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Comparative Real-World Outcomes of LifeStream and Viabahn VBX Balloon-Expandable Covered Stents for Iliac Artery Occlusive Disease

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Abstract

Purpose

Balloon-expandable covered stents (CSs) are increasingly used for complex iliac artery occlusive disease, but direct comparative data among CS platforms remain limited. This study compared 1-year restenosis and clinical outcomes between the LifeStream and Viabahn VBX CSs in patients undergoing endovascular treatment (EVT).

Methods

This multicenter retrospective study included 226 patients who underwent EVT for symptomatic iliac artery occlusive disease using either the LifeStream CS (n = 95) or Viabahn VBX CS (n = 131). Outcomes included restenosis, clinically driven target lesion revascularization (CD-TLR), re-occlusion, conversion to bypass surgery, and perioperative complications (POCs). Between-group comparisons were performed using inverse probability of treatment weighting (IPTW) based on propensity scores. Exploratory interaction analyses assessed whether selected clinical, lesion, or procedural characteristics modified the association between CS type and restenosis.

Results

One-year follow-up data were available for 163 of 226 patients (72.1%), and 10 restenosis events occurred during follow-up. After IPTW adjustment, the balance of measured covariates was substantially improved. The estimated 1-year freedom from restenosis was 97.7% (95% confidence interval [CI], 94.9–100.0%) in the LifeStream group and 95.5% (95% CI, 91.9–99.3%) in the Viabahn VBX group, with no statistically significant between-group difference ($p = 0.78$). No significant differences were detected in freedom from CD-TLR (99.2% [95% CI, 97.7–100.0%] vs. 96.1% [95% CI, 92.6–99.7%]; $p = 0.48$), re-occlusion (100.0% [95% CI, 100.0–100.0%] vs. 97.8% [95% CI, 95.1–100.0%]; $p = 0.30$), conversion to bypass surgery (100.0% [95% CI, 100.0–100.0%] vs. 98.2% [95% CI, 96.1–100.0%]; $p = 0.40$), or POCs. No statistically significant interaction was observed for any evaluated characteristic (all p values for interaction > 0.05).

Conclusion

In this IPTW-adjusted multicenter retrospective study, no statistically significant differences in 1-year restenosis or other clinical outcomes were detected between the LifeStream and Viabahn VBX balloon-expandable CSs. These findings should be considered hypothesis-generating because of the small number of events, incomplete follow-up, and potential residual confounding.

Introduction

Iliac artery occlusive disease is a common manifestation of symptomatic peripheral artery disease (PAD) and is increasingly treated using endovascular approaches. Although endovascular treatment (EVT) generally provides favorable technical and clinical outcomes, maintaining durable patency remains challenging in complex iliac

lesions. Long lesions, chronic total occlusion (CTO), severe calcification, and aortoiliac bifurcation involvement may increase the risks of elastic recoil, flow-limiting dissection, incomplete stent expansion, and restenosis [1–3]. Accordingly, optimal lesion coverage, adequate radial support, and precise stent deployment are particularly important in these anatomically complex settings.

Balloon-expandable covered stents (CSs) are increasingly used for the treatment of iliac artery occlusive disease because they combine the deployment accuracy and radial strength of balloon-expandable stents with a covered design that may reduce neointimal tissue ingrowth and seal arterial injury [4–7]. However, several balloon-expandable CS platforms are available, and device selection in routine practice is generally based on lesion anatomy, procedural findings, device characteristics, availability, and operator or institutional preference. Operators must consider factors such as deliverability, deployment precision, radial strength, conformability, available device sizes, and the need for treatment of bifurcation or multisegment disease.

The LifeStream and Viabahn VBX stent grafts are widely used balloon-expandable CS platforms for symptomatic iliac artery occlusive disease. Although both devices have demonstrated favorable clinical outcomes, direct comparative evidence remains limited. Moreover, differences in patient characteristics, lesion complexity, procedural strategies, and the use of adjunctive imaging or concomitant bare-nitinol stents (BNSs) may influence device selection and clinical outcomes in real-world practice. It therefore remains uncertain whether either platform is associated with different effectiveness or safety outcomes or whether the treatment effect varies across clinically relevant patient and lesion subgroups. We therefore conducted an inverse probability of treatment weighting (IPTW)-adjusted, multicenter retrospective study to compare the 1-year effectiveness and safety outcomes of LifeStream and Viabahn VBX implantation in patients undergoing EVT for symptomatic iliac artery occlusive disease. We also performed exploratory subgroup analyses to evaluate whether the association between CS type and restenosis differed according to selected clinical, lesion, and procedural characteristics.

Materials and methods

Study population

This retrospective multicenter study included consecutive patients with symptomatic lower-extremity PAD classified as Rutherford categories 2–6 who underwent EVT for iliac artery occlusive disease using a balloon-expandable CS between January 2020 and April 2025. Eligible lesions were de novo or restenotic occlusive lesions involving the common and/or external iliac artery. Patients scheduled for bypass surgery and/or major amputation at treatment planning were excluded. For patients with intermittent claudication, supervised exercise therapy and guideline-directed medical therapy were first initiated, and EVT was reserved for those with insufficient symptomatic improvement. Consecutive cases were reviewed from three Japanese cardiovascular centers. In total, 267 EVT procedures using the LifeStream CS or Viabahn VBX CS were identified. Procedures were excluded because of treatment of an aortic lesion (n = 34), concomitant use of both CS platforms in the same procedure (n = 3), or missing data required for the primary analysis (n = 5). To ensure a one-patient–one-treatment analysis, duplicate procedures were excluded, and each patient was counted once. The final cohort comprised 226 patients: 95 treated with LifeStream and 131 treated with Viabahn VBX. The study protocol was approved by the institutional ethics committee (approval no. 25052901) and was

conducted in accordance with the Declaration of Helsinki. Because of the retrospective design, written informed consent was waived.

Endovascular procedure and follow-up protocol

All patients received dual antiplatelet therapy for at least 2 days before EVT. In general, a 6- or 7-F sheath was inserted into the common femoral artery via an ipsilateral retrograde or contralateral crossover approach. After intra-arterial administration of 5,000 U of heparin, the lesion was crossed with a guidewire and predilated using an appropriately sized balloon. The distal reference vessel diameter was measured, and an appropriately sized balloon-expandable covered stent (CS) was deployed across the lesion. There were no prespecified or standardized criteria for CS selection, concomitant BNS implantation, or the number and configuration of stents. These decisions were made at the discretion of the treating operators according to lesion anatomy, procedural findings, and routine practice at each participating institution. Procedural details, including CS configuration, the numbers and dimensions of implanted CSs and BNSs, and the location of BNS implantation relative to the CS, were recorded and analyzed. Intravascular ultrasound (IVUS) was used at the operator's discretion as an adjunctive imaging modality. Follow-up was scheduled at 1 month and at least every 6 months thereafter and included clinical evaluation, ankle–brachial index measurement, and duplex ultrasonography. Repeat revascularization was performed when recurrent symptoms were accompanied by duplex ultrasonographic or angiographic evidence of restenosis [8].

Outcome measures and definitions

The primary outcome was freedom from loss of primary patency, defined as a peak systolic velocity ratio (PSVR) > 2.4 on DUS, corresponding to > 50% luminal narrowing [8]. Secondary outcomes included freedom from clinically driven target lesion revascularization (CD-TLR), re-occlusion, conversion to bypass surgery, and perioperative complications (POCs). Restenosis was defined as PSVR > 2.4 on DUS or > 50% diameter stenosis on angiography. CD-TLR was defined as repeat intervention for > 50% stenosis detected by DUS in the presence of recurrent clinical symptoms. POCs were defined as device- and/or procedure-related complications occurring within 30 days of the index EVT [9].

Statistical analysis

Data on baseline characteristics are presented as means ± standard deviation (SD) for continuous variables and frequencies (percentages) for categorical variables, if not otherwise stated. Intergroup differences in baseline characteristics were evaluated using the standardized difference. IPTW using the propensity score was performed to minimize intergroup differences in baseline characteristics for comparison of clinical outcomes between the two groups. The propensity score was developed using a logistic regression model for which the outcome variable was Lifestream versus Viabahn VBX use and the explanatory variables were: age, sex, smoking history, diabetes mellitus, renal failure on dialysis, medications, chronic limb-threatening ischemia (CLTI), ABI, bilateral iliac lesions, in-stent restenosis, severe calcification, CTO, reference vessel diameter, lesion length, IVUS use, BNS use, and femoral lesion. An absolute standardized difference < 0.18 was used to assess balance on baseline variables before and after IPTW [10]. For outcome analysis, IPTW was applied; in each model, the data for each patient was inversely weighted by the propensity score (for those receiving the

intervention of interest, i.e., LifeStream use) or 1 minus the propensity score (for the other intervention, i.e., Viabahn VBX stent use). The rates of freedom from time-to-event outcomes were estimated using the weighted Kaplan-Meier method. The intergroup difference in time-to-event outcomes was tested using the weighted log-rank test, whereas that in perioperative complication was tested using the conditional logistic regression model. A two-sided p value < 0.05 was considered to be significant. The interaction effect of baseline characteristics on the association between the stent type and restenosis risk were assessed using an IPTW-adjusted Cox proportional hazards regression model. All statistical analyses were performed with R ver. 4.1.1 (R Development Core Team, Vienna, Austria).

Results

Baseline clinical characteristics

Baseline clinical, lesion, and procedural characteristics before and after IPTW are summarized in Table 1. The study included 95 patients treated with the LifeStream CS and 131 treated with the Viabahn VBX CS. Before weighting, patients in the LifeStream group were slightly older (75 ± 9 vs. 73 ± 9 years) and more frequently had diabetes mellitus (52.6% vs. 42.0%), whereas the Viabahn VBX group included a higher proportion of men (71.8% vs. 60.0%). Compared with the LifeStream group, the Viabahn VBX group also had higher proportions of bilateral iliac lesions (47.3% vs. 30.5%) and chronic total occlusions (38.9% vs. 27.4%), longer lesions (100 ± 71 vs. 72 ± 64 mm), and more frequent IVUS use (96.9% vs. 69.5%). After IPTW, the balance of the measured clinical, lesion, and procedural characteristics was substantially improved, with all standardized differences below 18%. Modest residual imbalances remained in ABI, CTO, lesion length, and IVUS use, with standardized differences of 14.6%, 15.7%, 16.1%, and 17.9%, respectively.

Table 1
Baseline characteristics of the study population

	Overall population (before IPTW)			After IPTW		
	LifeStream	**Viabahn VBX**	**Standardized**	**LifeStream**	**Viabahn VBX**	**Standardized**
	(n = 95)	(n = 131)	difference (%)	(n = 95)	(n = 131)	difference (%)
Age (years)	75 ± 9	73 ± 9	18.7	74 ± 9	74 ± 8	1.5
Male sex	57 (60.0%)	94 (71.8%)	25.0	71.0%	70.4%	1.3
Smoking history	52 (54.7%)	81 (61.8%)	14.4	62.0%	58.7%	6.7
Diabetes mellitus	50 (52.6%)	55 (42.0%)	21.4	44.0%	46.9%	5.7
Renal failure on dialysis	24 (25.3%)	29 (22.1%)	7.4	22.8%	23.7%	2.2
DAPT	81 (85.3%)	105 (80.2%)	13.5	81.3%	79.0%	5.6
Cilostazol use	6 (6.3%)	12 (9.2%)	10.7	7.5%	9.7%	7.7
Anticoagulant use	15 (15.8%)	18 (13.7%)	5.8	16.5%	15.6%	2.6
Statin use	69 (72.6%)	87 (66.4%)	13.5	68.7%	66.9%	3.8
CLTI	22 (23.2%)	35 (26.7%)	8.2	25.3%	24.8%	1.1
Ankle-brachial index	0.50 ± 0.29	0.49 ± 0.29	3.4	0.52 ± 0.29	0.48 ± 0.30	14.6
Bilateral iliac lesion	29 (30.5%)	62 (47.3%)	35.0	40.1%	40.7%	1.3
In-stent restenosis	11 (11.6%)	17 (13.0%)	4.3	10.4%	13.0%	8.1
Severe calcification	42 (44.2%)	65 (49.6%)	10.9	52.1%	48.1%	7.9
Chronic total occlusion	26 (27.4%)	51 (38.9%)	24.7	30.5%	37.9%	15.7
Reference vessel	7.9 ± 0.9	8.0 ± 1.2	13.1	8.0 ± 1.0	8.0 ± 1.1	0.1

Data are expressed as mean ± SD or number (percentage).

Abbreviations: BNS, bare nitinol stent; CLTI, chronic limb-threatening ischemia; DAPT, dual antiplatelet therapy; IPTW, inverse probability of treatment weighting; IVUS, intravascular ultrasound.

	Overall population (before IPTW)			After IPTW		
	LifeStream	**Viabahn VBX**	**Standardized**	**LifeStream**	**Viabahn VBX**	**Standardized**
diameter (mm)						
Lesion length (mm)	72 ± 64	100 ± 71	41.2	80 ± 69	91 ± 66	16.1
IVUS use	66 (69.5%)	127 (96.9%)	79.0	85.9%	91.5%	17.9
BNS use	42 (44.2%)	46 (35.1%)	18.7	36.6%	37.1%	1.0
Femoral lesion	43 (45.3%)	57 (43.5%)	3.5	44.0%	43.1%	1.7

Data are expressed as mean ± SD or number (percentage).

Abbreviations: BNS, bare nitinol stent; CLTI, chronic limb-threatening ischemia; DAPT, dual antiplatelet therapy; IPTW, inverse probability of treatment weighting; IVUS, intravascular ultrasound.

Procedural characteristics after IPTW are summarized in Table 2. The distribution of CS configurations, including single, kissing, bilateral non-kissing, overlapping, and tandem stenting, did not differ significantly between the groups, with single stenting being the most frequently used strategy in both groups. The number of implanted CSs and mean CS diameter were also similar between the groups. However, the total CS length was shorter in the LifeStream group than in the Viabahn VBX group (55 ± 34 mm vs. 72 ± 39 mm; $p = 0.003$). Concomitant BNS implantation was performed in approximately one-third of patients in both groups (36.6% vs. 37.1%; $p = 0.95$). Among patients who received concomitant BNSs, no significant between-group differences were observed in the number, diameter, length, or location of the implanted BNSs. BNSs were most frequently implanted distal to the CS in both groups. Unilateral CS implantation with a single contralateral BNS alone was numerically more frequent in the LifeStream group, although the difference did not reach statistical significance (16.8% vs. 2.6%; $p = 0.065$).

Table 2
Procedural features after IPTW

CS placement	LifeStream group	Viabahn VBX group	P value
Single stenting	57.4%	54.2%	P = 0.72
Kissing stenting	23.0%	34.5%	P = 0.22
Bilateral non-kissing stenting	13.4%	9.5%	P = 0.49
Overlapping stenting.	11.3%	8.1%	P = 0.47
Tandem stenting	4.5%	0.6%	P = 0.10
Number of CS			P = 0.83
1 CS	57.9%	53.6%	
2 CS	29.3%	43.1%	
3 CS	12.8%	1.2%	
4 CS	0.0%	1.7%	
5 CS	0.0%	0.5%	
CS diameter, mm	7.5 ± 0.8	7.4 ± 0.7	P = 0.27
Total implanted CS length, mm	55 ± 34	72 ± 39	P = 0.003
Concomitant BNS use	36.6%	37.1%	P = 0.95
Number of BNS			P = 0.30
1 BNS	55.8%	59.2%	
2 BNS	30.1%	39.2%	
3 BNS	10.3%	0.0%	
4 BNS	3.8%	1.6%	
BNS diameter, mm	8.8 ± 1.3	8.6 ± 1.0	P = 0.55
Total implanted BNS length, mm	111 ± 71	101 ± 51	P = 0.50
BNS location			
Distal to CS	84.9%	90.1%	P = 0.50
Proximal to CS	17.8%	12.9%	P = 0.63
Unilateral CS with contralateral single BNS alone	16.8%	2.6%	P = 0.065
Data are expressed as mean ± SD or number (percentage).			
Abbreviations: BNS, bare nitinol stent; CS, covered stent; IPTW, inverse probability of treatment weighting.			

Clinical outcomes

Time-to-event outcomes are shown in Fig. 1. One-year clinical follow-up data were available for 163 of 226 patients (72.1%), and 10 restenosis events occurred. The estimated 1-year freedom from restenosis was 97.7% (95% confidence interval [CI], 94.9–100.0%) in the LifeStream group and 95.5% (95% CI, 91.9–99.3%) in the Viabahn VBX group, with no statistically significant between-group difference (p = 0.78) (Fig. 1A). No statistically significant between-group differences were detected in the other time-to-event outcomes. The estimated 1-year freedom from CD-TLR was 99.2% (95% CI, 97.7–100.0%) in the LifeStream group and 96.1% (95% CI, 92.6–99.7%) in the Viabahn VBX group (p = 0.48) (Fig. 1B). The estimated 1-year freedom from re-occlusion was 100.0% (95% CI, 100.0–100.0%) and 97.8% (95% CI, 95.1–100.0%), respectively (p = 0.30) (Fig. 1C). The corresponding freedom from conversion to bypass surgery was 100.0% (95% CI, 100.0–100.0%) and 98.2% (95% CI, 96.1–100.0%), respectively (p = 0.40) (Fig. 1D).

Details of POCs are shown in Table 3. After IPTW adjustment, POCs were infrequent and did not differ significantly between the LifeStream and Viabahn VBX groups (8.6% vs. 8.0%, p = 0.90). The distribution of specific complications was comparable: puncture-site complications occurred in 4.2% vs. 4.3%, wire perforation in 0.6% vs. 0.0%, stent-edge dissection in 2.9% vs. 1.6%, and stent dislodgement in 0.5% vs. 0.0% (LifeStream vs. Viabahn VBX group). Rare events occurred in only one group: distal embolization was observed exclusively in the Viabahn VBX group (0.0% vs. 2.1%), whereas retroperitoneal hemorrhage occurred only in the LifeStream group (0.4% vs. 0.0%).

Table 3
Perioperative complication after IPTW

Perioperative complication	**LifeStream group**	**Viabahn VBX group**	**P value**
	8.6%	**8.0%**	**P = 0.90**
Puncture site trouble	4.2%	4.3%	
Wire perforation	0.6%	0.0%	
Stent edge dissection	2.9%	1.6%	
Stent dislodgement	0.5%	0.0%	
Distal embolization	0.0%	2.1%	
Retroperitoneal hemorrhage	0.4%	0.0%	
Data are expressed as number (percentage).			
Abbreviations: IPTW, inverse probability of treatment weighting.			

Subgroup analysis

Exploratory subgroup analyses of restenosis are shown in Fig. 2. No statistically significant interaction was observed between covered-stent type and any of the evaluated clinical, lesion, or procedural characteristics (all p values for interaction > 0.05), including age ≥ 75 years, CLTI, severe calcification, chronic total occlusion, lesion length > 100 mm, bilateral iliac disease, IVUS use, and concomitant BNS use.

Discussion

The principal finding of this IPTW-adjusted multicenter retrospective study was that no statistically significant differences in 1-year restenosis or other clinical outcomes were detected between the LifeStream and Viabahn VBX balloon-expandable CSs in patients undergoing EVT for symptomatic iliac artery occlusive disease. The estimated rates of freedom from restenosis, CD-TLR, re-occlusion, conversion to surgical bypass, and POCs were favorable in both groups. Exploratory subgroup analyses did not identify significant treatment-effect modification by the evaluated clinical, lesion, or procedural characteristics. However, because the number of outcome events was small and 1-year follow-up was incomplete, these findings should not be interpreted as demonstrating equivalence between the two platforms. Rather, they provide hypothesis-generating comparative evidence regarding the short-term performance of these devices in contemporary real-world practice.

Iliac artery occlusive disease is a major manifestation of symptomatic peripheral artery disease, and EVT has become a cornerstone of contemporary management. Nevertheless, durable patency remains challenging in complex iliac lesions, particularly in the presence of long lesions, CTO, severe calcification, or bifurcation involvement, where elastic recoil, dissection, incomplete stent expansion, and inadequate lesion coverage may contribute to restenosis [1–3]. Balloon-expandable CSs are increasingly used to provide accurate deployment, radial support, and exclusion of diseased arterial segments [4–7]. However, selection among available CS platforms is commonly based on lesion anatomy, procedural findings, device characteristics, availability, and operator or institutional preference rather than robust comparative evidence. In this context, the present study provides multicenter real-world comparative data on the LifeStream and Viabahn VBX platforms.

The estimated 1-year freedom from restenosis exceeded 95% in both groups, and similarly high event-free rates were observed for the other time-to-event outcomes. These findings are broadly consistent with previous studies reporting favorable patency after balloon-expandable CS implantation and with contemporary recommendations supporting the use of CSs in selected aortoiliac interventions [11, 12]. Mechanistically, CSs may improve durability by excluding atherosclerotic plaque from the endoluminal surface and limiting tissue ingrowth through the stented segment [13]. The graft covering may also facilitate the treatment of vessel injury arising during lesion preparation or stent deployment. In the present cohort, no iliac artery rupture occurred, and POCs were infrequent. These outcomes were observed despite the inclusion of clinically and anatomically complex patients, including patients receiving maintenance hemodialysis, those with CLTI, and those with severely calcified or CTO lesions.

Although both devices incorporate stainless steel and polytetrafluoroethylene (PTFE), their structural designs differ. The LifeStream CS consists of a stainless-steel framework positioned between luminal and abluminal PTFE membranes, whereas the Viabahn VBX endoprosthesis consists of connected stainless-steel rings encapsulated in fluoropolymer and incorporates a heparin-bonded surface [14]. Bench testing has suggested that the LifeStream CS can accommodate overdilation but may demonstrate greater recoil, whereas the Viabahn VBX CS shows relatively limited recoil but may undergo longitudinal shortening when expanded beyond its nominal diameter [15]. Despite these structural differences, no significant between-device differences in clinical outcomes were detected in the present study. Careful vessel sizing, lesion preparation, deployment, and postdilation may mitigate potential platform-specific limitations; however, the limited number of events precludes determining whether specific technical characteristics influenced outcomes.

The small number of perioperative events also limited meaningful comparisons of individual complication types. Stent-edge dissection and stent dislodgement occurred more frequently in the LifeStream group, whereas distal embolization was observed only in the Viabahn VBX group. These observations should be interpreted cautiously and should not be considered evidence of device-specific safety differences. They may reflect differences in lesion anatomy, procedural strategy, operator technique, or device mechanics, and the study was not sufficiently powered to distinguish among these possibilities.

From a clinical perspective, an important question is whether specific patient or lesion characteristics should influence selection between these CS platforms. Exploratory interaction analyses did not identify a subgroup in which either platform was associated with a significantly different risk of restenosis. No significant interaction was observed according to advanced age, CLTI, severe calcification, CTO, longer lesion length, or concomitant BNS use. However, the small number of restenosis events resulted in imprecise subgroup estimates and wide CIs. Accordingly, the absence of statistically significant interaction should not be interpreted as demonstrating consistent equivalence across all subgroups or as excluding clinically relevant treatment-effect heterogeneity.

The present study also reflects the heterogeneity of procedural strategies encountered in routine practice. There were no prespecified or standardized criteria for CS selection, concomitant BNS implantation, or the number and configuration of implanted stents. These decisions were made by the treating operators according to lesion anatomy, procedural findings, and routine practice at each participating institution. After IPTW, the distributions of CS configurations, numbers of implanted CSs, concomitant BNS use, and BNS locations were generally similar between the groups, although the mean implanted CS length was greater in the Viabahn VBX group. Because the detailed rationale for each additional CS or BNS was not systematically recorded, the influence of individual technical decisions on clinical outcomes could not be determined. Unmeasured differences in operator judgment, institutional practice, and lesion complexity may therefore have contributed to treatment selection and outcomes.

A notable feature of this study was the high rate of IVUS use, particularly in the Viabahn VBX group. Although the study was not designed to evaluate the independent effect of IVUS, its frequent use may have contributed to procedural standardization and outcome optimization by providing information on vessel size, plaque distribution, calcification, reference segments, stent expansion, and apposition. IVUS may be particularly useful in iliac artery occlusive disease because angiography alone can underestimate vessel dimensions, calcification burden, and residual stent underexpansion. Therefore, the favorable outcomes observed in this study may partly reflect an IVUS-intensive practice environment and may not be directly generalizable to centers relying predominantly on angiographic guidance. Prospective studies are needed to determine whether IVUS-guided CS implantation improves patency or safety compared with angiography-guided treatment alone.

Study limitations

This study has several limitations. First, it was retrospective and nonrandomized, and device selection was determined by the treating operators rather than by random allocation. Although IPTW substantially improved the balance of measured covariates, modest residual imbalances remained in several clinical and procedural variables, and residual confounding from unmeasured factors cannot be excluded. In addition, potential center-level variation was not specifically modeled, and differences in institutional practice, operator experience, and device availability may have influenced treatment selection and outcomes. Second, aortic lesions were

excluded because the LifeStream CS was infrequently used in this setting and adequate covariate balance could not be achieved after IPTW. Therefore, the present findings may not be generalizable to extensive aortoiliac disease involving the abdominal aorta. Third, IVUS was used in a high proportion of procedures, particularly in the Viabahn VBX group. The favorable outcomes may therefore partly reflect an IVUS-intensive practice environment and may not be directly applicable to centers relying primarily on angiographic guidance. Fourth, clinical events were not adjudicated by an independent blinded clinical events committee. Fifth, although concomitant BNS use was included in the propensity-score model and was balanced after IPTW, the decisions regarding BNS implantation and the number, length, location, and configuration of CSs and BNSs were left to operator discretion. The detailed indications for each additional stent were not systematically recorded because of the retrospective study design. Consequently, residual confounding related to adjunctive stent implantation and procedural strategy cannot be excluded. Sixth, follow-up was limited to 1 year and was incomplete in a subset of patients, which may have introduced attrition bias and affected the estimated event rates. The follow-up period for some patients overlapped with the COVID-19 pandemic, during which restrictions on hospital visits and disruptions to routine clinical surveillance may have contributed to incomplete follow-up. However, the specific reasons for loss to follow-up were not systematically recorded, and the extent of the pandemic's influence could not be determined. Finally, the numbers of restenosis and POC events were small, resulting in limited statistical power and imprecise estimates, particularly in the subgroup and safety analyses. These findings should therefore be considered hypothesis-generating and require validation in adequately powered prospective studies with standardized procedural strategies and longer follow-up.

Conclusion

In this IPTW-adjusted multicenter retrospective cohort of patients undergoing EVT for symptomatic iliac artery occlusive disease, no statistically significant differences in 1-year restenosis or other clinical outcomes were detected between the LifeStream and Viabahn VBX balloon-expandable CSs. The estimated freedom from restenosis was high in both groups, and no significant between-group differences were observed in CD-TLR, re-occlusion, conversion to surgical bypass, or perioperative complications. However, these findings should be interpreted as hypothesis-generating because of the small number of events, incomplete follow-up, nonrandomized device selection, potential center-level variation, and residual confounding. Appropriate device selection, device-specific technical expertise, IVUS-guided optimization, and careful deployment may contribute to favorable outcomes in contemporary practice, but their independent effects require prospective evaluation.

Abbreviations

ABI
ankle–brachial index
BNS
bare nitinol stent
CD-TLR
clinically driven target lesion revascularization
CI
confidence interval
CLTI

chronic limb-threatening ischemia
CS
covered stent
CTO
chronic total occlusion
DUS
duplex ultrasonography
EVT
endovascular treatment
IPTW
inverse probability of treatment weighting
IVUS
Intravascular ultrasound
PAD
peripheral artery disease
POC
perioperative complication
PTFE
polytetrafluoroethylene
SD
standard deviation
PSVR
peak systolic velocity ratio

References

1. Mazzolai L, Teixido-Tura G, Lanzi S, Boc V, Bossone E, Brodmann M et al (2024) 2024 ESC guidelines for the management of peripheral arterial and aortic diseases. Eur Heart J 45:3538–3700
2. Yamauchi Y, Takahara M, Shintani Y, Iida O, Sugano T, Yamamoto Y et al (2019) One-year outcomes of endovascular therapy for aortoiliac lesions. Circ Cardiovasc Interv. ;12
3. Aihara H, Soga Y, Iida O, Suzuki K, Tazaki J, Shintani Y et al (2014) Long-term outcomes of endovascular therapy for aortoiliac bifurcation lesions in the REAL-AI registry. J Endovasc Ther 21:25–33
4. Laird JR, Zeller T, Holden A, Scheinert D, Moore E, Mendes R et al (2019) Balloon-expandable vascular covered stent in the treatment of iliac artery occlusive disease: 9-month results from the BOLSTER multicenter study. J Vasc Interv Radiol 30:836–844
5. Tomoi Y, Takahara M, Soga Y, Hata Y, Iida O, Yamaoka T et al (2023) Clinical outcome of endovascular therapy using a VIABAHN VBX-covered stent for complex aortoiliac artery disease: the AVOCADO II study. Heart Vessels 38:1288–1297
6. Deloose K, Gielis J, Maene L, Lansink W, Lerut P, Verbist J et al (2025) A Belgian physician-initiated trial investigating the LifeStream peripheral stent graft system for the treatment of complex TASC C and D iliac lesions. J Cardiovasc Surg (Torino) 66:37–45

7. Holden A, Takele E, Hill A, Sakhuja R, Metzger C, Gray BH et al (2025) Long-term follow-up of subjects with iliac occlusive disease treated with the Viabahn VBX balloon-expandable endoprosthesis. J Endovasc Ther 32:68–76
8. Patel MR, Conte MS, Cutlip DE, Dib N, Geraghty P, Gray W et al (2015) Evaluation and treatment of patients with lower extremity peripheral artery disease: consensus definitions from the Peripheral Academic Research Consortium (PARC). J Am Coll Cardiol 65:931–941
9. Stoner MC, Calligaro KD, Chaer RA, Dietzek AM, Farber A, Guzman RJ et al (2016) Reporting standards of the Society for Vascular Surgery for endovascular treatment of chronic lower extremity peripheral artery disease. J Vasc Surg ;64–e21
10. Austin PC (2009) Balance diagnostics for comparing the distribution of baseline covariates between treatment groups in propensity-score matched samples. Stat Med 28:3083–3107
11. Mwipatayi BP, Ouriel K, Anwari T, Wong J, Ducasse E, Panneton JM et al (2020) A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease. J Vasc Surg 72:1473–1486
12. Feldman DN, Armstrong EJ, Aronow HD, Banerjee S, Díaz-Sandoval LJ, Jaff MR et al (2020) SCAI guidelines on device selection in aorto-iliac arterial interventions. Catheter Cardiovasc Interv 96:915–929
13. Virmani R, Kolodgie FD, Dake MD, Silver JH, Jones RM, Jenkins M et al (1999) Histopathologic evaluation of an expanded polytetrafluoroethylene-nitinol stent endoprosthesis in canine iliofemoral arteries. J Vasc Interv Radiol 10:445–456
14. Fujihara M, Takahara M, Yamaoka T, Iida O, Kojima T, Tobita K et al (2021) Clinical outcomes of endovascular procedure using VIABAHN VBX covered stent in complex aortoiliac artery disease: result from the AVOCADO study. Catheter Cardiovasc Interv 98:928–937
15. Blais B, Carr K, Sinha SP, Salem MM, Levi DS (2021) Mechanical properties of low-diameter balloon expandable covered stents. Catheter Cardiovasc Interv 97:451–458

Figures

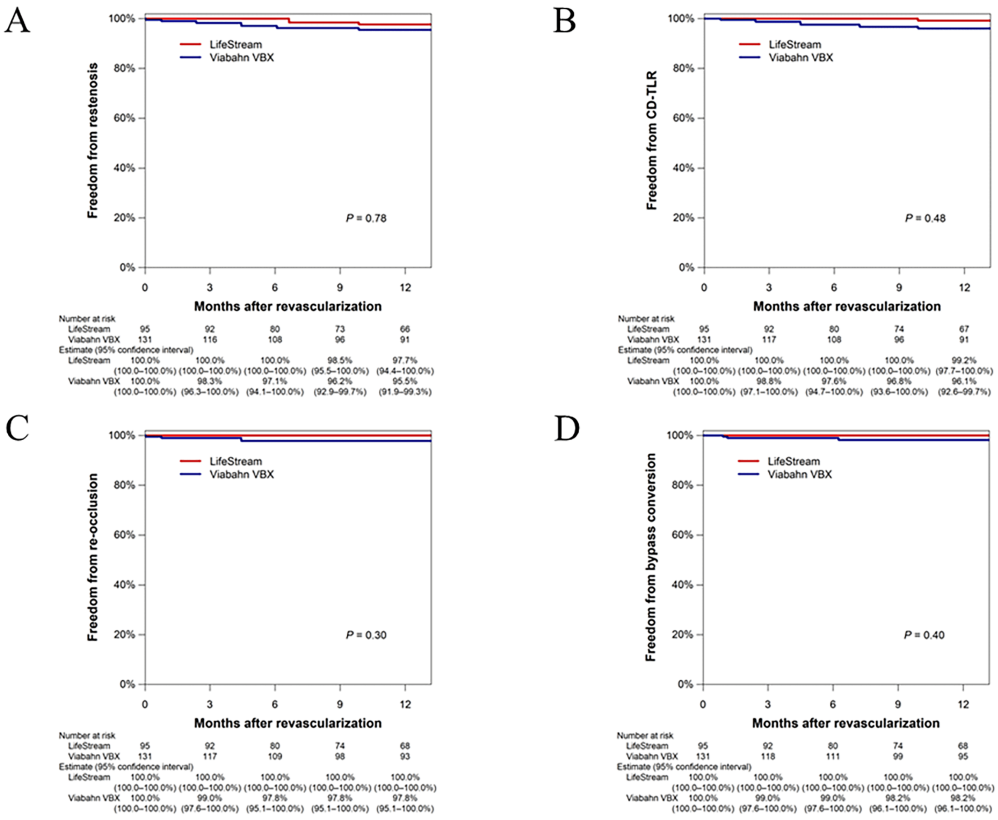


Figure 1

Freedom from restenosis (A), CD-TLR (B), re-occlusion (C), and surgical conversion (D) after IPTW.

Abbreviations: CD-TLR, clinically driven target lesion revascularization; IPTW, inverse probability of treatment weighting.

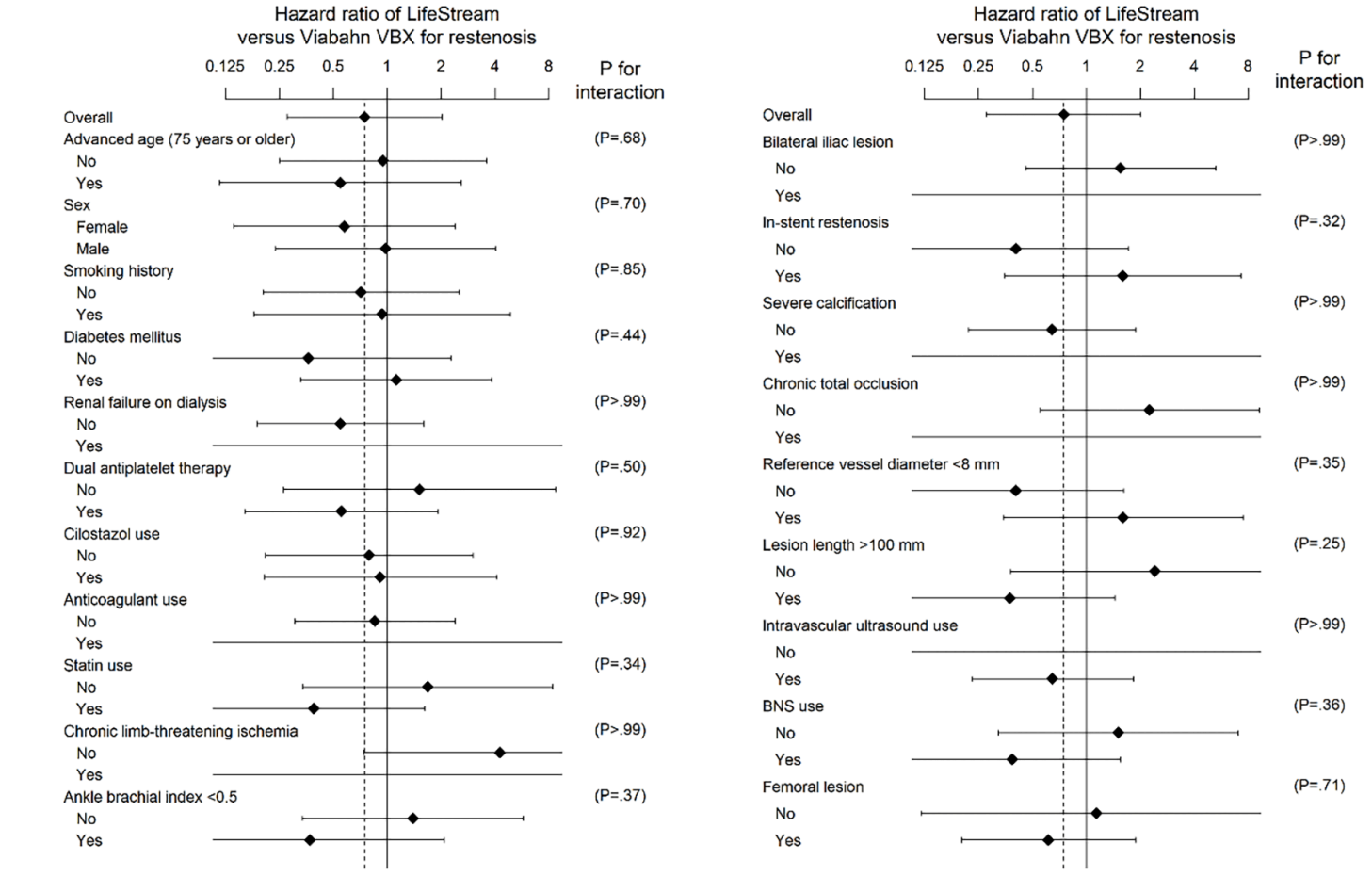


Figure 2

Interaction effects of baseline characteristics on the association between stent type and risk of restenosis.

Error bars indicate 95% confidence intervals.

Abbreviations: BNS, bare nitinol stent.