Editor's Choice — Outcomes of Self Expanding PTFE Covered Stent Versus Bare Metal Stent for Chronic Iliac Artery Occlusion in Matched Cohorts Using Propensity Score Modelling

M. Piazza [*], F. Squizzato, A. Dall'Antonia, S. Lepidi, M. Menegolo, F. Grego, M. Antonello

Vascular and Endovascular Surgery Clinic, Padova University, School of Medicine, Padua, Italy

WHAT THIS PAPER ADDS

This is the first study comparing the outcomes of self expanding covered stents (CS) with bare metal stents (BMS) in the primary treatment of iliac artery occlusions (IAOs) only. The use of CS has similar early and midterm outcomes compared with BMS; in the presence of specific pre-operative anatomical characteristics (IAO > 3.5 cm in length, IAO calcification involving > 75% of the arterial wall circumference, and IAO with total lesion length > 6 cm) CSs seem to demonstrate a higher patency rate at midterm follow-up. These specific parameters may be useful to the operator in the decision making during endovascular iliac revascularisation planning.

Objectives: The aim was to compare outcomes of self expanding PTFE covered stents (CSs) with bare metal stents (BMSs) in the treatment of iliac artery occlusions (IAOs).

Methods: Between January 2009 and December 2015, 128 iliac arteries were stented for IAO. A CS was implanted in 78 iliac arteries (61%) and a BMS in 50 (49%). After propensity score matching, 94 limbs were selected and underwent stenting (47 for each group). Thirty day outcomes and midterm patency were compared; follow-up results were analysed with Kaplan—Meier curves.

Results: Overall, iliac lesions were classified by limb as TASC B (19%), C (21%), and D (60%). Technical success was 98%. Comparing CS versus BMS, the early cumulative surgical complication rate (12% vs. 12%, $p = 1.0$) and 30 day mortality rate (2% vs. 2%, $p = 1.0$) were equivalent. At 36 months (average 23 ± 17), overall primary patency was similar between CS and BMS (87% vs. 66%, $p = .06$), and this finding was maintained after stratification by TASC B ($p = .29$) and C ($p = .27$), but for TASC D, CSs demonstrated a higher patency rate (CS, 88% vs. BMS, 54%; $p = .03$). In particular, patency was in favour of CSs for IAOs > 3.5 cm in length ($p = .04$), total lesion length > 6 cm ($p = .04$), and IAO with calcification > 75% of the arterial wall circumference ($p = .01$).

Conclusions: Overall, the use of self expanding CS for IAOs has similar early and midterm outcomes compared with BMS. Even if further confirmatory studies are needed, CSs seem to have higher midterm patency rates than BMSs for TASC D lesions, IAOs with a total lesion length > 6 cm, occlusion length > 3.5 cm, and calcification involving > 75% of the arterial wall circumference. These specific anatomical parameters may be useful to the operator when deciding between CS and BMS during endovascular planning.

Accepted 21 March 2017,

Keywords: Iliac artery occlusion, Iliac stenting, Stent, Peripheral artery disease, Hybrid procedure

INTRODUCTION

Endovascular treatment of iliac artery obstructive disease is now a safe and durable approach, and is often the first line therapy. Thanks to improvement in materials and operator expertise, more complex lesions can also now be treated endovascularly with good results,[1] even if open surgery remains the recommended approach (Trans-Atlantic InterSociety Consensus [TASC] II).[2] The severity of iliac artery obstructive disease and the associated complexity of the endovascular procedures are primarily related to the lesion characteristics and extent. In this regard, the presence of a chronic iliac artery occlusion (IAO), rather than a stenosis, is crucial in the decision making for the endovascular strategy to be adopted and for the type of material to be used. Various approaches to IAOs have been described over time: some authors suggest that subintimal recanalisation and angioplasty alone can be used as the first line with adequate early and midterm outcomes.[3] Angioplasty followed by the implantation of a bare metal stent (BMS) is accepted today as a valid technique for complex aorto-iliac lesions, also because it stabilises the plaque and limits the risk of early recoil.[4,5] In contrast, the specific use of a BMS for IAO may

* Corresponding author. Vascular and Endovascular Surgery Clinic, Padova University, School of Medicine, Via Giustiniani, 2, 35100, Padua, Italy.

E-mail address: mikpia79@hotmail.com (M. Piazza).

be limited by major early complications, such as distal embolisation and arterial rupture, or late failure because of in-stent restenosis; the use of a covered stent (CS), which allows pronounced IAO balloon dilatation, may reduce these risks. The COBEST is the only randomised controlled trial comparing the use of CS and BMS for complex lesions classified by the TASC II as class C and D. In this study, there was a significantly better patency in favour of CS both at 1 year[6] and at 5 years.[7] Recently it was reported,[8] in a single centre experience, that the use of a CS rather than a BMS has better early and midterm outcomes in cases of TASC D lesions with long segment severe stenosis involving both the common iliac artery (CIA) and the external iliac artery (EIA). However, no previous studies have focused on the outcomes of CS versus BMS in the primary treatment of IAOs only. Furthermore, there is still no evidence regarding the role of occlusion length, entire lesion length, plaque quality, and arterial site for decision making between CS and BMS.

The purpose of this study was to review experience in the endovascular treatment of IAOs comparing CS and BMS.

METHODS

Patient selection

A retrospective review of all patients admitted to the Clinic of Vascular and Endovascular Surgery of Padova University who underwent iliac artery stenting for IAO between January 2009 and December 2015 was carried out. During the study period, 386 iliac artery endovascular revascularisations were performed; among these, only the 128 limbs (33%) with a pre-operative computed tomography (CT) angiogram finding of an IAO were included. Informed consent and Institutional Review Board requirements were waived for this study. All data were collected prospectively in a dedicated database. Patients who had had previous endovascular procedures to the iliac segment, those with associated aortic thrombosis, or patients treated in the emergency setting were excluded. Patients were classified into two groups: those who received a PTFE CS and those who received a BMS. The two groups were matched using propensity score analysis, and all results are presented describing both the unmatched and the matched cohorts.

Treatment and definitions

Operative comorbidity risk was defined using the Society for Vascular Surgery (SVS) comorbidity score and the America Society of Anesthesiologist (ASA) score. Chronic limb ischaemia was defined by symptoms at presentation on the basis of the SVS reporting standards.[9]

Occlusion length, total lesion length, and lesion site were evaluated on the basis of the pre-operative CT angiogram. Calcification was evaluated at the level of the occlusion and was classified in four grades: (1) $< 25\%$ of the entire arterial circumference; (2) between 25% and 50%; (3) between 50% and 75%; (4) $> 75\%$. Common femoral artery (CFA) occlusive disease was classified according to CT imaging as mild ($< 50\%$), moderate (50—74% stenosis), or severe (75—99%), and occlusion.

Peri- and early post-operative (within 30 days of surgery) medical and surgical outcomes were collected. Follow-up evaluation included the presence of a palpable femoral pulse, resolution of symptoms, regular colour flow Doppler ultrasonography of the iliac and femoral axis, and ankle brachial index (ABI) at 3, 6, and 12 months and then yearly. Loss of patency was suspected in cases of loss of previously palpable pulses, symptom recurrence, Doppler ultrasound findings of stenosis or occlusion ($> 50\%$ stenosis defined as $> 100\%$ increase in the peak systolic velocity relative to the adjacent segments), drop in the ABI > 0.15, or a combination of these findings. All patients suspected of having stent restenosis or iliac stenosis underwent a CT angiogram for further evaluation. Patency and limb salvage were defined according to the SVS guidelines.[9]

Operative technique

Endovascular iliac treatment was performed by four members of the Vascular and Endovascular Surgery Division of the Padua University.

For bilateral CIA or aortic bifurcation intervention, a “kissing balloon” technique was performed. The preferred vascular access site was the ipsilateral femoral artery; in cases of unsuccessful recanalisation from this site, contralateral CFA or left brachial artery access was used. The access site was percutaneous if the CFA was free from stenotic plaque ($< 30\%$) with a non-calcified anterior wall; if not, a groin cut-down was performed.

IAO recanalisation was always approached first with intraluminal passage of a hydrophilic wire and catheter; only in cases of unsuccessful intraluminal recanalisation, both by a retrograde and antegrade route, was subintimal recanalisation obtained. No re-entry devices were used in this series. After successful iliac artery recanalisation, the choice of predilatation was left to the operator. Predilatation was performed when necessary, with variable diameter (4—7 mm diameter) non-compliant balloons especially in cases with long occlusions.

All the stents used in this study were self expanding nitinol stents. Even if the choice of CS versus BMS was on a case by case fashion at the discretion of the treating physician, a common strategy was usually followed. In particular, a CS was preferred to a BMS for short lesions only when there was a high risk of arterial rupture during ballooning. For long lesions, a CS was preferred if there was evidence on the pre-operative CT angiogram of diffuse calcification of the entire axis with concomitant severe stenosis/occlusion of the ipsilateral hypogastric, or for an occlusion undergoing subintimal recanalisation for a long tract. For long lesions, BMSs were used for lesions crossing the iliac bifurcation with a patent hypogastric artery, lesions with low grade calcification on the CT angiogram, and/or lesions that adequately responded to predilatation.

As also described by others,[10] the number of hybrid procedures at the authors’ clinic has increased in the last decade, and CFA endarterectomy and patch angioplasty (with the ipsilateral great saphenous vein) were included with iliac stenting in cases of concomitant CFA stenosis $> 50\%$; if distal

EIA stenting was necessary, the stent was uniformly deployed to overlap the proximal CFA endarterectomy line. General anaesthesia was usually used in patients requiring time consuming hybrid surgical procedures and more complex procedures; in other procedures, local anaesthesia with conscious sedation was used. All patients were prescribed aspirin (81—325 mg daily) after the procedure. Clopidogrel (75 mg daily) was routinely prescribed after the procedure, with dual antiplatelet therapy continued for at least 1 month.

Statistical analysis

Continuous data are presented as mean ± standard deviation, categorical data as number and percentage. Continuous variables were compared with the Wilcoxon rank sum test and the *t* test as appropriate. The Pearson chi-square and Fisher exact tests were used for analysis of categorical variables. The propensity score was estimated using logistic regression; baseline demographics and anatomical data (occlusion length, total lesion length, grade of calcifications, TASC classification), and the operator performing the procedure were considered. Propensity score matched cohorts of CSs and BMSs were created and yielded a matched cohort of 47 CS and 47 BMS treated limbs. The C statistic for this model was 0.85.

Kaplan—Meier survival curves for primary patency, secondary patency, and limb salvage were estimated, and the log-rank *p* value was used to compare the two groups. The cutoff for total lesion length and occlusion length used in the univariate analysis were defined on the basis of frequency distributions in the matched cohort. All analyses were carried out with R 3.1.2 software (R Foundation for Statistical Computing, Vienna, Austria), and $p < .05$ (two-tailed) was considered statistically significant.

RESULTS

During the study period, 107 patients (131 limbs) underwent endovascular treatment for IAOs. Iliac artery recanalisation failed in three cases (2%) because of a long heavily calcified IAO > 6 cm, and open repair was planned. The 128 limbs that were successfully treated by stenting were entered in the presented analysis. The use of a CS had been planned in 75 limbs and a BMS in 53 limbs. In three cases initially supposed to receive a BMS, iliac artery rupture occurred (2 cases after BMS implantation and angioplasty, 1 case during arterial predilatation), and a CS was used as a bailout treatment. These cases were then classified in the CS group, with a final count of 78 limbs (61%) included in the CS group and 50 limbs (39%) in the BMS group. To obtain groups as similar as possible, propensity score matching was used, giving 47 limbs in each group.

Baseline characteristics are reported in Table 1. Patients were selected for revascularisation for persistent severe

Table 1. Demographics, cardiovascular risk factors, and peri-operative risk assessment.

	Unmatched cohort (N = 128)			Propensity matched cohort (N = 94)		
	CS (N = 78)	BMS (N = 50)	*p*	CS (N = 47)	BMS (N = 47)	*p*
Demographics						
Age, years			.68			.48
Mean ± SD	67.8 ± 10.1	68.5 ± 10.6		66.9 ± 10.6	68.5 ± 10.9	
Median (range)	70 (43—92)	70 (43—86)		70 (43—85)	70 (43—86)	
Age < 60 years	13 (17)	13 (26)	.26	10 (21)	15 (32)	.35
Male gender	60 (77)	41 (82)	.65	34 (72)	39 (77)	.32
Cardiovascular risk factors						
Hypertension	62 (76)	37 (74)	.52	33 (70)	32 (68)	1.00
Diabetes	28 (35)	11 (22)	.11	10 (21)	9 (19)	1.00
Smoking[a]	57 (73)	36 (72)	1.00	29 (62)	30 (64)	1.00
Coronary artery disease	36 (46)	16 (32)	.14	18 (38)	15 (32)	.66
Renal insufficiency	19 (24)	7 (14)	.18	11 (23)	7 (15)	.43
Dialysis	4 (5)	5 (10)	.31	3 (6)	4 (9)	1.00
COPD	17 (22)	7 (14)	.35	5 (11)	5 (11)	1.00
Medical therapy						
None	12 (15)	8 (16)	1.00	5 (11)	7 (15)	.76
Antiplatelet	42 (54)	34 (68)	.31	30 (64)	33 (7)	.66
Dual antiplatelet	14 (18)	4 (8)	.52	6 (13)	3 (6)	.49
Anticoagulant	6 (8)	2 (4)	.70	4 (8)	2 (4)	.67
Antiplatelet + anticoagulant	4 (5)	2 (4)	1.00	2 (4)	2 (4)	1.00
Peri-operative assessment						
ASA score	2.7 ± 0.9	2.6 ± 0.7	.51	2.7 ± 0.8	2.7 ± 0.8	1.00
SVS cardiac score	1.04 ± 0.90	0.92 ± 0.98	.48	1.01 ± 0.92	0.98 ± 0.98	.88
SVS pulmonary score	0.27 ± 0.61	0.20 ± 0.57	.52	0.22 ± 0.71	0.21 ± 0.48	.93
SVS renal score	0.45 ± 0.91	0.47 ± 1.02	.91	0.53 ± 0.99	0.47 ± 1.02	.77
SVS sum score	0.94 ± 0.54	0.82 ± 0.64	.26	0.95 ± 0.66	0.84 ± 0.64	.41

ASA = American Society of Anesthesiologists; BMS = bare metal stent; COPD = chronic obstructive pulmonary disease; CS = covered stent; SVS, Society for Vascular Surgery.

[a] Includes current and former smokers.

claudication (< 100 m) after medical and physical rehabilitation, the presence of disabling claudication (< 30 m), and critical limb ischaemia. Clinical presentation was similar in the two groups (Table 2).

Mean occlusion length (4.6 ± 3.4 cm vs. 2.8 ± 2.2 cm; $p = .001$) and mean total lesion length (9.1 ± 4.1 cm vs. 5.8 ± 2.4 cm; $p < .001$) were higher in the CS group than in the BMS group in the unmatched cohort. Similarly, the number of occlusions involving the CIA + EIA was also higher in the CS group (19% vs. 4%; $p = .01$). In the propensity matched cohort, all these anatomical characteristics became similar between CS and BMS (mean occlusion length, 3.5 ± 1.8 cm vs. 2.8 ± 2.0 cm, $p = .05$; total lesion length, 7 ± 2.9 cm vs. 6 ± 2.3 cm, $p = .09$; CIA + EIA occlusion, 15% vs. 4%, $p = .15$)

General anaesthesia was used in the majority of patients in both groups, but patients treated with a CS were more likely to receive general anaesthesia (90% vs. 53%; $p < .001$); this outcome may be related to the fact that when time-consuming interventions are expected (complex recanalisation, groin cutdown) general anaesthesia is preferred. The average length of stay was longer in the CS group than in the BMS group (6.3 ± 6.4 days vs. 3.4 ± 2.6 days; $p = .005$). These findings may be explained by the fact that in presence of a variable degree of CFA anterior wall calcification, if larger introducers were needed (CSs usually require a larger introducer than BMSs), a groin cutdown with CFA control and direct puncture was preferred rather than a percutaneous approach.

Iliac recanalisation was achieved through an ipsilateral femoral access in the majority of cases (unmatched, 75% vs. 84%, $p = .28$; matched, 81% vs. 87%, $p = .57$). Overall, a contralateral femoral approach was needed in 12% of cases (unmatched, 9% vs. 12%, $p = .56$; matched, 9% vs. 11%, $p = 1.00$) and a left brachial approach in 13% of cases (unmatched, 15% vs. 4%, $p = .08$; matched, 10% vs. 2%, $p = .20$). The number of cases that underwent subintimal recanalisation was higher in the CS group (unmatched, 27% vs. 10%, $p = .02$; matched, 21% vs. 8%, $p = .14$). In 19% of cases ($n = 5$) a BMS was used after subintimal angioplasty. Patients in the CS group had a higher number of CIA + EIA as target lesion (65% vs. 44%; $p = .02$); similarly the mean number of stents (1.5 ± 0.6 vs. 1.3 ± 0.5; $p = .06$) and length of coverage (10.0 ± 4.3 vs. 6.3 ± 2.5; $p < .001$) were higher in this group. In the CS group, of 51 limbs with long lesions involving both the CIA and EIA, a single long CS

Table 2. Clinical and anatomical data for the limbs undergoing iliac occlusion endovascular treatment.

	Unmatched cohort ($N = 128$)			Propensity matched cohort ($N = 94$)		
	CS ($N = 78$)	BMS ($N = 50$)	p	CS ($N = 47$)	BMS ($N = 47$)	p
Clinical data						
Rutherford category						
3	31 (39)	23 (46)	.58	19 (40)	22 (47)	.67
4	34 (43)	15 (30)	.14	21(45)	13 (28)	.13
5–6	12 (15)	12 (24)	.25	7 (15)	12 (25)	.30
Anatomical data						
Aorto-iliac TASC II classification						
B	11(14)	13 (26)	.11	11 (23)	12 (26)	1.00
C	15 (19)	12 (24)	.52	13 (28)	11 (23)	.81
D	52 (66)	25 (50)	.07	23 (49)	24 (51)	1.00
Grade of calcification						
< 25%	8 (10)	5 (10)	1.00	13 (28)	16 (34)	.65
25–50%	13 (16)	14 (28)	.18	12 (26)	16 (34)	.50
50–75%	12 (15)	10 (20)	.63	8 (17)	6 (13)	.77
> 75%	45 (57)	21 (42)	.10	14 (30)	9 (28)	.33
Occlusion length, cm			.001[a]			.05
Mean ± SD	4.6 ± 3.4	2.8 ± 2.2		3.5 ± 1.8	2.8 ± 2.0	
Median (range)	4.00 (1–16)	2.0 (1–7.5)		3.0 (1–8)	2.0 (1–7.5)	
Total lesion length, cm			< .001[a]			.09
Mean ± SD	9.1 ± 4.1	5.8 ± 2.4		7.0 ± 2.9	6.0 ± 2.3	
Median (range)	9.0 (2–16)	5.5 (2–12.5)		7.0 (2–15)	6.0 (2–12.5)	
Site of occlusion						
CIA	45 (57)	35 (70)	.19	31 (66)	34 (72)	.65
EIA	18 (23)	13 (26)	.83	9 (28)	11 (23)	.80
CIA–EIA	15 (19)	2 (4)	.01[a]	7 (15)	2 (4)	.15
Aortic bifurcation disease	32 (41)	13 (26)	.09	21 (36)	13 (28)	.16
CFA grade of stenosis						
Minimal (< 50%)	41 (52)	31 (62)	.36	23 (49)	30 (64)	.21
Moderate/high (50–74%)	14 (17)	6 (12)	.46	7 (15)	5 (10)	.76
High (75–99%)	18 (23)	10 (20)	.83	8 (17)	9 (28)	1.00
Occlusion	5 (6)	3 (6)	1.00	5 (11)	4 (9)	1.00

CIA = common iliac artery; EIA = external iliac artery; CFA = common femoral artery.
[a] Statistically significant.

(8 cm, $n = 3$; 10 cm, $n = 9$; 15 cm, $n = 8$) was used to treat the entire axis in 20 cases (39% of target lesion CIA + EIA); all of these cases presented concomitant ipsilateral hypogastric occlusion/sub-occlusion. However, after propensity score matching, the two groups were similar for major anatomical and technical characteristics (CIA + EIA lesions, 51% vs. 43%, $p = .53$; mean number of stents, 1.4 ± 0.5 vs. 1.3 ± 0.5, $p = .29$; mean length of coverage, 7.8 ± 3.1 vs. 6.5 ± 2.5, $p = .06$). Additional procedural data are reported in Table 3.

In the peri-operative period (within 24 h of surgery), there was only one case of distal embolisation in the BMS group that was treated medically. Iliac rupture occurred in five cases (3.9%); four were intra-operative and one was diagnosed six hours after the intervention. In two cases rupture occurred after BMS implantation and PTA, and in three cases after predilatation; in all cases the rupture was managed by covering the arterial breach with a CS.

Within 30 days after surgery, there were no differences in mortality and major medical and surgical outcomes between patients in the CS and BMS group (Table 4). In both cases early mortality was related to myocardial infarction. The 30 day cumulative surgical complications rate was respectively 9% versus 12% in the CS versus the BMS group ($p = 1.00$) in the unmatched cohort and 12% versus 12% ($p = 1.00$) in the propensity matched cohort.

The average follow-up period was 25 ± 16 months (range, 30 days to 72 months), with an average of 23 ± 16 months for the CS group and 27 ± 16 months for the BMS group. Survival at 36 months was 83% for the CS group and 87% for the BMS group ($p = .44$).

Overall primary patency was higher in the CS than in the BMS group (88% vs. 68%) even if this finding was not statistically significant ($p = .07$); this finding was confirmed after propensity score matching (87% vs. 66%, $p = .06$) (Fig. 1).

Table 3. General operative and procedural information in the limbs undergoing iliac occlusion endovascular treatment.

	Unmatched cohort ($N = 128$)			Propensity matched cohort ($N = 94$)		
	CS ($N = 78$)	BMS ($N = 50$)	p	CS ($N = 47$)	BMS ($N = 47$)	p
Operative data	Pts = 61	Pts = 43		Pts = 45	Pts = 43	
General anaesthesia	55 (90)	23 (53)	< .001[a]	38 (84)	23 (53)	.02[a]
Length of stay, days			.005[a]			.05
Mean ± SD	6.3 ± 6.4	3.4 ± 2.6		5.1 ± 5.0	3.4 ± 2.6	
Median (range)	5 (1—18)	3 (1—12)		4 (1—15)	3 (1—12)	
Procedural data	Limbs = 78	Limbs = 50		Limbs = 47	Limbs = 47	
Vascular access						
Ipsilateral	59 (75)	42 (84)	.28	38 (81)	41 (87)	.57
Contralateral	7 (9)	6 (12)	.56	4 (9)	5 (11)	1.00
Left brachial	12 (15)	2 (4)	.08	5 (10)	1 (2)	.20
Endovascular target						
CIA	24 (30)	24 (48)	.06	21 (45)	24 (51)	.68
EIA	3 (4)	4 (8)	.43	3 (6)	3 (6)	1.00
CIA + EIA	51 (65)	22 (44)	.02[b]	24 (51)	20 (43)	.53
Mean number of stents	1.5 ± 0.6	1.3 ± 0.5	.06	1.4 ± 0.5	1.3 ± 0.5	.29
Length of coverage, cm			< .001[a]			.06
Mean ± SD	10.0 ± 4.3	6.3 ± 2.5		7.8 ± 3.1	6.5 ± 2.5	
Median (range)	10.0 (3.7—17)	6.0 (4—12.5)		8.0 (3.7—15)	6.0 (4—12.5)	
Type of stent						
Viabahn[b]	47 (60)	—	—	31 (65)	—	—
Fluency[c]	31 (40)	—	—	16 (35)	—	—
GPS Protégé[d]	—	10 (20)	—		9 (19)	—
SMART Control[e]	—	15 (30)	—		13 (27)	—
Easy Flype[f]	—	25 (50)	—		25 (53)	—
Subintimal recanalisation	21 (27)	5 (10)	.02[a]	10 (21)	4 (8)	.14
Predilatation	47 (60)	22 (44)	.10	25 (53)	18 (38)	.21
Associated procedures						
CFA endarterectomy	37 (47)	19 (38)	.36	20 (43)	18 (38)	.83
Femoro-popliteal bypass	4 (5)	2 (4)	1.00	1 (2)	0 (—)	1.00
SFA PTA/stent	2 (2)	2 (4)	.64	0 (—)	2 (4)	.49

CIA = common iliac artery; EIA = external iliac artery; CFA = common femoral artery.

[a] Statistically significant.

[b] W.L. Gore & Associates, Inc., Flagstaff, AZ, USA.

[c] Bard Peripheral Vascular, Tempe, AZ, USA.

[d] Covidien ev3, Plymouth, MN, USA.

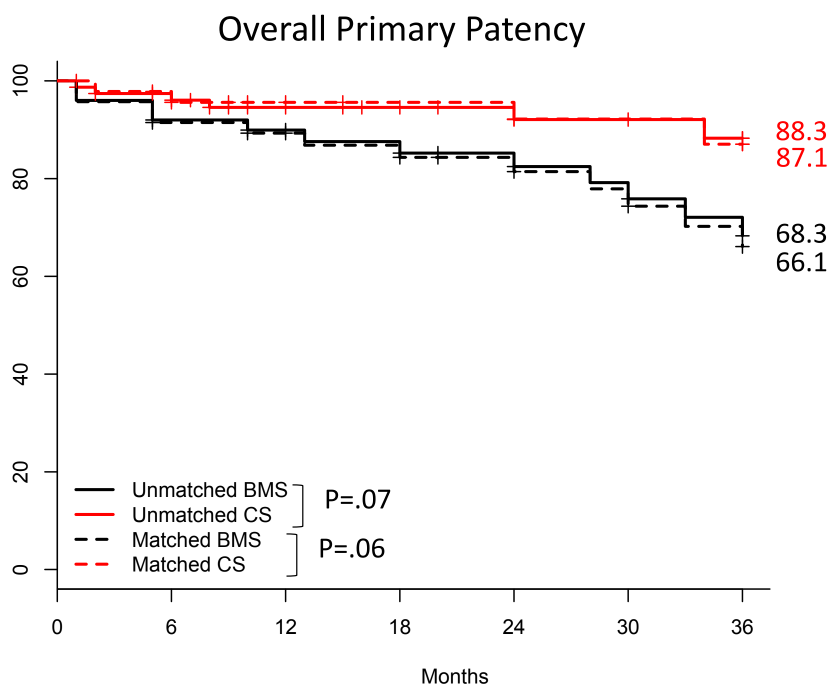
[e] Cordis Corporation, Miami Lakes, FL, USA.

[f] Alvimedica Medical, Milan, Italy.

Table 4. Early outcomes (< 30 days from surgery) in the limbs undergoing iliac occlusion endovascular treatment.

	Unmatched cohort (N = 128)			Propensity matched cohort (N = 94)		
	CS (N = 78) Limbs = 78	BMS (N = 50) Limbs = 50	p	CS (N = 47) Limbs = 47	BMS (N = 47) Limbs = 47	p
Ankle brachial index						
Before	0.46 ± 0.35	0.53 ± 0.29	.24	0.49 ± 0.33	0.54 ± 0.30	.44
After	0.91 ± 0.32	0.88 ± 0.38	.63	0.90 ± 0.27	0.89 ± 0.38	.88
Increase	0.44 ± 0.37	0.36 ± 0.33	.21	0.43 ± 0.35	0.35 ± 0.34	.26
Surgical complications	7 (9)	6 (12)	.80	6 (12)	6 (12)	1.00
Requiring re-intervention	4 (5)	3 (6)	.67	3 (6)	3 (6)	1.00
Haematoma	3 (4)	2 (4)	1.00	2 (4)	2 (4)	1.00
Wound infection[a]	1 (2)	0 (–)	1.00	1 (2)	0 (–)	1.00
Amputation	0 (–)	1 (2)	1.00	0 (–)	1 (2)	1.00
Conservative treatment	3 (4)	3 (6)	.67	3 (6)	3 (6)	1.00
Wound infection[a]	1 (2)	1 (4)	1.00	1 (2)	1 (2)	1.00
Distal embolisation	0 (–)	1 (2)	1.00	0 (–)	1 (2)	1.00
Lymph leak[a]	0 (–)	1 (4)	1.00	0 (–)	1 (2)	1.00
Buttock claudication	2 (2)	0 (–)	.52	2 (4)	0 (–)	.12
	Pts = 61	**Pts = 43**		**Pts = 45**	**Pts = 43**	
Medical complications	3 (5)	1 (2)	.45	3 (6)	1 (2)	.61
Major cardiac[b]	1 (1)	1 (2)	1.00	1 (2)	1 (2)	1.00
Respiratory failure[c]	2 (3)	0 (–)	.53	2 (4)	0 (–)	.49
Dialysis	0 (–)	0 (–)	–	0 (–)	0 (–)	1.00
Death	1 (1)	1 (2)	1.00	1 (2)	1 (2)	1.00

[a] Percentages are expressed in comparison with the number of inguinal cut-downs.
[b] Intra-operative or peri-operative major cardiological event that required intervention (cardiac massage, coronary artery bypass grafting, percutaneous transluminal angioplasty, pacemaker implantation).
[c] Pulmonary embolism or severe respiratory distress.



N. At risk: unmatched cohort

BMS: 50 47 45 37 31 24 19

CS: 78 72 62 50 38 50 24

N. At risk: matched cohort

BMS: 47 45 42 35 29 22 17

CS: 47 44 40 35 28 22 18

Figure 1. Overall Kaplan–Meyer estimates of primary patency in the two groups in both the unmatched and matched cohort. Standard error < 10%.

After stratification by TASC II, primary patency was not significantly different between CS and BMS in the unmatched cohort for TASC B (100% vs. 70%; $p = .32$) and C (83% vs. 100%; $p = .27$) lesions, but became significant among TASC D patients (89% vs. 56%, $p = .01$) these outcomes were also confirmed in the matched cohort (TASC B, 100% vs. 67%, $p = .29$; TASC C, 81% vs. 100%, $p = .27$; TASC D, 88% vs. 54%, $p = .03$) (Fig. 2).

The descriptive frequencies distribution of “occlusion length” and “total lesion length” stratified for patency status in the propensity matched cohort (Fig. S1) identified a cutoff of 3.5 cm (CS, 3.7 cm; BMS, 3.5 cm) and 6 cm (CS, 6.5 cm; BMS, 5.5 cm) respectively. The patency analysis confirmed these trends, showing that CS was superior to BMS in case of occlusion length > 3.5 cm (unmatched, 90% vs. 48%, $p = .01$; matched, 87% vs. 48%, $p = .04$) and total lesion length $\geq$ 6 cm (unmatched, 78% vs. 53%, $p = .02$; matched, 81% vs. 53%, $p = .04$). In particular, in cases of occlusion length > 3.5 cm, the difference between CS and BMS was not significant after 24 months ($p = .10$ in the unmatched cohort; $p = .43$ in the matched cohort), but became significant after 30 months ($p = .01$ in the unmatched cohort; $p = .01$ in the matched cohort). This finding may be explained by the fact that the BMS group carries more residual stenosis after PTA than the CS group. Finally, CS demonstrated a better patency rate in the presence of calcifications involving > 75% of the arterial circumference (unmatched, 96% vs. 63%, $p = .03$; matched, 100% vs. 63%, $p = .01$) (Table 5). No differences were found between CS and BMS groups regarding overall secondary patency (unmatched, 98% vs. 88%, $p = .13$; matched 97% vs. 89%, $p = .22$) or limb salvage rates (unmatched, 96% vs. 93%, $p = .77$; matched, 96% vs. 93%, $p = .91$) at 36 months.

DISCUSSION

The definition of “iliac artery occlusion” is today widely adopted to define a range of lesions independently of their length and characteristics; this definition does not specify the severity of the disease of the challenges for an endovascular approach. Comparing the endovascular treatment of IAOs to stenosis, Pulli et al.[11] did not find significant differences in terms of early outcomes and longterm patency (82.4% vs. 77.7% at 60 months; $p = 0.9$).

It is well known in everyday clinical practice that in presence of an IAO, endovascular repair is planned on the basis of occlusion length and grade of calcification, entire lesion length, site, and laterality. These aspects influence

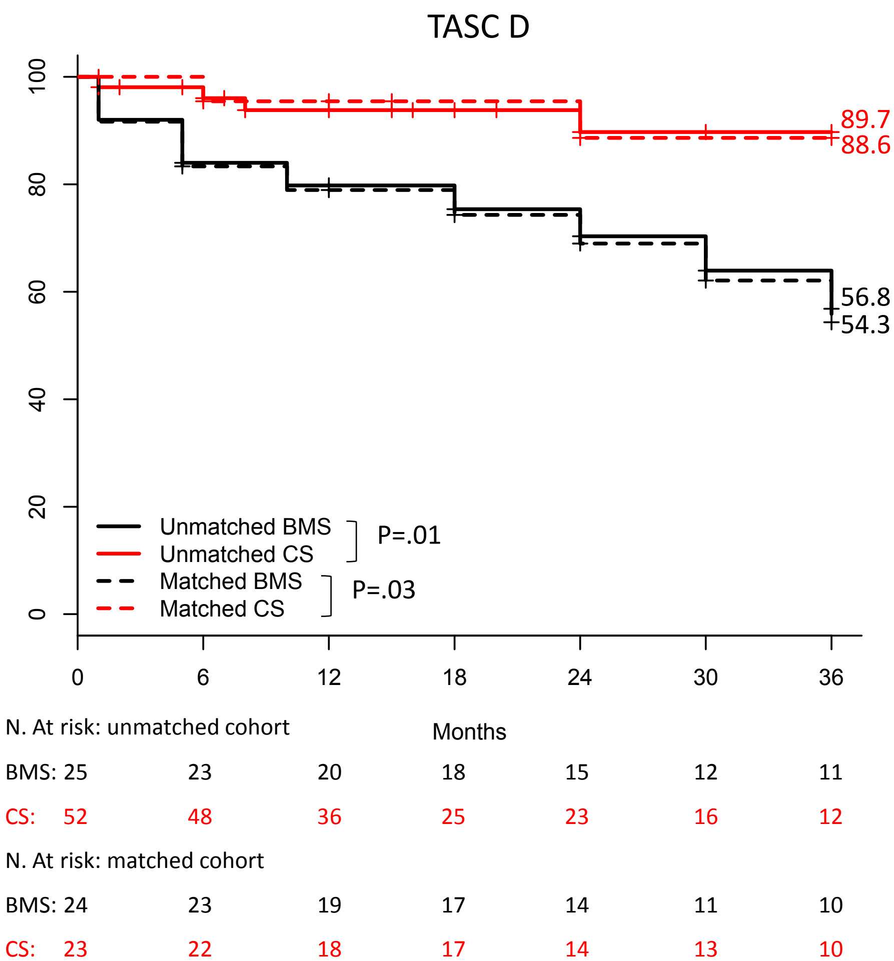


Figure 2. Kaplan–Meier estimates of primary patency in the two groups in lesions classified as TASC II D in both the unmatched and matched cohort. Standard error < 10%.

Table 5. Kaplan–Meier estimates of primary patency at 36 months, stratified by anatomical factors.

	Unmatched cohort 36 months	p	Propensity matched cohort 36 months	p
TASC				
TASC B CS	100 (–)	.32	100 (–)	.29
TASC B BMS	70.3 (47–100)		66.8 (42–100)	
TASC C CS	83.0 (64–100)	.27	80.8 (60–100)	.27
TASC C BMS	100 (–)		100 (–)	
TASC D CS	89.7 (80–100)	.01[a]	88.6 (74–100)	.03[a]
TASC D BMS	56.8 (38–84)		54.3 (35–84)	
Occlusion length				
$\leq$ 3.5 cm CS	78.2 (51–100)	.71	77.8 (53–100)	.94
$\leq$ 3.5 cm BMS	83.9 (70–100)		82.0 (67–100)	
$>$ 3.5 cm CS	89.8 (76–100)	.01[a]	87.3 (72–100)	.04[a]
$>$ 3.5 cm BMS	47.9 (28–82)		47.9 (28–82)	
Total lesion length				
$<$ 6 cm CS	89.5 (76–100)	.60	94.1 (84–100)	.47
$<$ 6 cm BMS	84.2 (69–100)		82.0 (65–100)	
$\geq$ 6 cm CS	78.3 (58–100)	.02[a]	81.5 (63–100)	.04[a]
$\geq$ 6 cm BMS	52.8 (33–83)		52.8 (33–84)	
Calcifications				
$<$ 75% CS	79.5 (64–98)	.65	77.3 (59–100)	.54
$<$ 75% BMS	71.5 (55–94)		68.2 (50–94)	
$\geq$ 75% CS	96.7 (91–100)	.03[a]	100 (–)	.01[a]
$\geq$ 75% BMS	63.2 (42–95)		63.2 (41–96)	

[a] Statistically significant.

not only the choice between an open or an endovascular approach, but also in this second case the strategy to be adopted for IAO recanalisation and the type of stent to be implanted.

However, the literature has reported outcomes of endovascular IAO treatment primarily in relation to the TASC classification, and results are often merged together with stenotic lesions.

For these reasons, outcomes of BMS vs. CS for IAOs were compared, with particular attention to midterm patency in relation not only to the TASC classification but also to lesion characteristics and site. In this series, overall primary patency was not significantly different between CS and BMS ($p = .07$), and this result was also maintained after stratification by TASC B ($p = .32$) and C ($p = .27$). In particular, BMSs had excellent primary patency varying from 91% to 100% at 2 years in this subset of patients. These results are in line with the previous experience of Araki[5] with self expanding BMSs used after intimal recanalisation; in their study 65% of IAOs were in TASC B and C, and the overall primary patency at 2 years was 96.5%.

By contrast, the study showed a significant benefit of CS in cases of IAO classified as TASC D, with a primary patency at 36 months of 89% versus 57% respectively ($p = .01$). This result follows the trend of the COBEST trial;[6,7] in their subanalysis, the 5 year primary patency of CS was superior to BMS for TASC C and D lesions ($p = .003$). However, in the COBEST trial, TASC C and D lesions included both stenosis and IAOs and the CSs used were balloon expandable, although in this series they were all self expanding.

In this study, CSs were preferred to BMSs, especially after subintimal recanalisation ($p = .02$); they were also used more often in long occlusions and lesions involving both the CIA and the EIA ($p = .01$). In particular, for long occlusions a CS was preferred, because it allows flow restoration creating a new endo-conduit from healthy to healthy vessels (from the aorta to the femoral artery), mimicking the concept of the traditional aorto-bifemoral bypass. This technical choice is corroborated by the excellent results obtained by Psacharopulo et al.,[12] which demonstrated similar 2 year primary patency using this approach compared with standard open repair (91% vs. 95%).

Interestingly, the estimates of primary patency stratified by anatomical factors demonstrate that the use of CSs was superior to BMSs in the presence of IAO calcification at the level of the occlusion $>$ 75% (unmatched, $p = .03$; matched, $p = .01$), total lesion length of $>$ 6 cm (unmatched, $p = .02$; matched, $p = .04$), and occlusion length longer that 3.5 cm (unmatched, $p = .01$; matched, $p = .04$).

It is believed that the identification of these parameter cutoffs may be useful to the operator when deciding between CS and BMS at the time of endovascular planning.

Another crucial point during endovascular IAO treatment is the risk of rupture. In this series it occurred in five cases (3.9% of IAOs). Even if rare and easy to resolve, this complication is feared because it may cause acute bleeding with severe hypotension, it may be difficult to identify at the final angiogram, or delayed rupture may occur;[13,14] and in this scenario heavily calcified lesions are considered a major risk factor.[14]

In cases of heavy IAO calcification associated with subintimal recanalisation, CSs are used in order to abolish the risk of possible related complications.

Obviously the policy is to attempt endoluminal crossing of the lesion first; this was impossible in about 27% of cases where a CS was implanted and in 10% of cases with a BMS ($p = .02$), thus subintimal recanalisation was needed. The higher number of subintimal recanalisation in the CS group is related to the fact that the more complex and longest lesions are more often treated with CSs. In case of subintimal recanalisation, an antegrade approach is preferred (either from the contralateral common femoral or left brachial artery) to reduce the possible retrograde aortic dissection where re-entry is not possible; in addition, there is greater pushability of the entire system and easier control of the guidewire. By adopting this strategy, a high rate of technical success (98%) has been achieved.

The study has some limitations that are worthy of mention. This was a retrospective, non-randomised study with a medium term follow-up; the limited number of patients may affect the power of statistical analysis especially in subgroup comparisons. The choice between a CS or a BMS was left to the discretion of the surgeon treating the patient; furthermore, the type of stent used was influenced by anatomical factors such as lesion length, severity, and quality, thus leading to inherent biases. However, these limitations were reduced as much as possible, using the propensity matched cohort comparison between CS and BMS. The prospective data collection allowed reliable information regarding follow-up outcomes. Finally, all the stents used were self expanding, thus limiting the biases related to technical characteristics of the stents.

CONCLUSIONS

Even if further confirmatory studies are needed, both CSs and BMSs provide excellent early and midterm results in the endovascular treatment of IAOs.

CSs seem to show higher midterm patency rates than BMSs in cases of TASC D lesions, IAOs with a total lesion length > 6 cm, occlusion length > 3.5 cm, and calcifications involving $> 75\%$ of the arterial wall circumference.

These specific anatomical parameters may be useful to the operator when deciding between CS and BMS during endovascular planning.

CONFLICT OF INTEREST

None.

FUNDING

None.

REFERENCES

1 Leville CD, Kashyap VS, Clair DG, Bena JF, Lyden SP, Greenberg RK, et al. Endovascular management of iliac artery occlusions: extending treatment to TransAtlantic Inter-Society Consensus class C and D patients. *J Vasc Surg* 2006;**43**(1): 32—9.
2 Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG. TASC II Working Group. Inter-society consensus for the management of peripheral arterial disease (TASC II). *J Vasc Surg* 2007;**45**(Suppl. S):S5—67.
3 Chen BL, Holt HR, Day JD, Stout CL, Stokes GK, Panneton JM. Subintimal angioplasty of chronic total occlusion in iliac arteries: a safe and durable option. *J Vasc Surg* 2011;**53**(2):367—73.
4 Uher P, Nyman U, Lindh M, Lindblad B, Ivancev K. Long-term results of stenting for chronic iliac artery occlusion. *J Endovasc Ther* 2002;**9**(1):67—75.
5 Araki M, Hirano K, Nakano M, Ito Y, Ishimori H, Yamawaki M, et al. Two-year outcome of the self-expandable stent for chronic total occlusion of the iliac artery. *Cardiovasc Interv Ther* 2014;**29**(1):40—6.
6 Mwipatayi BP, Thomas S, Wong J, Temple SE, Vijayan V, Jackson M, et al. A comparison of covered vs. bare expandable stents for the treatment of aortoiliac occlusive disease. *J Vasc Surg* 2011;**54**(6):1561—70.
7 Mwipatayi BP, Sharma S, Daneshmand A, Thomas SD, Vijayan V, Altaf N, et al. Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease. *J Vasc Surg* 2016;**64**(1). 83—94.e1.
8 Piazza M, Squizzato F, Spolverato G, Milan L, Bonvini S, Menegolo M, et al. Outcomes of polytetrafluoroethylene-covered stent versus bare-metal stent in the primary treatment of severe iliac artery obstructive lesions. *J Vasc Surg* 2015;**62**(5). 1210—1218.e1.
9 Rutherford RB, Baker JD, Ernst C, Johnston KW, Porter JM, Ahn S, et al. Recommended standards for reports dealing with lower extremity ischemia: revised version. *J Vasc Surg* 1997;**26**: 517—38.
10 Aho PS, Venermo M. Hybrid procedures as a novel technique in the treatment of critical limb ischemia. *Scand J Surg* 2012;**101**(2):107—13.
11 Pulli R, Dorigo W, Fargion A, Innocenti AA, Pratesi G, Marek J, et al. Early and long-term comparison of endovascular treatment of iliac artery occlusions and stenosis. *J Vasc Surg* 2011;**53**(1):92—8.
12 Psacharopulo D, Ferrero E, Ferri M, Viazzo A, Singh Bahia S, Trucco A, et al. Increasing efficacy of endovascular recanalization with covered stent graft for TransAtlantic Inter-Society Consensus II D aortoiliac complex occlusion. *J Vasc Surg* 2015;**62**(5):1219—26.
13 Sobrinho G, Albino JP. Delayed rupture of the external iliac artery after balloon angioplasty and stent placement. *J Vasc Interv Radiol* 2008;**19**(3):460—2.
14 Allaire E, Melliere D, Poussier B, Kobeiter H, Desgranges P, Becquemin JP. Iliac artery rupture during balloon dilatation: what treatment? *Ann Vasc Surg* 2003;**17**(3):306—14.