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Covered stents for symptomatic iliac artery in-stent restenosis treatment: Midterm Results

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ABSTRACT

Purpose: To evaluate the safety and efficacy of balloon-expandable covered stent (CS) for treatment of symptomatic iliac artery in-stent restenosis (ISR).

Material and methods: This was a retrospective, single-arm, single-centre study, which included 25 consecutive patients referred for percutaneous endovascular treatment of angiographically proven symptomatic iliac artery ISR using balloon expandable CS. All patients presented with recurrent Rutherford 1 to 3 chronic limb ischaemia that deteriorated over an average period of 45 months after bare stenting. Study's primary safety outcome measures were peri-procedural (30-days) device-related major complications rate and 12 months patient survival rate, while primary efficacy outcome measure was 12-months clinically-driven target lesion reintervention rate. Secondary endpoints included 12-months binary restenosis rates and 30-day procedure related complication rates.

Results: Initial technical success was 100%. No device-related major complications occurred. No patient was lost to follow up. According to Kaplan-Meier analysis target lesion revascularisation-free survival rates were 92% at 6- and 12-months follow up, respectively. Restenosis rates were 8% and 12% at 6- and 12-months follow up, respectively. Survival was 100% (25/25 patients). No major complications were noted (0%). Minor complication rate was 4% (1/25 case of medium size haematoma).

Conclusions: The use of a balloon-expandable covered stent seems to achieve promising results in the management of symptomatic iliac artery in-stent restenosis.

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1. Introduction

Symptomatic iliac artery atherosclerotic disease is generally effectively treated with endovascular techniques. However, neointimal hyperplasia causing restenosis and disease recurrence is a commonly noted drawback of iliac artery balloon angioplasty and has been correlated with several factors, such as lesion type and morphology, acute luminal gain and risk factors or comorbidities including smoking and diabetes [1, 2]. Although bare metal stents have been reported to produce excellent long-term patency outcomes in iliac artery disease, in-stent restenosis (ISR) remains a major issue compromising long-term clinical success [3]. Furthermore, ISR remains challenging, as high recurrence rates of clinically significant ISR following initial treatment have been reported. Even though various treatment methods such as coaxial bare stent-in-stent deployment, directional atherectomy, athero-ablative techniques, and cutting balloon angioplasty have shown promising results, optimal treatment of iliac ISR remains to be determined [4-18].

Metallic stents with a biologically compatible polymer cover usually made of polyester or polytetrafluoroethylene (PTFE covered stents) have been used in peripheral arteries to treat lesions such as arteriovenous fistulae, aneurysms, pseudoaneurysms, dissections, and arterial rupture [19-25], as well as to improve initial technical success and patency of both iliac and femoropopliteal steno-occlusive disease [26-32]. Possible added advantage of polymer cover is preventing or limiting stent in-growth along the length of the treated segment, compared to conventional stent placement, while development of low-profile covered stent delivery systems has expanded their everyday use in more peripheral applications. The aim of this study was to investigate mid-term safety and efficacy outcomes of balloon expandable covered stent angioplasty for symptomatic iliac artery ISR.

2. Material and Methods

2.1 Study Design

This is a retrospective, single arm, single centre, study investigating all patients who underwent percutaneous covered stent treatment of an angiographically proven symptomatic (intermittent claudication or critical limb ischaemia) iliac artery ISR, between 2002 and 2010, in the Interventional Radiology department.

All patients presented with recurrent chronic limb ischaemia that had deteriorated by at least 1 Rutherford category over an average period of 45 months (range: 24-96 months) after initial stenting and underwent digital subtraction angiography (DSA) following clinical suspicion of significant ISR (recurrence of symptoms, ABI decrease, diminished peripheral pulses). A symptomatic ≥50% reduction in diameter within the stent or within 5 mm from stent edge, demonstrated by DSA, was the indication for stent-graft (SG) treatment. Initial bare stents detected with restenosis were mainly self-expandable stents (*n*=20 Palmaz® Peripheral Stent, Cordis, USA) and five balloon-expandable stents (Omnilink®, Abbott, USA).

2.2 Procedure

Endovascular procedures were performed in the angiography suite by two interventional radiologists with over 15-year experience in vascular procedures. Treatment decision was reached by a multi-disciplinary meeting. All procedures were performed under local anaesthesia and mild conscious sedation was administered only if requested by the patient. Following common femoral artery access and appropriate sheath positioning (6 to 8Fr), intra-arterial bolus dose of 5,000 IU of heparin was administered. Patients were under continuous pulse oximetry, electrocardiography, and blood pressure monitoring.

After angiographic confirmation of iliac artery ISR, lesions were crossed using standard endovascular guide-wires and catheters and primary covered stenting was performed. In severe restenosis (>90% probably), or in cases of total occlusion, angioplasty with a 6 mm balloon (Abbott Laboratories, IL, USA) was initially performed to allow the passage of the covered stent. In the first cases until 2006, balloon expandable covered stents (Abbott Laboratories, IL, USA) were hand crimped on deflated non-hydrophilic balloons (equal to or slightly longer than the covered stent size) and delivered within target lesion. Between 2007 and 2010, pre-mounted balloon-expandable covered stents with lower profile delivery systems were used (Advanta V12; MAQUET, Rastatt, Germany). The sizes selected were 6-12 mm in diameter (maximum inflation equal to the diameter of the bare stent) and 10% longer than the bare stents as to fully cover edge stent stenosis. Small 6 mm balloon-expandable covered stents were used in distal external iliac arteries of two female patients. Correct position of the stent was verified by

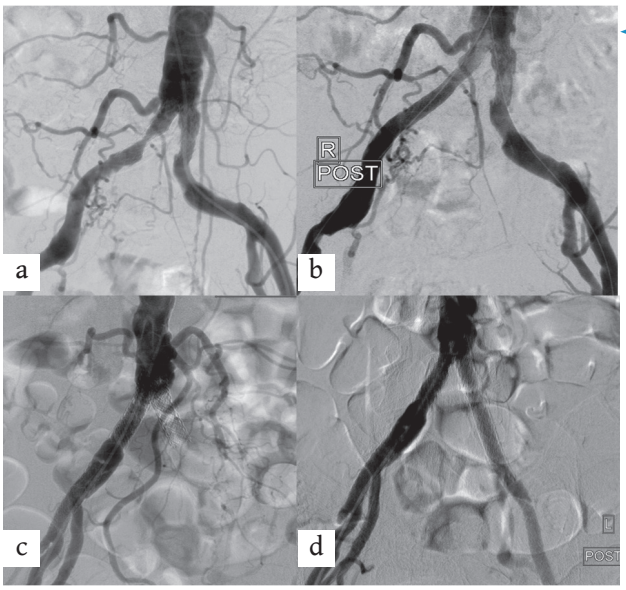
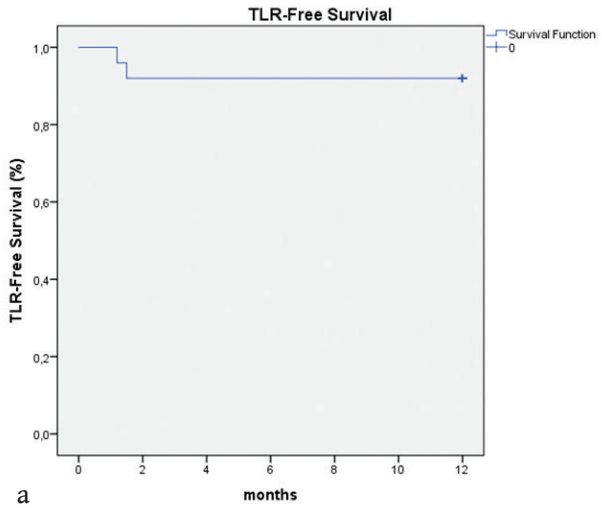
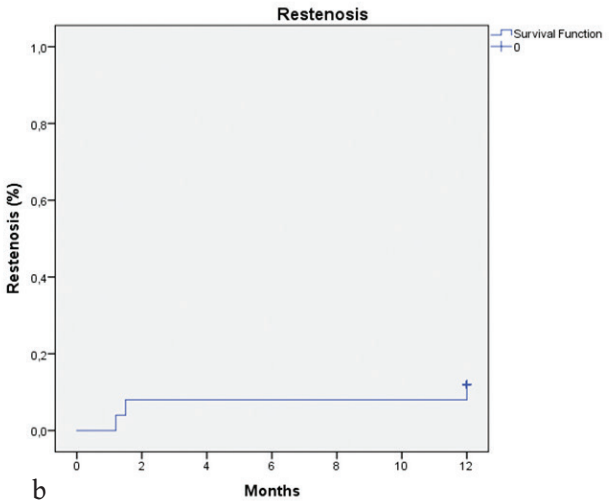


Fig.1 ***(a)*** *DSA demonstrating considerable focal restenosis in the mid segment of a balloon-expandable bare metal stent of the right common iliac artery (CIA) and moderate diffuse restenosis in a balloon-expandable bare metal stent in the left CIA.* ***(b)*** *Both lesions were treated with kissing covered stents, dilated up to 9 mm.* ***(c)*** *Total occlusion of another balloon-expandable bare metal stent.* ***(d)*** *Occlusion was revascularised and a balloon expandable stent graft was placed, which was dilated to 9 mm*

Fig. 2. *Kaplan-Meier plots of* ***(a)*** *target lesion reintervention-free survival and* ***(b)*** *restenosis rates up to 12 months follow up*





contrast injection before inflating the delivery balloon. Dilation was halted if a patient complained of significant pain. A satisfactory result was verified angiographically. If residual stenosis exceeded 30%, additional balloon inflations were performed at higher pressure or a larger balloon was used. Two Clopidogrel tablets (75 mg) were administered routinely at the end of the procedure. All patients were hospitalised overnight for surveillance and were discharged on continuous antiplatelet treatment with life-long Clopidogrel 75 mg once daily according to International guidelines for patients with intermittent claudication, while aggressive risk factor modification using statin, antihypertesive and antidiabetic drug therapy was adopted during follow up.

2.3 Study outcomes, definitions and follow up

Study's primary safety outcome measures were peri-procedural (30-days) device-related major complication-free survival rate and 12-months patient survival rate. Primary efficacy outcome measure was 12-months clinically-driven target lesion reintervention-free survival, defined as patient survival period without any additional revascularisation procedure due to recurrence of ischaemic symptoms. Secondary endpoints were technical success defined as <30% residual stenosis by visual estimation and gradient across the treated lesion <5 mm Hg, 12-months binary restenosis rates detected by Duplex ultrasound (DUS) (peak systolic velocity index >2.0) and verified by angiography and 30-day procedure related complication rates classified as major or minor accord-

Table 1. Characteristics of study patients: risk factors and their distribution by gender

	Men (*n* = 23)	Women (*n* = 2)
Age, yr (mean)	47-75 (58.5)	57-73 (65)
Smoking habit, *n* (%)	19 (82)	1 (50)
Hypertension, *n* (%)	18 (78)	2 (100)
Hypercholesterolaemia, *n* (%)	8 (35)	1 (50)
Diabetes, *n* (%)	9 (39)	1 (50)
End-stage renal disease, *n* (%)	2 (9)	-
Coronary artery disease, *n* (%)	8 (35)	1 (50)

ing to international reporting standards [33]. A residual mean pressure gradient ≥10 mm Hg indicated a haemodynamically significant residual stenosis and was further dilated with balloon larger diameter balloon catheters until gradient <5 mm Hg was detected. Pressure gradients post-covered stent deployment was recorded in all patients. Patient follow-up included clinical evaluation, palpation of femoral and distal pulses, and ankle-brachial index (ABI) measurements. Postoperative surveillance protocol included 6- and 12-months clinical and DUS assessment. Angiography was performed in cases of symptoms recurrence, decrease in the ABI of more than 0.15, or target lesion DUS peak systolic velocity index >2.0.

2.4 Statistical analysis

Discrete variables are given as counts and percentages. Continuous variables are reported as means ± standard error (SE). Kaplan-Meier analysis was performed for estimation of patient survival, reintervention-free survival and restenosis rates. Statistical analysis was performed using the SPSS statistical analysis software (version 23, IBM, NY, USA). Level of statistical significance was set at $p<0.05$.

3. Results

In total, 25 consecutive patients (mean age 59.0 ± 8.1 years; range: 48-75) with 25 lesions [20 (80%) common iliac artery lesions and 5 (20%) external iliac artery lesions] were included in the study. Mean ISR length was 17.4 mm (range 5-45 mm). Mainly >70% stenosis (22/25; 88%), but also three stent occlusions (3/25; 12%) were treated. Patients' baseline demographics are demonstrated in **Table 1**. In total, 80% of patients treated were smokers, 40% suffered from diabetes mellitus, 36% from coronary disease and 8% from end-stage renal disease. Thirteen ISR lesions were classified as focal (<10 mm long), fourteen as diffuse (>10 mm), and four as proliferative (diffuse extending outside the stent margins) (**Table 2**). Two cases required the deployment of kissing covered stents. All lesions were crossed intraluminally and a substent technique was not required. Initial technical success was 100%. No device-related major complications occurred (0%). No patient was lost to follow up. According to Kaplan-Meier analysis target lesion revascularisation-free survival rates were 92% at 6- and 12-months follow up, respectively (**Fig. 3a**). Restenosis rates were 8% and 12% at 6- and 12-months follow up, respectively (**Fig. 3b**). Survival was 100% (25/25 patients). Cumulative, 2/25 patients (8%) experienced total reocclusion, both within the first 2 months following the procedure. In both patients, covered stents were deployed following bare metal stent total occlusion. In one patient 50-60% restenosis was detected by DUS during 12-month visit. However, patient was asymptomatic and no further reintervention was attempted.

No major complications were noted (0%). Minor complication rate was 4% as one case of medium size haematoma was detected following 8 Fr sheath positioning, which resolved without requiring further treatment.

4. Discussion

Endovascular stenting has been established as choice of treatment in iliac artery atherosclerotic disease [34, 35]. Bare stents are widely used to repair angioplasty failures and mechanical complications, such as elastic recoil, occlusive intimal flaps, and dissections while supporting

Table 2. Data of our patient population

Pt	Age	Limb ischaemia category	Location	% Restenosis	Length (mm)	Pattern
1	58	3	Left CIA	Occl	40	-
2	61	2 1	Right CIA Left CIA	70-90 <70	12 18	Diffuse Diffuse
3	71	2	Left CIA	<70	8	Focal
4	56	2 3	Right CIA Left CIA	>90 >90	18 15	Diffuse Pro
5	65	2	Right CIA	>90	5	Focal
6	57	2	Right CIA	70-90	7	Focal
7	50	2	Right CIA	70-90	36	Diffuse
8	65	3 2	Right CIA Left CIA	Occl 70-90	40 15	- Diffuse
9	73	2	Left CIA	Occl	45	Diffuse
10	70	2	Left EIA	70-90	35	Diffuse
11	50	1	Left EIA	<70	12	Diffuse
12	48	2	Left CIA	70-90	8	Focal
13	68	2	Left CIA	70-90	6	Focal
14	48	3	Left EIA	70-90	23	Pro
15	75	2	Left CIA	<70	30	Diffuse
16	56	2	Left CIA	>90	8	Focal
17	57	2 3	Right CIA Left CIA	70-90 >90	15 8	Diffuse Focal
18	52	2	Left CIA	70-90	15	Diffuse
19	62	3 2	Right CIA Left CIA	Occl 70-90	35 7	- Focal
20	50	2	Left EIA	>90	8	Focal
21	57	2 2	Right CIA Left CIA	70-90 70-90	15 10	Diffuse Focal
22	47	2 2	Right CIA Left CIA	70-90 70-90	12 10	Diffuse Focal
23	60	2 2	Right CIA Left CIA	>90 70-90	6 25	Focal Diffuse
24	60	2	Left CIA	70-90	20	Pro
25	58	2	Left EIA	70-90	7	Focal

EIA: external iliac artery, CIA: common iliac artery, ABI: Ankle-brachial index, Pro: proliferative, Occl: Total occlusion

vessel wall during remodeling. However, long-term patency is compromised by in-stents restenosis [36]. Iliac artery ISR has been observed in 13% to 39% of patients in reported series [37, 38]. Currently, the most widely used treatment for ISR is dilation with a conventional angioplasty balloon and/or implantation of a second stent.More recently, cutting balloon angioplasty has been used with acceptable and possible promising results [39]. More recently, cutting balloon angioplasty has been used with acceptable and possible promising results [12]. Balloon-expandable stent grafts have been recently associated with significantly better patency long-term outcomes for the treatment of aortiliac occlusive disease compared to bare metal stents [40, 41]. As a result, authors speculated that there might be a role for covered stents in the treatment of ISR.

In this series, very low clinical relapse rates were noted, as expressed by 92% TLR-free survival rate, which is deemed extremely satisfactory and superior to previous reported outcomes of plain balloon angioplasty and bare metal stenting of iliac ISR [42].

Katsanos et al. recently reported the incidence of acute limb ischaemia (ALI) following stent graft occlusion in the iliac and femoropopliteal arteries. Nonetheless, covered stent occlusion resulting in clinically significant ALI was more frequently noted in the femoropopliteal arteries and iliac covered stent occlusion was rare [43]. In the herein presented study 1-year restenosis rate was 12%, while clinically significant restenosis resulting in reintervention occurred in two cases of reocclusion, just over 1 month following covered stent deployment and could be therefore attributed to stent grafts thrombosis. Nonetheless, reocclusion resulted in relapse of claudication symptoms and not in acute ALI, so patients were scheduled for further endovascular treatment with plain balloon angioplasty or stenting. This could be attributed to the fact the specific lesions were stent occlusions and the development of chronic collateral circulation was probably enough to avoid ALI following reocclusion. The authors believe that if the initial lesion was a stenosis, acute covered stent thrombosis could incite ALI and surgery would be required [43]. As a result, authors strongly recommend prescription of dual antiplatelet therapy for 6 months following iliac artery stent graft deployment, although high levels of evidence to support this notion are awaited.

Patient survival rate was 100% after 1 year follow up. This could be explained by the fact that all patients in the analysis suffered from intermittent claudication (mainly moderate Rutherford 1 and 2 disease) and no CLI patients were treated.

Technical success was also 100% demonstrating the advantage of balloon-expandable stent graft use in achieving excellent immediate outcomes with maximal acute luminal gain. Theory can support that balloon-expandable stent-grafts may improve technical success rate by fixing obstructive flaps and dissections, by preventing elastic recoil, and by permanently compressing plaque, while in the long term, the stent structure may prevent remodeling, and the fabric tube may prevent tissue infiltration and intimal hyperplasia. Several researchers [44–47] have tested these hypotheses and evaluated tissue response to the presence of endovascular stent-grafts. Dolmatch et al. [44] studied the tissue response to ePTFE-covered Palmaz stents in a dog model. They compared two stent grafts with ePTFE graft material that covered either the luminal or abluminal surface of Palmaz stents; a bare stent served as the control stent. They reported patency rates to be highest in the bare stent control group and intimal thickness to be greatest in the stent-graft group when the graft material was on the luminal surface of the stent. The ePTFE material was sutured only at the ends of the stent; therefore, it is possible that movement of the graft material accounted for the neointimal thickening and poor patency. Virmani et al. [45] found nitinol stents with an ePTFE inner lining (a 4.5 cm-long prototype of the stent used in the present study) placed in the iliofemoral arteries of adult greyhound dogs remained patent up to 1 year and showed almost complete endothelialisation of the flow surfaces after 3 months. As neointimal formation peaked at 3 months and then progressively decreased, authors speculated that very thin ePTFE material may have allowed graft endothelialisation to occur by means of transgraft migration of endothelial cells. They also suggested the self-expanding nature of the device limited medial injury and, thereby, reduced proliferation of smooth muscle cells.

The healing associated with graft materials is known to be less extensive in humans. Marin et al. [46, 47] studied the development of intimal hyperplasia and healing associated with stent-grafts in humans and found endothelium 1-3 cm from the ends of the stent-grafts at 3 months and 8 cm from the ends at 5 months. However, there was

also tissue ingrowth through the grafts. Thus, experimental studies have provided limited evidence that stent grafts may undergo re-endothelialisation and reduce the amount of intimal hyperplasia.

Covered stents have been tested for primary atherosclerotic disease and not for ISR. In the SFA region, a balloon-mounted PTFE covered stent was initially used for treating lesions that averaged 17 cm in length; this resulted in a very disappointing 29% primary patency rate at 1 year [48]. Subsequently, prospective evaluation of the Hemobahn PTFE-nitinol self-expanding stent provided encouraging patency rates of 90% and 79% at 6 and 12 months, respectively, for treatment of infrainguinal lesions [49]. These results were not reproduced by other investigators who reported a 49% primary patency rate at 18 months using the same device [50]. Dacron was also investigated as an alternative stent-graft material in the SFA. In a prospective study involving 30 patients [51], Dacron-covered stents implanted in femoropopliteal lesions showed poor (23%) patency at 12 months, with a high rate of adverse events such as pain and fever. Feasibility of implanting PTFE-covered self-expanding Wallgrafts in iliac occlusive disease was shown in a small prospective series that failed to demonstrate significant benefit over bare stenting [52].

Limitations of the study include the fact that some data could have been omitted due to the retrospective design, while the validity of the results is further compromised by the single-centre design and small sample size. Moreover, small number of patients included does not allow a valid statistical analysis as to identify possible factors influencing outcomes. Furthermore, different covered stent types were used producing further heterogeneity outcome bias. Finally, no control group was available as to compare outcomes with standard balloon angioplasty and/or bare metal stent placement.

In conclusion, in this series balloon-expandable covered stents were proven safe and effective for the treatment of ISR in the iliac arteries achieving satisfactory mid-term reintervention and restenosis rates. To our knowledge, this is the first report of successful application of covered stents in iliac ISR, and as midterm results are promising it might constitute valid therapeutic alternative to plain balloon angioplasty and bare metal stenting. Larger prospective controlled trials are required to validate the benefits of balloon expandable covered stents use for iliac in-stent restenosis. **R**

Conflict of interest:
The authors declared no conflicts of interest.

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