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Peripheral Arterial Occlusive Disease

Real-World Comparison of Drug-Eluting and Bare-Metal Stents in Superficial Femoral Artery Occlusive Disease with Trans-Atlantic Intersociety Consensus B Lesions: A 2-Year, Single-Institute Study

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Background: Endovascular stenting has surpassed bypass surgery to become the first-line treatment for superficial femoral artery (SFA) occlusive disease, and various types of stents including bare-metal stents (BMSs), covered stents, and drug-eluting stents (DESs), have been approved for treatment. This retrospective, single-institute study compared the short-term, real-world outcomes of BMSs and DESs for treating SFA occlusive disease.

Methods: A retrospective chart review was used to enroll 94 patients who received a DES (n = 24) or BMS (n = 70) between 2009 and 2014. All patients had SFA occlusive disease with critical limb ischemia and an intermediate length of SFA occlusion [Trans-Atlantic Intersociety Consensus (TASC)-II B lesions] and were regularly followed for 2 years. All patient characteristics, procedural details, and outcomes were recorded.

Result: The 1-year primary patency rates in the BMS and DES groups were 71.4% and 87.5% (p = 0.169), respectively, and the corresponding 2-year rates were 61.4% and 79.2% (p = 0.139). The target lesion revascularization rate was 38.6% versus 20.8% (p = 0.139), the in-stent restenosis rate was 22.9% versus 0% (p = 0.009), the major limb amputation rate was 4.3% versus 0% (p = 0.568), the peripheral arterial disease-related mortality rate was 8.6% versus 0% (p = 0.332), and the all-cause mortality rate was 11.4% versus 0% (p = 0.109), respectively.

Conclusions: The 2-year results revealed higher safety, superior efficacy, and greater clinical benefits of DESs than BMSs for treating TASC-II B SFA occlusive disease. However, more cases and long-term follow-up are warranted.

Key Words: Bare-metal stent • Drug-eluting stent • Superficial femoral artery • Trans-Atlantic Intersociety Consensus (TASC)-II B superficial femoral artery lesion

INTRODUCTION

Current interventional options for superficial femoral artery (SFA) occlusive disease include bypass surgery and endovascular therapies such as percutaneous transluminal angioplasty (PTA) and self-expanding metallic stent implantation. Traditional bypass surgery yields durable outcomes but is associated with increased morbidity and prolonged recovery compared with less-invasive endovascular therapies.[1] Hence, in recent decades, endovascular therapies have surpassed traditional bypass surgery to become the treatment of choice for SFA occlusive disease. Randomized trials, including the ABSOLUTE,[2] RESILIENT,[3] and Zilver PTX trials,[1] have reported that primary SFA stent implantation is more favorable than PTA for treating longer lesions.[4] The Zilver PTX stent, which is composed of a self-expanding, flexible nitinol

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stent platform with a 3-mg/mm^2 polymer-free coating of paclitaxel on its outer surface, is the only drug-eluting stent (DES) approved by the Food and Drug Administration for treating SFA occlusive disease.[1,4] In the propensity-matched cohort study of Taiwan beneficiaries with CAD, the implantation of DES during the coronary intervention was related to better outcomes than BMS, in terms of reducing MI and mortality after PCI. The survival benefits of DES were even greater for patients with stable CAD compared to BMS.[5] However, few current studies have conducted direct real-world comparisons between primary DESs and bare-metal stents (BMSs) for SFA occlusive disease. Therefore, we conducted this retrospective, single-institute study in Taiwan to compare the real-world short-term outcomes of primary DESs and BMSs for treating SFA occlusive disease with TransAtlantic Intersociety Consensus (TASC)-II B lesions.

MATERIALS AND METHODS

We used a retrospective chart review to enroll 94 patients who received a DES (n = 24) or BMS (n = 70) between July 2009 and December 2014. This study was approved by the Institutional Review Board of our institute. All patient characteristics, procedural details, and outcomes were recorded. Patients who had SFA occlusive disease with TASC-II B lesions and were indicated to receive endovascular revascularization for severe intermittent claudication and critical limb ischemia including resting pain and non-healing foot ulcers were included. Those lost to follow-up for 2 years were excluded.

Zilver PTX (CooK Medical Inc., Bloomington) was used as the DES, and LifeStent (BARD Peripheral Vascular Inc., Tempe, Arizona), EverFlex stent (EV3 Inc., Polymouth, Minnesota), and Zilver Flex (CooK Medical Inc., Bloomington) were used as the BMSs. Each surgeon followed his own preference regarding which type of BMS to use. The routine procedure started from a contralateral retrograde or ipsilateral antegrade femoral puncture, according to the patients' anatomy and lesion site. In most cases, the wire could be antegradely passed through the occluded segment of the SFA by either using the complete true lumen or subintimal approach. If the antegrade approach failed, a retrograde puncture was performed either via the distal femoropopliteal or below-the-knee (BTK) arteries to facilitate wiring through the occlusive lesions. Predilatation was always performed using a 3-4-mm diameter balloon before stenting. Similarly, postdilatation was always performed using a compliant balloon with either the same diameter or 1 mm less than the implanted stent diameter. BTK angioplasty was also performed if required. After completion of the angiography, the access sheath was removed and the punctured arteriotomy was manually compressed or repaired using a vascular closure device.

Rutherford classification and the ankle brachial index (ABI) were assessed preoperatively and postoperatively. Contrast computed tomography angiography (CTA) of the lower limbs was performed preoperatively in patients without renal function impairment, and non-contrast magnetic resonance angiography (MRA) of the lower limbs was performed preoperatively in patients with renal function impairment. The size of the SFA stent was determined from the preoperative measurement obtained through CTA or MRA. Postoperative routine follow-up included ABI and either CTA or MRA at 6, 12, and 24 months. The patency of the SFA stent was determined in cases of less than 50% stenosis. Target lesion revascularization (TLR) was performed if clinical symptoms or critical stenosis were present.

Continuous variables are summarized as the mean ± standard deviation, with p values calculated using the Mann-Whitney test (Wilcoxon test). Dichotomous and polytomous variables are reported as frequencies and percentages, with p values calculated using Fisher's exact test. Results with $p < 0.05$ were considered to be significant. Survival curves were estimated using the Kaplan-Meier method to assess the patency over time; p values were calculated using the log-rank test. All statistical analyses were performed using SPSS (Version 22; IBM).

RESULTS

The characteristics, procedural details, and outcomes of all patients enrolled in this 2-year follow-up study are shown in Tables 1, 2, and 3, respectively. No significant differences were observed in the demographic characteristics of the two groups except for the preoperative ABI, which was significantly lower in the DES group than in the BMS group (p = 0.026). The mean lesion lengths were

Table 1. Demographic characteristics

Demographic characteristics	BMS	DES	p value
Patients	70	24	
Men	52 (74.3%)	19 (79.2%)	0.786
Mean age (yrs)	70.86 ± 8.8	70.92 ± 7.28	0.945
Body mass index (kg/m^2)	24.59 ± 3.6	24.18 ± 2.16	0.866
Claudication (Rutherford class 2 or 3)	2 (2.9%)	4 (16.7%)	
Critical limb ischemia (Rutherford classes 4-6)	68 (97.1%)	20 (83.3%)	0.231
Smoking	39 (55.7%)	16 (66.7%)	0.472
Hypertension	31 (44.3%)	13 (54.2%)	0.48
Diabetes mellitus	46 (65.7%)	17 (70.8%)	0.8
Hyperlipidemia	26 (37.1%)	11 (45.8%)	0.476
Carotid stenosis > 75%	13 (18.6%)	7 (29.2%)	0.385
Chronic obstructive pulmonary disease	21 (30%)	9 (37.5%)	0.613
Old cerebrovascular accident	18 (25.7%)	2 (8.3%)	0.088
Coronary artery disease	33 (47.1%)	14 (58.3%)	0.478
Hemodialysis	18 (25.7%)	7 (29.2%)	0.79
Gastroduodenal ulcer	13 (18.6%)	4 (16.7%)	> 0.99
Preop ABI	0.627 ± 0.06	0.579 ± 0.09	0.026*

Values are n (%) or mean ± SD. * Statistically significant.
ABI, ankle brachial index; BMS, bare metal stent; DES, drug-eluting stent.

Table 2. Procedure characteristics

Procedure characteristics	BMS	DES	p value
Lesion length	10.79 ± 2.66	10.54 ± 1.62	0.93
Retrograde	10 (14.3%)	3 (12.5%)	> 0.99
Crossover	49 (70%)	17 (70.8%)	> 0.99
Number of stent	1.03 ± 0.17	1.08 ± 0.28	0.269
Size of stent	6.09 ± 0.28	6 ± 0	0.332
Technical success	100%	100%	1
Number of distal runoff	2.26 ± 0.67	2.13 ± 0.68	0.398
BTK intervention	30 (42.9%)	18 (75%)	0.009*
Complications	4 (5.7%)	3 (12.5%)	0.366
Contrast amount	46.01 ± 24.3	45.29 ± 22.6	0.712

Values are n (%) or mean ± SD. * Statistically significant.
BMS, bare metal stent; BTK, below the knee; DES, drug-eluting stent.

Table 3. Outcome characteristics

Outcome characteristics	BMS	DES	p value
Deaths	8 (11.4%)	0 (0%)	0.109
PAD related death	6 (8.6%)	0 (0%)	0.332
Major amputation	3 (4.3%)	0 (0%)	0.568
AMI	1 (1.4%)	1 (4.2%)	0.447
Stroke	1 (1.4%)	1 (4.2%)	0.447
New HD	9 (12.9%)	0 (0%)	0.106
TLR	27 (38.6%)	5 (20.8%)	0.139
Time to free from TLR	18.83 ± 7.26	22.04 ± 4.48	0.06
12 month ABI	0.895 ± 0.25	0.959 ± 0.1	0.493
24 month ABI	0.861 ± 0.31	0.979 ± 0.05	0.249
12 month primary patency	50 (71.4%)	21 (87.5%)	0.169
12 month secondary patency	66 (94.3%)	24 (100%)	0.569
24 month primary patency	43 (61.4%)	19 (79.2%)	0.139
24 month secondary patency	61 (87.1%)	24 (100%)	0.106
Stent fracture	8 (11.4%)	0 (0%)	0.109
ISR	16 (22.9%)	0 (0%)	0.009*

Values are n (%) or mean ± SD. * Statistically significant.
ABI, ankle brachial index; AMI, acute myocardial infarction; BMS, bare metal stent; DES, drug-eluting stent; HD, hemodialysis; ISR, in-stent restenosis; TLR, target lesion revascularization.

10.79 ± 2.66 and 10.54 ± 1.62 cm in the BMS and DES groups, respectively, with no significant difference between them. In addition, for most patients in the DES group, only one stent was used during the operation. However, the number of stents used did not differ significantly between the two groups (p = 0.269).

Safety

The 2-year TLR rate in the DES group was lower than that in the BMS group (20.8% versus 38.6%); however, the difference was non-significant (p = 0.139). The freedom from TLR rate was 18.83 ± 7.26 months in the BMS group and 22.04 ± 4.48 months in the DES group, also

with no significant difference (p = 0.06). No patient deaths, major amputations, or new hemodialysis (HD) occurred in the DES group. The 2-year all-cause mortality rate was 11.4% (n = 8) in the BMS group, and there was no significant difference in overall mortality rate between the two groups (p = 0.109). Peripheral arterial disease-related deaths (8.6%), major amputations (4.3%), and new HD (12.9%) occurred in the BMS group, but there were no significant differences between the two groups. Over the 2-year study period, stroke and acute myocardial infarction were rare in both groups.

Patency

Compared with the BMP group, the DES group exhibited higher rates of 1-year primary patency (87.5% versus 71.4%; p = 0.169), 2-year primary patency (79.2% versus 61.4%; p = 0.139), 1-year secondary patency (100% versus 94.3%; p = 0.569), and 2-year secondary patency (100% versus 87.1%; p = 0.106), although the differences were non-significant. There was neither stent fracture nor in-stent restenosis (ISR) in the DES group, although five cases of in-stent thrombosis were found during follow-up thus resulting in further revascularization interventions. In comparison, both stent fracture (11.4%) and ISR (22.9%) occurred in the BMS group. The difference between the two groups was non-significant for stent fracture (p = 0.109) but significant for ISR (p = 0.009).

Covariates

Covariates for TLR and patency were analyzed. Smoking was the only significant factor in the TLR analysis;[1] however, the TLR rates showed no significant variations in the BMS and DES groups or in all patients who had never smoked compared with those who still smoked. Litsky et al.[4] reported that diabetes mellitus was an independent predictor of decreased long-term patency in SFA interventions. However, in our study, 1- and 2-year primary patency rates did not vary significantly in the BMS or DES group or in all patients with a history of diabetes mellitus compared with those without diabetes mellitus.

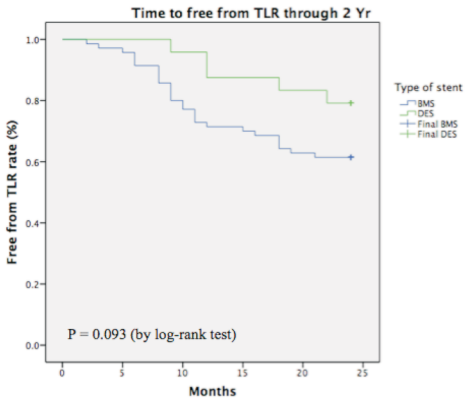
Clinical benefit

There were no significant differences between the two groups in Kaplan-Meier curves of being free from TLR (Figure 1) and primary patency rate (Figure 2). A significant improvement was observed in the preoperative and 1- and 2-year postoperative ABI in both groups (p < 0.0001).

DISCUSSION

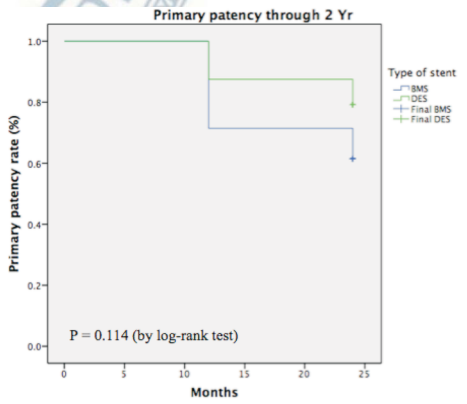
Patency

Zilver PTX is a recently developed DES used to treat



Months post-procedure	Freedom from TLR estimate (%) ± standard error (%)		Cumulative number censored		Patients remaining at risk	
	BMS	DES	BMS	DES	BMS	DES
6	91.4 ± 3.3	100.0 ± 0.0	6	0	64	24
12	71.4 ± 5.4	87.5 ± 6.8	20	3	50	21
24	61.4 ± 5.8	79.2 ± 8.3	27	5	43	19

Figure 1. *Kaplan-Meier curve of free from TLR between two groups. BMS, bare metal stent; DES, drug eluting stent; TLR, target lesion revascularization.*



Months post-procedure	Primary patency estimate (%) ± standard error (%)		Cumulative number censored		Patients remaining at risk	
	BMS	DES	BMS	DES	BMS	DES
6	100.0 ± 0.0	100.0 ± 0.0	0	0	70	24
12	71.4 ± 5.4	87.5 ± 6.8	20	3	50	21
24	61.4 ± 5.8	79.2 ± 8.3	27	5	43	19

Figure 2. *Kaplan-Meier curve of primary patency rate between two groups. BMS, bare metal stent; DES, drug eluting stent.*

SFA lesions in which long-term patency is the main challenge. Dake et al. reported significantly higher 2-year and 5-year primary patency rates in a provisional DES group (83.4% and 72.4%, respectively) than in a provisional BMS group (64.1%, $p < 0.01$; 53.0%, log-rank $p = 0.03$, respectively).[1,6] A similar result was obtained in our study, however the difference was non-significant ($p = 0.139$). This difference maybe due to the smaller number of cases in our study. In addition, the preoperative ABI was significantly lower in the DES group ($p = 0.026$), which may also explain our results. Iida et al. reported 1-year real-world outcomes after DES placement for femoropopliteal lesions with a patency rate of 63%,[7] which was lower than that reported by Dake et al.;[1] this discrepancy maybe due to the severity of the conditions reported by Iida et al., who classified 58% of the lesions as TASC-II C and D lesions,[7] reflecting a real-world setting, which may have yielded a lower patency rate. Fanelli et al. reported 1-year primary patency rates of 86.6% and 85.4% for DESs in patients with and without diabetes, respectively (log-rank, $p = 0.55$).[8] Our study yielded a similar result. Zeller et al. reported a Kaplan-Meier estimate of 78.8% for 1-year primary patency for SFA ISR lesions after DES placement,[9] and Yokoi et al. reported a primary patency rate of 86.4% under identical conditions.[10] Our results after DES placement were similar.

Target lesion revascularization

Dake et al. reported that the 2-year freedom from TLR rate with primary DES placement was 86.6% in a randomized trial.[1] In addition, they reported 5-year freedom from TLR rates of 84.9% and 71.6% after provisional DES and BMS placement, respectively (log-rank, $p = 0.06$).[6] These values are higher than those obtained in our study. Fanelli et al. reported that the 1-year freedom from TLR rates for DES were 90.6% and 85.4% in diabetic and non-diabetic groups, respectively (log-rank, $p = 0.71$).[8] Our study yielded a similar result (87.5%). In addition, Zeller et al. reported that the Kaplan-Meier estimate of freedom from TLR rates for SFA ISR lesions after DES placement were 81.0% and 60.8% after 12 and 24 months, respectively.[9] Moreover, in the study by Yokoi et al., the 12-month Kaplan-Meier estimate of the freedom from TLR rate was 91.0% after DES placement.[9]

Amputation and overall mortality

Dake et al. reported no device-related deaths, and 2-year mortality rates of 3.4% and 7.6% in PTA and primary DES groups, respectively. These rates did not differ significantly between the two groups ($p = 0.12$).[1] In another study conducted by the same group in the following year, the 5-year all-cause mortality rate was 13.6% (primary DES group, 10.2% and PTA group, 16.9%; $p = 0.03$), with no procedural or device-related deaths.[6] In the second study by Dake et al.,[6] the 5-year mortality rate for the primary DES group was significantly lower. The overall mortality rate in the DES group in our study was lower than that reported by Dake et al.,[1] despite the higher number of cases with Rutherford class 4 to 6 in our study. Incontrast, Dake et al. reported a 2-year amputation rate of less than 1%,[1] whichis similar to the results obtained in our study. Zeller et al. reported neither deaths nor amputations for SFA ISR lesions after DES placement,[9] and Yokoi et al. reported a 1-year all-cause mortality rate of 5.1% and amputation rate of 0.8% after DES placement.[10] These results may be because of the longer mean lesion length and more TASC-II C and D lesions in the study by Yokoi et al. compared with our study.

In-stent restenosis

Because the number of people with SFA stenting is increasing, managing the incidence rate of ISR is increasingly challenging. Dake et al. reported a 2-year ISR rate of 13.2% after primary DES placement.[1] Incontrast, Zeller et al. reported an ISR rate of 19% to 37% for SFA lesions treated with BMSs within 1 year postoperatively, and that the risk of ISR increased with a longer lesion length.[9] The mean lesion length in our study was longer than that previously reported (10.54 versus 6.32 cm);[1] however, the ISR rate was lower in our study. Consequently, DESs may be used to prevent and treat SFA ISR. Zeller et al. also confirmed that the treatment of SFA ISR with DESs yielded favorable acute, mid-term, and long-term outcomes.[9] In addition, Iida et al. and Yokoi et al. reported 1-year ISR rates of 15% and 18.6%, respectively, in their DES groups,[7,10] and these differences maybe due to the longer mean lesion lengths observed in those studies (17 ± 10 and 14.7 ± 9.7 cm, respectively). Yeh et al. reported the mean neointimal thickness was significantly reduced in the DES group compared to the BMS group in porcine coro-

nary artery disease.[11] It may be the histological reason why DES groups have lower ISR rates.

Stent fracture

Dake et al.[1] reported a 5-year overall DES fracture rate of 1.9%,[6] and Zeller et al. reported a 1-year stent fracture rate of DESs used for treating ISR lesions of 1.2%.[9] In addition, Yokoi et al. reported a 1-year stent fracture rate of 1.5% in their DES group.[10] These results are similar to that reported in our study.

Endovascular treatment is the gold standard for treating the SFA of TASC-II A (< 5 cm) and B (5 to 15 cm) lesions[12] because it is less invasive and has lower complication rates than surgical revascularization. Endovascular interventions have shown a high recurrence of restenosis in treating the SFA of TASC-II C (> 15 cm) and D (> 20 cm) lesions.[12] Previous prospective and retrospective studies, including those by Dake et al.,[1] Dick et al.,[13] Krankenberg et al.,[14] Duda et al.,[15] and Fanelli et al.,[8] have mostly reported results for TASC-II A and B lesions. In addition, the mean lesion length in our study was typically longer than those in the previous studies. However, the use of DESs for longer lesions (TASC-II C and D lesions) has not yielded desirable long-term results, and no thorough prospective studies have been conducted.[4] Therefore, we selected the SFA of TASC-II B lesions in our study. Additional prospective studies on the use of DESs for longer lesions (TASC-II C or D lesions) are warranted.

In the present study, a similar improvement ($p < 0.0001$) was observed in the preoperative and 2-year postoperative ABI in both DES and BMS groups. However, these clinical outcomes were obtained from patients who underwent TLR, and more frequent TLR was required in the BMS group than in the DES group to achieve similar outcomes. A 2-year, randomized, single-arm study did not report any adverse events caused by the paclitaxel coating on the DES.[1] Similarly, no adverse effects or reactions associated with this coating were observed throughout our study.

Limitations

First, this study was a retrospective analysis with a relatively low number of cases with DESs and BMSs, which may have influenced the interpretation of the results. In addition, a larger sample is required in order to assess the effectiveness of DESs and BMSs in actual clinical practice. Second, the current study included only Taiwanese patients, and the results should be confirmed in patients of other ethnicities. Third, the walking impairment questionnaire score, a tool to evaluate the effects of revascularization, was not used in our study and may be used in the future to further evaluate the clinical benefits of using DESs and BMSs. Forth, neutrophil-to-lymphocyte ratio (NLR) is an important prognostic predictor of all major clinical outcomes, including all-cause mortality or major amputation, in patients with advanced CKD and PAD receiving PTA.[16] Therefore, NLR also may be used as risk factor in further studies.

CONCLUSIONS

Our 2-year real-world outcomes showed higher safety, superior efficacy, and greater clinical benefits of DESs than BMSs for treating TASC-II B SFA occlusive disease. A lower overall mortality rate, a longer time to recovery rate of TLR, a significantly lower ISR, and higher 2-year primary and secondary patency rates were observed in the DES group than in the BMS group. However, further studies with a larger sample and long-term follow-up are warranted.

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None.

DISCLOSURES

The authors declare that there are no conflicts of interest.

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