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# Role of intravascular ultrasound for the technical assessment of endovascular reconstruction of the aortic bifurcation

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## ABSTRACT

**Objective:** The aim of this study was to evaluate the role of intravascular ultrasound (IVUS) for the technical assessment of kissing stents (KSs) and covered endovascular reconstruction of the aortic bifurcation (CERAB) in the treatment of aortoiliac obstructive disease involving the aortic bifurcation.

**Methods:** We conducted a single-center retrospective review of patients undergoing endovascular treatment of severe aorto-iliac obstructive disease (2019-2023). IVUS was performed in patients treated by KSs or CERAB according to preoperative indications, in cases of moderate/severe calcifications, mural thrombus, total occlusions, and lesion extension towards the proximity of renal or hypogastric arteries. Indications for IVUS-guided intraoperative revisions were residual stenosis or compression >30%, incomplete stent-to-wall apposition, or flow-limiting dissection at the landing site. Follow-up assessment was performed at 6 and 12 months, and then yearly. Thirty-day outcomes and 2-year patency rates were evaluated. Logistic regression was used to identify factors associated with significant technical defects detected by IVUS needing intraoperative revision.

**Results:** IVUS was used for the technical assessment of 102 patients treated by KSs (n = 57; 56%) or CERAB (n = 45; 44%) presenting with severe intermittent claudication (39%), rest pain (39%), or ischemic tissue loss (25%). Twenty-nine significant technical defects were identified by IVUS in 25 patients (25%) who then had successful intraoperative correction by additional ballooning (n = 23; 80%) or stenting (n = 6; 20%). Patients with a severely calcified chronic total occlusion (odds ratio, 1.85; 95% confidence interval, 1.01-5.27; $P = .044$) or severely calcified narrow aortic bifurcation with <12 mm diameter (odds ratio, 2.34; 95% confidence interval, 1.10-8.64; $P = .032$) were at increased risk for IVUS-guided intraoperative revision. There were no postoperative deaths and no major adverse events. Two-year primary patency was 100%.

**Conclusions:** IVUS was used for the technical assessment of KSs/CERAB in a selected cohort of patients with severe aorto-iliac obstructive disease. This allowed the identification and intraoperative correction of a significant technical defect not detected by completion angiogram in one-quarter of patients, achieving optimal 2-year results. IVUS assessment of KSs/CERAB may be considered especially in patients with a calcified total occlusion or narrow aortic bifurcation. (J Vasc Surg 2024;80:441-50.)

**Keywords:** Stent; Peripheral arterial disease; Iliac artery; Intravascular ultrasonography; Kissing stent; CERAB

The endovascular treatment of obstructive disease involving the aortic bifurcation may be performed either with the kissing stents (KSs) or covered endovascular reconstruction of the aortic bifurcation (CERAB) techniques.[1-3] These two types of endovascular reconstructions may be adopted in different anatomical situations, providing excellent clinical results in terms of technical success and patency rates, and have also been used for the treatment of challenging situations characterized by total occlusion, calcification, thrombus, or extension towards the renal or external iliac arteries.[1-6]

To ensure optimal clinical results, a final optimal KSs/CERAB conformation should be achieved, with proximal and distal stent ends placed in a disease-free aortic and iliac zone, proper stent expansion with absence of significant residual stenosis, optimal stent-to-aortic wall apposition, symmetric shape of the KSs, and minimization of the radial and protrusion mismatch.[7,8] Therefore, the intraoperative technical assessment of KSs/CERAB may be particularly important. This has been traditionally based on completion digital subtraction angiography

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Presented at the 2023 Vascular Annual Meeting of the Society for Vascular Surgery, National Harbor, Maryland, June 14-17, 2023.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214



https://doi.org/10.1016/j.jvs.2024.03.014

(DSA) that may be limited by the bi-dimensional view and the use of contrast media and radiation exposure. DSA may not identify some technical defects that might lead to a later technical failure. Cone-beam computed tomography represents an adjunctive intraoperative diagnostic modality that has been used with promising results for the intraoperative evaluation of endovascular interventions for aorto-iliac obstructive disease.[9]

Although largely used in the context of iliac vein disease,[10] infrainguinal peripheral artery disease,[11] and complex aneurysm repair,[12,13] the use of intravascular ultrasound (IVUS) for the technical assessment of aortoiliac endovascular reconstruction is currently underreported,[14-16] and no prior descriptions are available regarding its use with the KSs and CERAB techniques. Potential advantages in this setting are related to the precise assessment of the arterial wall and stents while maintaining the guidewire in place, the lack of contrast and radiation use, and the possibility for in-situ sizing and re-assessment after eventual intraoperative revision.

The objective of the study was to investigate the role of IVUS for the technical assessment of endovascular reconstruction of the aortic bifurcation using the KSs and CERAB techniques.

## ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center retrospective study
- **Key Findings:** Intravascular ultrasound (IVUS) was used for the technical assessment of kissing stents and covered endovascular reconstruction of the aortic bifurcation in a selected cohort of 102 patients with severe aorto-iliac obstructive disease involving the aortic bifurcation. Twenty-nine significant technical defects were identified with IVUS in 25 patients (25%). These were a stent compression at the level of the aortic bifurcation in 12 patients (12%), an external iliac stent compression/residual stenosis in 12 patients (12%), and a residual stenosis or dissection at the distal landing site in six patients (6%). A successful intraoperative correction was achieved in all cases. Presence of severely calcified chronic total occlusion (odds ratio, 1.85; 95% confidence interval, 1.01-5.27; $P = .044$) or severely calcified aortic bifurcation diameter <12 mm (odds ratio, 2.34; 95% confidence interval, 1.10-8.64; $P = .032$) were at increased risk for a IVUS-guided intraoperative revision. Primary patency at 24 months was 100%.
- **Take Home Message:** IVUS can be safely used for the technical assessment of aortoiliac obstructive disease treated by kissing stents or covered endovascular reconstruction of the aortic bifurcation, allowing the identification of a technical defect not evident on completion digital subtraction angiography in one-quarter of patients. IVUS should be considered in particular in presence of calcified narrow aortic bifurcation or heavily calcified total occlusion to optimize patency and clinical outcomes.

## METHODS

**Patient population.** We conducted a single-center retrospective chart review on patients operated on between 2019 and 2023 for aortoiliac obstructive disease. Only patients with aorto-iliac Trans-Atlantic Inter-Society Consensus (TASC) C/D lesions involving the aortic bifurcation and treated by KSs or CERAB technique with the use of covered stents were included. By our procedural protocol, IVUS is not used in TASC A/B lesions. Patients with unilateral iliac disease or treated by KSs/CERAB without the use of IVUS were excluded from the analysis. This retrospective chart review study was exempt from institutional review board full review.

**Data collection and definitions.** Patients' demographics, cardiovascular risk factors, and symptoms at presentation were evaluated. Hypertension was defined as blood pressure >140/90 mmHg or specific medical therapy. Dyslipidemia was defined as total cholesterol >200 mg/dL (5.2 mmol/L) or low density lipoprotein cholesterol >120 mg/dL (3.1 mmol/L) or specific medical therapy. Chronic renal insufficiency was defined as glomerular filtration rate <60 mL/min/1.73 $m^2$.[17] Congestive heart failure and coronary artery disease were defined according to current standards.[18,19] Chronic obstructive pulmonary disease was defined according to Global initiative for chronic Obstructive Lung Disease (GOLD) criteria.[20] Cerebrovascular disease was defined as a clinical history of prior stroke, transient ischemic attack, or carotid intervention. Indications for vascular surgery were lifestyle-limiting claudication non-responsive to conservative treatment, rest pain, or ischemic tissue loss. Symptoms at presentation were defined according to the Rutherford classification.[21] Diagnosis confirmation and anatomical assessment were performed through computed tomography angiography (CTA). Data on TASC II classification, extension of the disease, presence of chronic total occlusion, grade of calcification, and presence of thrombus were obtained from the CTA. Severity of calcification was categorized as none (<25% circumference), mild (26%-50%), moderate (51%-75%), or severe (>75%).[4]

Technical success was defined on an intention-to-treat basis, as the successful recanalization and deployment of the stents, re-establishing vessel patency with a residual stenosis <30%.[5,21] Early (30 days) systemic complications included death, myocardial infarction, dysrhythmia (needing medications, electric cardioversion, or pacemaker implantation), respiratory failure (prolonged intubation >24 hours, reintubation, or need for noninvasive ventilation), and acute renal insufficiency (>50% decrease in estimated glomerular filtration rate or new onset dialysis). Surgical complications included arterial access complications needing treatment, bowel ischemia (requiring surgical resection or intensive medical care), distal embolization, thrombosis, or wound complications occurring intraoperatively or within 30 days from the primary procedure.

Follow-up and surveillance included clinical examination and duplex ultrasound at 6 and 12 months and then yearly. During ultrasound examinations, the patency of the treated vessels and the status of the inflow and outflow arteries were assessed. CTA was performed as needed to confirm ultrasound findings and/or in case of symptom recurrence. Primary patency, secondary patency, primary assisted patency, and limb salvage were defined according to the current reporting standards.[21]

**Operative technique.** All procedures were performed by vascular surgeons in a hybrid operating room (with ArtisPheno angiographer, Siemens). Both the CERAB and KSs techniques were performed with the use of covered stents.[7,22] The KSs technique was preferred in cases with proximal disease extension below the level of the inferior mesenteric artery (IMA); CERAB was mostly selected in cases of proximal disease extension above the IMA.

Bilateral percutaneous femoral access was obtained using ultrasound guidance if the common femoral artery (CFA) was free from stenotic plaque (<30%) with a non-calcified anterior wall. In case of CFA stenosis >50%, an endarterectomy with patch angioplasty was performed first, using the great saphenous vein or a bovine pericardial patch. A 9Fr introducer sheath was placed in both common femoral arteries. The obstructive lesion was crossed from the ipsilateral femoral access; if this was unsuccessful or in the most challenging cases, a left brachial or contralateral approach was adopted. After recanalization, a stiff guidewire (Amplatz Super Stiff, Boston Scientific) was advanced in the aorta and was used to deploy the aortic component of CERAB. An 11-mm sized Viabahn balloon expandable stent (VBX, WL Gore & Associates) was used in most cases; this was deployed in the infrarenal aorta and post-dilated to 16 mm in its proximal part with a non-compliant balloon (Atlas Gold PTA dilatation catheter, Bard). In case of aortic inner diameter ≥16 mm or in cases with parietal aortic thrombosis, a self-expanding Excluder Aortic Extender (WL Gore & Associates) or other balloon-expandable stents were used for the aortic coverage. Two 8 mm "large" VBX stents were then advanced to the aortic bifurcation over stiff guidewires and deployed simultaneously from the aortic cuff (with an approximately 15 mm overlapping) to the common iliac arteries. Post-dilatation of the proximal portion of the two parallel stents was performed in a kissing fashion using two 12 × 20 mm semi-compliant balloons (Powerflex Pro PTA, Cordis). In case of stand-alone KSs, the two stents were deployed in a similar fashion, protruding into the aorta for approximately 1.5 cm, and post-dilated in a similar way. Both in CERAB and KSs, in case of disease extension extending towards the external iliac arteries, coverage was extended with self-expanding covered stents.[23] An interposition bare metal stent was deployed at the level of the internal iliac artery ostium to maintain hypogastric artery patency if needed.[24] Routine post-dilatation of common and external iliac stents was performed with a same size balloon. A completion DSA was obtained in all cases before IVUS, and a supplemental stenting or post-dilatation was performed in case of residual stenosis >30%.

**Intravascular ultrasound.** From 2019, we started using IVUS in selected cases of aortoiliac obstructive disease to assess the endovascular reconstruction of the aortic bifurcation. IVUS was performed according to preoperative indications in cases characterized by moderate/severe calcifications, parietal thrombus, total occlusions, and lesion extension towards the proximity of renal or hypogastric arteries. In these selected cases, IVUS was routinely performed after DSA using the Philips Core M2 peripheral vascular system with Volcano Vision PV 0.035' probe. The IVUS catheter was advanced in the aorta over a standard non-stiff guidewire, and then slowly retracted to visualize the entire infra-renal aorta and iliac axis; the procedure was performed from both femoral accesses. IVUS technical assessment included evaluation of stent patency, apposition to arterial wall, expansion, conformation, and quality of the proximal and distal landing sites. Indications for IVUS-guided intraoperative revisions were residual stenosis or compression >30%, incomplete stent apposition to the arterial wall, or flow-limiting dissection at the landing site (Fig 1). In cases where an adjunctive maneuver was performed, IVUS was repeated afterwards to evaluate the result.

**Endpoints.** Endpoints were IVUS-guided intraoperative adjunctive maneuvers, early (30-days) outcomes, and 2-year patency rates.

**Statistical analysis.** Results were reported as a number and percentage for categorical variables, mean ± standard deviation or median (interquartile range) for continuous variables. Time-dependent outcomes were reported using Kaplan-Meier estimates. Univariate and multivariable logistic regression models were used to identify factors associated with a need for IVUS-guided intraoperative revisions. Covariates with univariate significance $P < .200$ were entered into the initial multivariable model; a backward stepwise selection of covariates was performed, and the most parsimonious model with inclusion of significant factors and confounders was selected as the final model. A penalized likelihood method based on Firth's regression[25] was

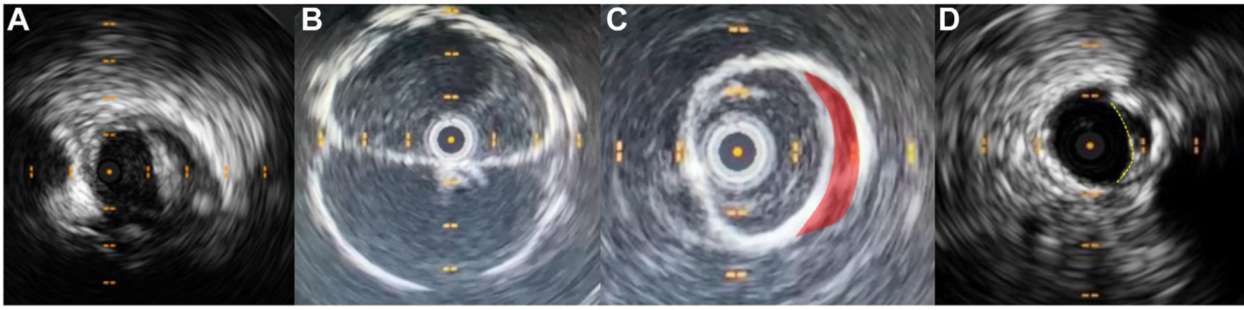


**Fig 1.** Intravascular ultrasound (*IVUS*) technical assessment. **A,** Presence of residual stenosis at the level of the distal landing site in the external iliac artery. **B,** Evaluation of the conformation of the two kissing stents. Note the symmetric D-shape morphology. **C,** Inadequate stent-to-arterial wall apposition in a common iliac stent (*red area*). **D,** Residual dissection at the level of the distal edge of the stent in the common iliac artery.

adopted to account for the limited number of events. A $P < .05$ was used to determine statistical significance. The R 4 software (R Foundation for Statistical Computing) was used for the analysis.

## RESULTS

**Patient cohort.** During the study period, 194 patients received endovascular treatment of aorto-iliac obstructive disease involving the aortic bifurcation, and 23 received open surgical treatment (21 aorto-bifemoral bypasses and 2 axillo-femoral bypasses). Of the 194 patients treated by endovascular means, IVUS was not performed in 92 patients with less complex arterial disease, and 102 patients were included in the final analysis: 57 (62%) treated by KSs and 45 (38%) by CERAB. Preoperative indications to IVUS were moderate/severe calcifications in 34 patients (33%), total occlusion in 56 patients (55%), mural thrombosis in 19 patients (19%), and disease extension until the renal arteries in 10 patients (10%). The mean age was 71 ± 8 years, and 76 patients (73%) were male. Clinical presentation was intermittent claudication in 40 (39%), rest pain in 37 (36%), and tissue loss in 25 (25%), without differences between the KSs and CERAB cohorts ($P = .522$) (Table I).

Anatomical data are summarized in Table II. Proximal disease extension above the IMA was more frequent in the CERAB cohort (n = 37; 82%) compared with the KSs cohort (n = 10; 18%). Distal lesion extension was in the common iliac arteries in 65 patients (64%) and in the external iliac arteries in 37 patients (36%); a total iliac occlusion was present in 56 limbs (27%) and a concomitant significant CFA stenosis in 76 limbs (36%).

**Intravascular ultrasound assessment.** Twenty-nine significant technical defects were identified by IVUS in 25 patients (25%). These were a stent compression at the level of the aortic bifurcation in 12 (12%), an external iliac stent compression/residual stenosis in 12 (12%), and a residual stenosis or dissection at the distal landing site in five (5%) (Table III); residual thrombus was detected at the proximal landing site in one case (1%). Intraoperative correction was achieved by additional ballooning in 23 cases (80%) and additional stenting in six (20%). After IVUS reassessment, technical success of the intraoperative revision was achieved in all cases.

At the logistic regression, chronic total occlusion of the external iliac artery (odds ratio [OR], 2.94; 95% confidence interval [CI], 1.02-6.15; $P = .021$), and aortic bifurcation diameter <12 mm (OR, 3.11; 95% CI, 0.99-5.13; $P = .050$) were at higher risk for a IVUS-guided intraoperative revision. Presence of severe calcification by itself was not significantly associated with the need for intraoperative revision (OR, 4.09; 95% CI, 0.94-38.4; $P = .062$), whereas the presence of severely calcified chronic total occlusion (OR, 1.85; 95% CI, 1.01-5.27; $P = .044$) or severely calcified aortic bifurcation diameter <12 mm (OR, 2.34; 95% CI, 1.10-8.64; $P = .032$) were at increased risk in the multivariable analysis. Type of endovascular reconstruction (KSs vs CERAB: OR, 0.78; 95% CI, 0.19-1.29; $P = .101$), TASC classification (OR, 1.12; 95% CI, 0.91-1.99; $P = .508$), and common iliac artery diameter (OR, 1.09; 95% CI, 0.34-3.20; $P = .873$) were not at increased risk for significant technical defects detected by IVUS (Table IV).

**Early and 2-year outcomes.** Procedural technical success was achieved in all patients. At 30 days, there were two access site complications needing reintervention and one iliac artery rupture (bleeding from hypogastric artery origin in a patient with bare metal stent deployment at this level) that was successfully treated with a covered stent. There were no IVUS-related complications. Primary patency at 30 days was 100%.

The median follow-up was 24 months; seven patients died, and four were lost to follow-up Overall survival at 2 years was 91% (95% CI, 85%-97%). After 24 months of follow-up, there were no restenosis or reinterventions both in the KSs and CERAB group, with a 100% primary patency (Fig 2). No patient required CTA owing to suspect restenosis or occlusion during follow-up. The limb salvage rate was 100% for both groups.

**Table I.** Demographics and risk factors of the 102 patients treated by kissing stents (*KSs*) or covered endovascular reconstruction of the aortic bifurcation (*CERAB*) for aorto-iliac obstructive disease involving the aortic bifurcation

| Demographics | All patients (N = 102) | KSs (n = 57) | CERAB (n = 45) | *P* |
|---|---|---|---|---|
| Age, years | 71 ± 8 | 72 ± 9 | 71 ± 9 | .899 |
| Male sex | 76 (73) | 40 (70) | 36 (80) | .360 |
| Risk factors | | | | |
| Hypertension | 93 (91) | 54 (96) | 39 (85) | .056 |
| Diabetes | 32 (31) | 17 (29) | 15 (33) | .832 |
| Dyslipidemia | 70 (68) | 40 (70) | 30 (67) | .830 |
| Smoking history | | | | |
| Active smoker | 22 (21) | 13 (33) | 9 (20) | .811 |
| Former smoker | 31 (30) | 18 (32) | 13 (29) | .830 |
| Coronary artery disease | 29 (28) | 19 (33) | 10 (22) | .271 |
| CHF | 9 (9) | 4 (7) | 5 (11) | .502 |
| Cerebrovascular disease | 4 (4) | 2 (4) | 2 (4) | .999 |
| Renal insufficiency | 15 (15) | 8 (14) | 7 (16) | .999 |
| COPD | 19 (19) | 11 (19) | 8 (18) | .999 |
| ASA score | 2.8 ± 0.5 | 2.8 ± 0.5 | 2.7 ± 0.6 | .952 |

*ASA*, American Society of Anesthesiologists; *CHF*, congestive heart failure; *COPD*, chronic obstructive pulmonary disease.
Data are presented as number (%) or mean ± standard deviation.

**Table II.** Clinical and anatomical data of the 102 patients treated by kissing stents (*KSs*) or covered endovascular reconstruction of the aortic bifurcation (*CERAB*) for aorto-iliac obstructive disease involving the aortic bifurcation

| Clinical data | All patients N = 102 patients | KSs n = 57 patients | CERAB n = 45 patients | *P* |
|---|---|---|---|---|
| Rutherford Category | | | | .522 |
| 3 | 40 (39) | 26 (45) | 14 (31) | |
| 4 | 37 (36) | 21 (37) | 16 (36) | |
| 5/6 | 25 (25) | 10 (18) | 15 (33) | |
| Anatomical data | 70 (68) | 40 (70) | 30 (67) | |
| Proximal disease extension | | | | < .001[a] |
| Aortic bifurcation | 33 (32) | 33 (57) | 0 (0) | |
| Aorta below IMA | 22 (22) | 14 (25) | 8 (18) | |
| Aorta above IMA | 47 (46) | 10 (18) | 37 (82) | |
| Distal iliac disease extension | | | | .408 |
| CIA | 65 (64) | 34 (59) | 31 (69) | |
| EIA | 37 (36) | 23 (41) | 14 (31) | |
| Aortic bifurcation size, mm | 13 ± 5 | 12 ± 6 | 13 ± 5 | .670 |
| Aortic bifurcation size <12 mm | 31 (31) | 18 (32) | 13 (29) | .830 |
| Aortic bifurcation severe calcification | 34 (33) | 15 (26) | 19 (42) | .100 |
| | N = 204 limbs | n = 114 limbs | n = 90 limbs | |
| Total occlusion | 56 (55) | 32 (57) | 24 (53) | .257 |
| CIA size, mm | 9 ± 3 | 9 ± 4 | 8 ± 4 | .359 |
| CIA severe calcification | 120 (59) | 74 (65) | 46 (51) | .062 |
| CFA stenosis >50% | 76 (37) | 42 (37) | 34 (38) | .999 |

*CFA*, Common femoral artery; *CIA*, common iliac artery; *EIA*, external iliac artery; *IMA*, inferior mesenteric artery.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.

**Table III.** Procedural data and early (30-days) outcomes in the 102 patients treated by kissing stents (*KSs*) or covered endovascular reconstruction of the aortic bifurcation (*CERAB*) for aorto-iliac obstructive disease involving the aortic bifurcation

| Procedural data | All patients (n = 102) | KSs (n = 57) | CERAB (n = 45) | *P* |
|---|---|---|---|---|
| Aortic coverage | | | | |
| VBX stent | 31 (30) | – | 31 (69) | – |
| Other balloon-expandable stent | 3 (3) | – | 3 (7) | – |
| Gore Excluder | 11 (11) | – | 11 (24) | – |
| Aortic length of coverage, cm | 5.1±3.2 | 2.3±1.1 | 6.3±4.6 | < .001[a] |
| | N = 204 limbs | n = 114 limbs | n = 90 limbs | |
| KSs | | | | .999 |
| VBX stents | 93 (92) | 52 (91) | 41 (91) | |
| Other balloon-expandable stent | 9 (8) | 5 (9) | 4 (9) | |
| Iliac length of coverage, cm | 6.3±3.4 | 5.5±3.9 | 6.9±4.1 | .861 |
| Associated IVL | 22 (22) | 12 (21) | 10 (22) | .999 |
| Associated CFA endarterectomy | 76 (37) | 42 (37) | 34 (38) | .999 |
| | N = 102 patients | n = 57 patients | n = 45 patients | |
| IVUS- guided intraoperative revision | 25 (25) | 14 (25) | 11 (24) | .999 |
| Aortic stent | 0 (0) | – | 0 (0) | – |
| KSs | 12 (12) | 5 (9) | 7 (15) | .359 |
| External iliac stent | 11 (11) | 7 (12) | 4 (9) | .751 |
| Proximal or distal landing site | 6 (6) | 4 (7) | 2 (4) | .691 |
| Early systemic outcomes | | | | |
| Death | 0 (0) | 0 (0) | 0 (0) | .999 |
| Myocardial infarction | 0 (0) | 0 (0) | 0 (0) | .999 |
| Acute kidney injury | 3 (3) | 2 (4) | 1 (2) | .999 |
| Respiratory failure | 0 (0) | 0 (0) | 0 (0) | .999 |
| Early procedural outcomes | | | | |
| Technical success | 102 (100) | 57 (100) | 45 (100) | .999 |
| Early reintervention | 1 (1) | 1 (2) | 0 (0) | .999 |
| Access site complication | 2 (2) | 1 (2) | 1 (2) | .999 |
| Distal embolization | 0 (0) | 0 (0) | 0 (0) | .999 |

*CFA*, Common femoral artery; *IVL*, intravascular lithotripsy; *IVUS*, intravascular ultrasound.
Data are presented as number (%) or mean ± standard deviation.
[a]Statistically significant.

## DISCUSSION

This study investigated the role of IVUS for the technical assessment of endovascular reconstruction of the aortic bifurcation by KSs/CERAB techniques in a selected cohort of patients, characterized by advanced obstructive lesions involving the aortic bifurcation. The overall complexity of the treated disease was high, with presence of a total occlusion in 55%, aortic involvement in 68%, aortoiliac severe calcification in 60%, and extension into the EIA in 36%. IVUS was able to identify a significant technical defect that was not recognized by DSA in one-quarter of patients, driving a successful adjunctive endovascular maneuver in these cases. In particular, the preoperative presence of a narrow calcified aortic bifurcation or a calcified complete occlusion were significantly associated with the need for an IVUS-guided intraoperative revision.

Prior studies highlighted the importance of the final conformation of KSs and CERAB to ensure durable results.[7,8,26,27] A suboptimal conformation that might not result in any clinical consequences in the early postoperative period may predispose to blood-flow alterations and stent thrombosis/restenosis during follow-up. The presence of heavy calcification represents a major factor potentially leading to an inadequate endovascular result. The most common defect requiring correction was represented by unilateral KSs compression at the level of the proximal edge or aortic bifurcation (Fig 3). A useful IVUS tool to evaluate this aspect consists in measuring the area of the stent and comparing it with the area of the contralateral KS at the same level. In case there is only a mild stent under-expansion, an invasive pressure measurement above and below the level of the IVUS

**Table IV.** Univariate and multivariable logistic regression for intravascular ultrasound (IVUS)-guided intraoperative revision

| | Univariate | | Multivariable | |
|---|---|---|---|---|
| Covariate | OR (95% CI) | *P* | OR (95% CI) | *P* |
| Age, years | 1.07 (0.38-3.12) | .893 | – | – |
| Male sex | 0.78 (0.21-2.75) | .635 | – | – |
| TASC D | 1.12 (0.91-1.99) | .508 | – | – |
| Aortic bifurcation diameter, mm | 0.32 (0.21-1.34) | .093 | – | – |
| Aortic bifurcation diameter <12 mm | 3.11 (0.99-5.13) | .050[a] | 2.56 (0.95-6.83) | .142 |
| Common iliac artery diameter | 1.09 (0.34-3.20) | .873 | – | – |
| Chronic total occlusion | 2.16 (0.41-5.50) | .785 | – | – |
| Chronic total occlusion location | | | | |
| Common iliac | Ref. | | – | – |
| Aorta | 1.23 (0.87-3.15) | .131 | – | – |
| External iliac | 2.94 (1.02-6.15) | .021[a] | – | – |
| Severe calcification | 4.09 (0.94-38.4) | .062 | 3.00 (0.89-40.11) | .321 |
| Severe calcification + total occlusion | – | – | 1.85 (1.01-5.27) | .044[a] |
| Severe calcification + narrow aortic bifurcation <12 mm | – | – | 2.34 (1.10-8.64) | .032[a] |
| Technique | | | | |
| KSs | Ref. | | – | – |
| CERAB | 0.78 (0.19-1.29) | .101 | – | – |

*CERAB*, Covered endovascular reconstruction of the aortic bifurcation; *CI*, confidence interval; *KS*, kissing stent; *OR*, odds ratio; *Ref*, reference; *TASC*, Trans-Atlantic Inter-Society Consensus.
[a]Statistically significant.

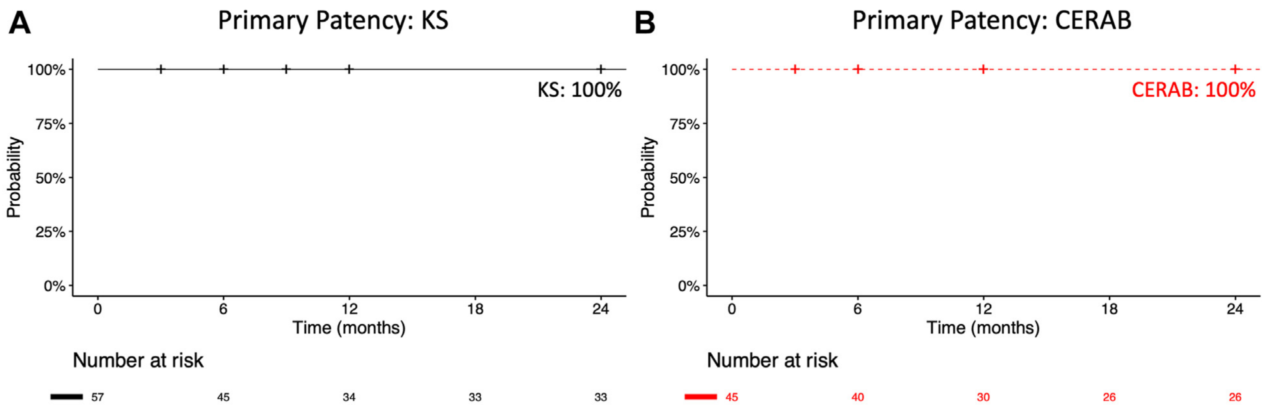


**Fig 2. A,** Kaplan-Meier curve of primary patency for the 57 patients with aorto-iliac obstructive disease treated by kissing stents (*KSs*) and intravascular ultrasound (*IVUS*) technical assessment. Standard error <10%. **B,** Kaplan-Meier curve of primary patency for the 45 patients with aorto-iliac obstructive disease treated by covered endovascular reconstruction of the aortic bifurcation (*CERAB*) and IVUS technical assessment. Standard error <10%.

defect can be helpful to guide the indication to further post-dilatation.

The external iliac artery represents another critical segment of the iliac axis, usually characterized by smaller size and disease extension to the CFA, needing for concomitant endarterectomy and patch angioplasty.[23] Especially in cases with calcified complete occlusion receiving subintimal recanalization, a residual stent compression may be present at this level after standard stenting and post-dilatation. This was detected in 11 patients and was treated by a more aggressive post-dilatation with a non-compliant balloon in all cases, achieving a disruption of the plaque protected by the presence of the covered stent. These results may reflect our preferential use of self-expanding covered stents for the external iliac artery,[23] but different results might be obtained with other types of stent with a higher radial force.

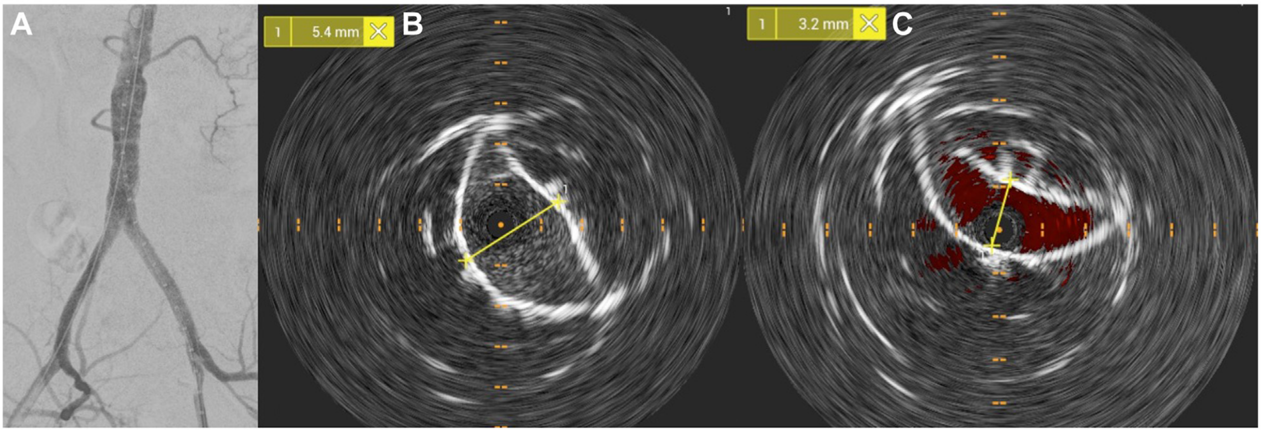


**Fig 3. A,** Completion digital subtraction angriography (*DSA*) after covered endovascular reconstruction of the aortic bifurcation (*CERAB*), showing patency of the treated segment without evidence of any residual defect. **B,** Intravascular ultrasound (*IVUS*) of the right iliac axis of the same case, showing adequate D-shape and expansion of the right kissing stent (*KS*) (minor axis diameter: 5.4 mm). **C,** IVUS of the left iliac axis of the same case, showing compression and inadequate expansion of the left KS (minor axis diameter: 3.2 mm).

IVUS use in the aorto-iliac segment carries several advantages. It does not require iodinated contrast and radiation exposure and can be safely repeated as many times as needed throughout the procedure. It can be performed with the guidewire still in place, and it is possible to reassess the endovascular reconstruction also after eventual intraoperative revision. Aside from the technical assessment of the stents (in terms of expansion, residual stenosis, wall apposition, and conformation), it is also useful for in situ sizing and for determination of the quality of the artery at the level of the intended proximal and distal landing sites. On the other hand, it does not provide any information on blood flow, runoff, and eventual contrast extravasation, which is always a possible risk when dealing with severe calcified lesions. Therefore, IVUS is not intended to be used as an alternative to DSA, as both studies provide different and complimentary information.[16]

An interesting result of our study is that technical defects detected by IVUS were not clearly evident on conventional angiography. In our opinion, this is related to the quality of information provided by IVUS on stent conformation, which may be difficult to assess by DSA. Also, in case of nonocclusive mural thrombus that can be difficult to assess by DSA, IVUS imaging after stent deployment allows confirmation of the status of the landing zone, and eventually overstent if excessive thrombus is still visualized. The high IVUS sensitivity may have led to a high number of intraoperative revisions that may also be associated with increased operating time and costs. The rationale for these maneuvers is to optimize patency and freedom from reintervention, but at the current status, it may be still difficult to determine whether the technical defect visible on IVUS needs an immediate revision or can be considered not clinically relevant. The results of our study seem to suggest that IVUS-guided technical success may be valuable in terms of clinical results. After 24 months of follow-up, we achieved a promising 100% primary patency on 102 patients with complex aortoiliac lesions. However, larger experience and longer follow-up are still needed to investigate the clinical impact of IVUS. In particular, a better standardization of the indications to IVUS-guided adjunctive maneuvers is desirable, to allow improvement of clinical results avoiding the risk of overtreatment.

According to the results of this study, we recently changed our practice. In patients requiring KSs or CERAB, we perform routine IVUS assessment in presence of calcified aortic bifurcation diameter $<12$ mm, and we expanded its use to patients with severely calcified occlusions and complete occlusions of the external iliac artery. Given the higher sensitivity of IVUS compared with DSA, we now use IVUS as initial completion assessment and repeat it as needed in case further ballooning or stenting is warranted. DSA is obtained only after IVUS-driven technical success, to assess for eventual contrast extravasation (suggestive for arterial rupture) and to evaluate the runoff. At this time, the rationalization of costs does not allow the routine use of IVUS in all patients, and it is necessary to select cases that might benefit best from its use. Therefore, we currently do not preoperatively anticipate using IVUS in case of TASC A/B lesions, stenotic (not completely occluded) lesions, or lesions limited to the iliac axis without involvement of the aortic bifurcation; in these situations, IVUS can be still used selectively only in case of intraoperative need.

The present study had some notable limitations. This was a single-center, retrospective study, where IVUS was performed in a selected cohort of patients with extensive disease involving the aortic bifurcation. Our results reflect the characteristics of the included cohort, and a less frequent IVUS-guided intraoperative revision might be needed in patients with less complex aortoiliac lesions. The power of the statistical analysis may have been limited by the low number of events, and follow-up duration was limited. Also, although the indication to IVUS-guided intraoperative revisions followed general criteria, this might have been influenced by the operator and learning curve. Finally, a cost-effectiveness analysis was not available at this stage.

Strengths of the study are the standardization of preoperative indications to IVUS and IVUS-guided intraoperative revisions that allowed identification of a subset of lesions that benefit more from the use of this technique. To the authors' knowledge, this represents the first report of the use of IVUS in the aortoiliac segment, and our results lay the foundation for further studies. Future comparison of IVUS vs non-IVUS procedures may be useful to understand its role in terms of patency rates and reinterventions.

## CONCLUSIONS

IVUS was used for the technical assessment of KSs/CERAB in a selected cohort of patients with severe aorto-iliac obstructive disease. This allowed the identification and intraoperative correction of a significant technical defect in 25% of patients, achieving optimal 2-year results. The presence of narrow (<12 mm) calcified aortic bifurcation and highly calcified total occlusion were associated with significant technical defects detected by IVUS. IVUS technical assessment may be considered in these patients to optimize early and late outcomes.

## AUTHOR CONTRIBUTIONS

Conception and design: MA, MP, FG, FS
Analysis and interpretation: MA, MP, MM, FS
Data collection: SM, EC
Writing the article: MA, FS
Critical revision of the article: MA, MP, SM, EC, FG, MM, FS
Final approval of the article: MA, MP, SM, EC, FG, MM, FS
Statistical analysis: FS
Obtained funding: Not applicable
Overall responsibility: MA

## DISCLOSURES

None.

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Submitted Feb 2, 2024; accepted Mar 5, 2024.