested that the outcome of DCB treatment of an edge stenosis would have a better one-year outcome, compared to the data presented in literature on PBA for this specific indication. Consecutive patients from two hospitals in the Netherlands, treated with a DCB between November 2013 and December 2017 for edge stenosis, were included and retrospectively analyzed. Angiographies were routinely performed after the index procedure to confirm patency. Asymptomatic patients were identified using duplex ultrasound (peak systolic velocity (PSV) ratio >2.5). The same criteria were used at all follow-up moments. Follow-up was performed at six weeks, six months, and one year, according to the clinical follow-up protocol in both participating sites. Follow-up included clinical assessment, duplex ultrasound imaging, and ankle brachial indices (ABI) measurements.

The primary endpoint was primary patency at one year after DCB treatment. Secondary endpoints included procedure-related complications until six weeks of follow-up, secondary patency, freedom from target lesion reinterventions (TLR), and overall number of reinterventions.

Definitions

Primary patency refers to patency that is obtained without the need for additional or secondary surgical or endovascular procedures. Assisted primary patency is patency of the endovascular intervention achieved with the use of an additional or secondary surgical or endovascular procedure, as long as occlusion of the primary treated site has not occurred. Secondary patency is patency obtained with the use of an additional or secondary surgical or endovascular procedure after occlusion occurs.[23] Freedom from TLR was defined as freedom from a flow-reducing stenosis (PSV ratio >2.5) of the target lesion. Clinically driven TLR (CD-TLR) is defined as a TLR performed because of clinical symptoms of the patients requiring intervention.

Procedure and device

Patients were treated percutaneously using local anesthesia. After passing the lesion, the edge stenosis was treated using the IN.PACT Admiral™ DCB (Medtronic, Santa Rosa, CA, USA), according to the instructions for use (IFU). Predilatation, as required per IFU of the IN.PACT Admiral™ DCB, was left at discretion of the interventionalist. The drug coating used is called FreePac™ and consists of the antiproliferative drug paclitaxel and the natural component urea as the carrier substance. The DCB has two modes of action: the device's primary mode of action is attributed to the balloon's percutaneous transluminal angioplasty mechanical dilatation of the vessel lumen, while the secondary mode of action consists of drug elution into the vessel wall with inhibition of restenosis, normally caused by the proliferative response to the PBA. The IN.PACT Admiral™ DCB is utilized within its intended purpose in this study and is indicated for PBA in subjects with obstructive disease of peripheral arteries. After treatment, all patients received dual antiplatelet therapy, including clopidogrel and acetylsalicylic acid, and statins. Patients who developed thrombosis were treated with coumarin derivatives.

Statistical analysis

Normality was visually inspected and tested using the Shapiro–Wilk test. Continuous variables are presented as median and interquartile range (IQR). Categorical data are presented as a number followed by a percentage. Patency was analyzed using Kaplan–Meier analyses including censoring for patients lost to follow-up. A two-sided p value < 0.05 was considered significant. Statistical analyses were performed using IBM SPSS Statistics (SPSS version 25.0 for windows, IBM Corporation, Armonk, NY, USA).

Results

Patient characteristics

A total of 21 patients with 28 edge stenoses were included. The median age was 74 years old (IQR 61; 79 years). Twelve of the patients were men (57.1%). The majority of patients had a history of smoking (all except two), and five were current smokers. Six patients had renal insufficiency (28.6%), and one was on permanent dialysis. Also, 16 patients were treated for dyslipidemia (76.1%), 10 for diabetes mellitus (47.6%), 15 for hypertension (71.4%), and 5 patients (23.8%) had a history of ischemic heart disease. All patients were on either antiplatelet or anticoagulant therapy at the time of treatment (acetylsalicylic acid $N = 12$; clopidogrel $N = 12$; coumarin derivatives $N = 5$; $N = 7$ had dual antiplatelet therapy; and $N = 1$ was treated with acetylsalicylic acid and coumarin derivatives).

Procedural details

The median time from insertion of the self-expanding covered stent to treatment of the edge stenosis using the DCB was 19 months (IQR 8; 52 months). At the time of DCB treatment, four patients (19%) were asymptomatic. The remaining suffered from Rutherford 2 ($N = 6$, 28.6%), 3 ($N = 6$, 28.6%), and 5 ($n = 1$, 4.7%). Previous toe amputation(s) of the target limb were performed in two patients before treatment of the edge stenosis. Median ABI of the target limb was 0.83 (IQR 0.67; 0.93) at time of treatment of the edge stenosis (three patients had noncompressible arteries). All patients had an uncompromised inflow; 2 patients had no unstenosed below-the-knee arteries, 1 patient had one patent below-the-knee artery, 3 patients had two patent below-the-knee arteries, and the remaining 14 patients had three patent below-the-knee arteries.

Localization of the edge stenosis was proximal in eight patients (38.0%) and distal in six patients (28.6%). Seven patients (33.3%) presented with an edge stenosis of both the proximal and the distal edge of the self-expanding covered stent. Four patients (19.0%) were treated with a DCB following thrombolysis for an acute thrombosis of the self-expanding covered stent, caused by edge stenosis, and 57% of patients were treated for restenosis. These lesions were previously treated by PBA. In total, 14 patients had an endograft crossing the Hunter canal of which eight patients were treated at the distal lesion for edge stenosis. In addition, seven patients had an endograft landing in the SFA, of which five patients were treated for a distal edge stenosis.

Lesion length at the proximal edge was longer than at the distal edge (proximal 20 mm (IQR 12; 32 mm) versus distal 12 mm (IQR 8; 16 mm)). The median percentage of the stenosis was 70% (IQR 55; 90) at the proximal and 50% (IQR 48; 73) at the distal edge. In eight patients, lesions were predilated, and in five patients, more than one DCB was used to treat a single lesion. In two patients presenting with stenoses at both edges, one DCB was used to treat both the proximal and distal lesion. All others ($n = 5$) were treated with a separate DCB for the proximal and distal edge stenoses. In one patient, an adjunctive bare metal stent (Everflex, Medtronic, Santa Rosa, CA, USA) was needed because of a persistent $> 30\%$ residual stenosis at the distal edge. During the procedure, two type B dissections, according to Rogers et al.[24] (luminal flap parallel to the vessel wall, but without impairment of flow), were reported and were left untreated. In one patient, PBA of the tibio-

peroneal trunk was performed in the same session. Procedural success was reported in all lesions. In one patient, a scheduled minor amputation of digits II, III, and IV was performed after two days.

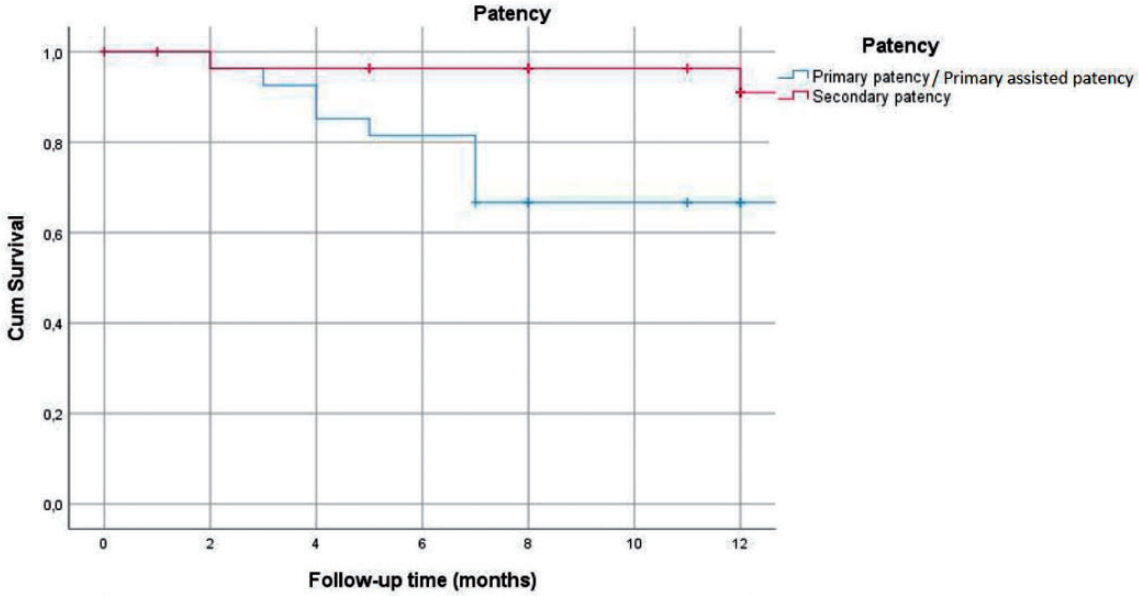
Hospitalization and early outcome

Patients were hospitalized for a median of one day (IQR 1; 3 days), and median ABI at discharge was 0.91 (IQR 0.83; 0.98, $p = 0.263$ compared to baseline). No complications were reported during admission and through six weeks of follow-up. The median time until first follow-up was 45 days (IQR 35; 60), and at that time, the ABI was 0.95 (IQR 0.93; 1.01). Twelve patients (57%) had an improved Rutherford Classification (RC) compared to baseline; in three of these patients, the classification was equal, and in two patients, the RC deteriorated compared to baseline. Also, one patient suffered from severe claudication due to a significant stenosis in the popliteal artery, distal from the treated segment. The other patient presented with an occlusion resulting from a significant restenosis of the target lesion at first follow-up, that which was left untreated because of treatment of recently diagnosed malignancy.

One-year outcome

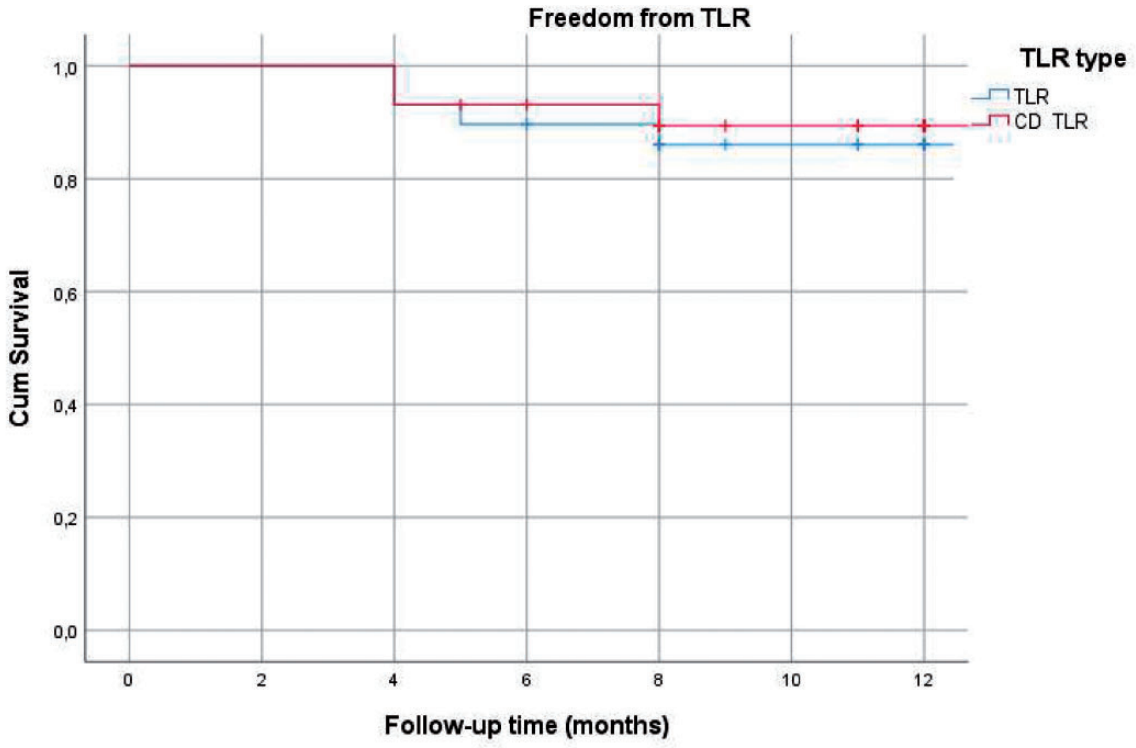
One-year follow-up data was available for 24 lesions in 17 patients. The primary patency at one year was 66.7%, the assisted primary patency was 66.7%, and the secondary patency was 90.9% (Figure 1). The freedom from TLR was 86.1% with a freedom from CD-TLR of 89.4% (Figure 2). There were no major amputations performed until one-year follow-up. The Kaplan–Meier estimates for overall survival and amputation-free survival rates were both 69.5% at one-year follow-up.

At one-year follow-up (IQR 12; 13 months), median ABI was 0.82 (IQR 0.69; 0.95). The PSV ratio showed



Primary	0	6	12
No. At Risk	28	22	13
Patency (%)	100	81.5	66.7
SE	0.0	0.075	0.091
Prim. Assisted	0	6	12
No. At Risk	28	22	13
Patency (%)	100	81.5	66.7
SE	0.0	0.075	0.091
Secondary	0	6	12
No. At Risk	28	24	17
Patency (%)	100	96.3	90.9
SE	0.0	0.036	0.062

Figure 1. Estimated cumulative survival for primary, assisted primary, and secondary patency.
SE: standard error.



TLR	0	6	12
No. At Risk	28	25	17
Patency (%)	100	89.7	86.1
SE	0.0	0.075	0.065
CD_TLR	0	6	12
No. At Risk	28	25	17
Patency (%)	100	93.1	89.4
SE	0.0	0.047	0.058

Figure 2. Estimated cumulative survival for freedom from TLR and CD-TLR.
TLR: target lesion revascularization; CD-TLR: clinically driven target lesion revascularization; SE: standard error.

an improvement from baseline through one year of follow-up ($p = 0.02$) (Figure 3). Nine patients showed an improved RC, four showed an equal RC, and two showed a worsened RC, all compared to baseline. Seven patients showed improved RC compared to baseline at six weeks and one year of follow-up. From four patients, RC data at 12 months were missing. Of the two patients with a worsened RC at six weeks of follow-up, one also showed worsened RC compared to baseline, and the other patient died after nine months of follow-up due to cardiogenic shock and pneumonia after a hip fracture. Another patient was diagnosed with advanced bladder cancer, and euthanasia was performed after six months of follow-up.

In seven patients, a failure of DCB treatment occurred; three patients presented with an occlusion and four with a significant restenosis. Occlusions were reported at two, four, and eight months of follow-up. Two patients showed failure of treatment at six months of follow-up due to significant stenoses and were lost to follow-up afterward. The other two patients presenting with significant restenoses were conservatively followed. Median time to failure was six months (IQR 3.5; 7.0), and median time to occlusion was four months (IQR 3.0; 6.0 months). In total, six TLRs were performed in three patients presenting with occlusions between 6 and 12 months of follow-up; one had three CD-TLRs, all for occlusion of the self-expanding covered stent based on restenosis of the edge within one year (thrombolysis and PBA; thrombolysis, PBA, and additional self-expanding covered stent placement; thrombolysis and DCB). One patient had two

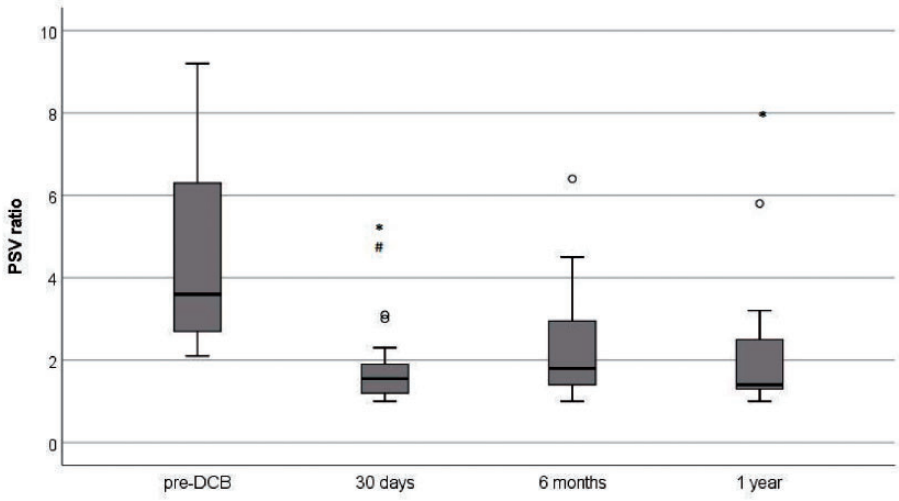


Figure 3. Box plots of PSV ratio before treatment and at 30 days, 6 months, and 12 months of follow-up, respectively. Results are illustrated as median (horizontal line) interquartile range (boxes) and 10th and 90th percentiles (error bar); the circles represent the outliers. $^{*}p < 0.02$ compared to baseline and $^{\#}p < 0.05$ compared to previous timepoint.
PSV: peak systolic velocity; DCB: drug-coated balloon.

reinterventions (based on imaging, without clinical symptoms): the first was a PBA, followed by an endarterectomy of the common femoral artery and proximal SFA. The third patient had one CD-TLR during follow-up for an acute occlusion. Time to first TLR was four, five, and eight months.

Discussion

In the current study, we have shown that edge stenosis of a self-expanding covered stent can safely be treated using a DCB with a still sober, but reasonable one-year outcome with respect to other treatment modalities. When comparing the outcomes with the literature on PBA for this specific indication, the results appear to be more favorable for DCB treatment. A previously published retrospective study, focusing on PBA of edge stenosis, described primary and secondary patency rates of 48.7% and 80.6%, respectively, compared with 66.7% and 90.9% in the current study.[11] However, this observation needs to be confirmed in a larger multi-center prospective comparative trial. In addition, our results confirm the necessity of close follow-up of patients after treatment, as still one in three patients have a loss of primary patency within one year after treatment.

Results of PBA for an ISR are related to a disappointing outcome with regard to patency. Treatment for an ISR using a DCB has been associated with more favorable patency rates. In a meta-analysis, a reduction of 45% in TLR at one-year follow-up was observed after DCB treatment for an ISR in the femoropopliteal artery when compared to PBA.[25] The Paclitaxel Balloon Versus Standard Balloon in In-Stent Restenoses of the Superficial Femoral Artery (PACUBA) study, focusing on DCB treatment of ISR, resulted in a primary vessel patency rate of 40.7% in the DCB group compared to 13.4% in the PBA group.[26] Another single-arm study resulted in primary patency rates of 92.1% at one-year follow-up for DCB treatment for an ISR, which appears to be better than the results for edge stenosis in the current study.[19] TLR rates in our study, however, are more in line with the literature on ISR. The femoral artery in-stent restenosis study showed a one-year freedom from TLR of 90.8% after DCB treatment of an ISR in the femoropopliteal artery, which was significantly better compared to the PBA group.[27] The evidence is thus accumulating that DCBs may play a significant role in improving patency and reducing TLR rates after treatment of restenosis in the femoropopliteal artery.

The occurrence of an edge stenosis poses the risk of acute thrombosis of the self-expanding covered stent. In a previous study, it was found that in about 70% of patients that present with an acute thrombosis of a self-expanding covered stent, an edge stenosis is the underlying cause.[28] An edge stenosis may present at either the proximal or distal edge, but it appears to be more frequent at the proximal edge. The Viabahn Endoprosthesis With Heparin Bioactive Surface in the Treatment of Superficial Femoral Artery Obstructive Disease (VIPER) study reported nine proximal edge stenoses, two distal edge stenoses, and six dual edge stenoses at one year of follow-up in a series of 119 limbs in 113 patients treated with a self-expanding covered stent for long-segment occlusive disease of the femoropopliteal artery.[13] In the current study, the site was more equally

divided with eight proximal edge stenoses, six distal edge stenoses, and seven dual edge stenoses. The incidence of edge stenosis could be reduced by avoiding oversizing,[13] by adjunctive DCB treatment,[22] and by covering healthy to healthy artery segments. The latter could be difficult when the lesion starts at the orifice of the SFA. The performance of a concomitant endarterectomy of the common femoral artery might, therefore, improve patency rates in these patients, as was previously suggested.[9]

The location of the distal edge of the endografts might play a role in the origin of distal edge stenosis, as this may be different in the superficial femoral and popliteal artery. This, however, was not obvious in the current study. Completion angiographies were routinely performed to confirm patency. Currently, the acquisition of multiple series, with the leg in both the extended and flexed positions, is advocated to get a three-dimensional view of the result. Furthermore, endovascular imaging, such as intravascular ultrasound, might play a role.

Another aspect that should be considered is the cost-effectiveness, especially as DCBs are more costly than a regular balloon. A cost-effectiveness analysis of the IN.PACT SFA II trial showed that, after two years of follow-up, the limb-related costs were comparable between DCB and PBA in patients with femoropopliteal disease.[29] Treatment with a DCB for edge stenosis might, therefore, be cost-effective; however, the literature is lacking. Future studies should include a cost-effectiveness analysis to draw conclusions on this matter.

Since the report of Katsanos et al.[30] on a potentially increased mortality after treatment with paclitaxel-based devices, the global use of DCBs has been reduced. More recently, other evidence became available refuting this observation. Schneider et al.[31] found in an independent patient-level meta-analysis that the use of a DCB is safe and that there is no correlation between the level of paclitaxel exposure and mortality. A more recent study on 37,914 patients even showed that paclitaxel-coated balloons were associated with improved overall survival.[32] In the current study, two patients died within one-year follow-up, both of these deaths appearing to be unrelated to the procedure or device.

The retrospective nature and the small sample size are the main limitations of this study. Furthermore, not all information of each of the cases was available, some patients were previously treated, and in addition, no core-lab imaging analysis was done. Also, the follow-up was limited to only one year, and four patients were lost to follow-up. These confounding factors make it difficult to draw conclusions from the current findings, and the results should, therefore, be interpreted with caution. Nevertheless, this study was preformed to obtain the first outcomes on this clinically relevant topic. Confirmative and preferable multi-center randomized controlled trials with longer follow-up data are necessary to draw final conclusions about the role of DCBs in treating edge stenosis.

In conclusion, treatment of edge stenosis using a DCB is associated with a safe one-year outcome, but continuous surveillance of patients is indicated, as are confirmative trials.

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