# Covered versus bare metal kissing stents for reconstruction of the aortic bifurcation in the ILIACS registry

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## ABSTRACT

**Objective:** We compared the early and midterm outcomes of polytetrafluoroethylene covered stents (CSs) vs bare metal stents (BMSs) used in the kissing conformation for the reconstruction of the aortic bifurcation in aortoiliac obstructive disease.

**Methods:** A multicenter cohort registry (2015-2019) collected data from 1306 patients who had undergone endovascular treatment of aortoiliac arterial obstructive disease. Only patients who had received bilateral iliac kissing stents for TransAtlantic Inter-Society Consensus (TASC) class C and D lesions were included in the present analysis. The 30-day outcomes, midterm primary patency, and limb salvage rates were compared between the CSs and BMSs in matched patient cohorts after propensity score matching. The follow-up results were analyzed using Kaplan-Meier curves. Cox proportional hazards models were used to identify the predictors of primary patency.

**Results:** A total of 336 patients were treated with kissing stents, 201 with CSs (60%) and 135 with BMSs (40%). In the unmatched cohort, patients receiving CSs were more likely to have critical limb ischemia (41% vs 30%; $P = .038$), complex iliac lesions, such as TASC D (90% vs 56%; $P < .01$), and iliac occlusions (59% vs 44%; $P < .01$). After propensity score matching, 220 patients were selected (110 with CSs and 110 with BMSs), without differences in the clinical presentation (critical limb ischemia, 41% vs 33%; $P = .167$), or anatomic complexity (TASC D, 66% vs 60%, $P = .21$; iliac occlusion, 48% vs 49%, $P = .89$). The 30-day mortality was 0%. The early medical (unmatched, 5% vs 4%, $P = 1.00$; matched, 5% vs 4%, $P = .75$) and surgical (unmatched, 5% vs 5%, $P = 1.00$; matched, 5% vs 3%, $P = .72$) complication rates were similar between the CSs and BMSs. However, the CSs resulted in a lower risk of intraoperative iliac rupture (0% vs 3.5%; $P = .013$) and greater ankle-brachial index improvement (0.43 ± 0.22 vs 0.36 ± 0.24; $P = .02$). At 36 months, the overall primary patency (92% ± 7% vs 92% ± 8%; $P = .38$), secondary patency (98% ± 3% vs 98% ± 4%; $P = .50$), and limb salvage (93% ± 9% vs 97% ± 5%; $P = .20$) rates were similar. In cases of moderate to severe iliac calcification, the CSs showed better results in the matched cohort (100% vs 89% ± 9%; $P = .048$). On multivariate analysis, CS use (hazard ratio [HR], 1.67; $P = .45$) did not significantly affect primary patency, but older age (HR, 0.93; $P = .03$) and kissing stent diameter ≥8 mm (HR, 0.25; $P = .03$) were significantly associated.

**Conclusions:** In the present multicenter study, the use of kissing stents for the treatment of the aortic bifurcation provided good early and midterm results. CSs were preferred for more complex lesions, were protective from iliac rupture, and allowed for greater ankle-brachial index improvement. The 3-year patency rates were similar between the CSs and BMSs. However, CSs showed improved results in the case of moderate to severe calcification. (J Vasc Surg 2021;73:1980-90.)

**Keywords:** Aortic bifurcation; Endovascular procedures; Iliac artery; Peripheral artery disease; Registries; Stents

Open surgery has been traditionally considered the reference standard for the treatment of aortoiliac obstructive disease involving the aortic bifurcation. However, the non-negligible morbidity and mortality can limit its application, especially in older and high-risk patients. Nevertheless, during the past decade, great

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*A complete list of the ILIACS Registry Group can be found in the Appendix (online only).

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improvement has occurred in the endovascular techniques and materials, and the endovascular approach can be accepted as the first-line option, because it provides satisfactory long-term results with low early complication rates.[1] In particular, the use of covered stents (CSs) has shown improved midterm patency rates in the treatment of TransAtlantic Inter-Society Consensus (TASC) class D lesions,[2,3] iliac occlusions,[4] long lesions involving both the common iliac arteries (CIAs) and the external iliac arteries (EIAs),[5] and multilevel peripheral arterial disease.[6]

For TASC class C and D bilateral obstructive lesions involving the aortic bifurcation, the traditional endovascular approach has been the kissing stent technique. The kissing stent technique consists of the simultaneous deployment of two parallel stents from the distal aorta to both CIAs and has demonstrated high technical success, low early complication, and satisfactory midterm patency rates.[7,8] Previous series have reported the results of the kissing stent technique using bare metal stents (BMSs),[9-11] CSs,[12-14] and different stent types.[15,16] However, data from comparisons between kissing BMSs and CSs are scarce.[17]

The aim of the present study was to compare the early and midterm outcomes of kissing CSs vs BMSs in the treatment of TASC C and D aortoiliac obstructive disease involving the aortic bifurcation, using data from a multicenter cohort registry. Propensity score matching was used to account for differences in the baseline clinical and anatomic characteristics between patients treated with CSs vs BMSs.

## ARTICLE HIGHLIGHTS

- **Type of Research:** A multicenter, retrospective cohort study of registry data (ILIACS)
- **Key Findings:** In TransAtlantic Inter-Society Consensus class C and D aortoiliac obstructive lesions involving the aortic bifurcation, the kissing stent technique provided good early and midterm outcomes. Overall, no differences were found between the covered and bare metal stents in the early complication rate (medical, 5% vs 4%, $P = .75$; surgical, 5% vs 3%, $P = .72$) and midterm primary patency (92% ± 7% vs 92% ± 8%; $P = .38$), secondary patency (98% ± 3% vs 98% ± 4%; $P = .50$), and limb salvage (93% ± 9% vs 97% ± 5%; $P = .20$) at 3 years. However, the covered stents provided greater ankle-brachial index improvement (0.43 ± 0.22 vs 0.36 ± 0.24; $P = .02$), a lower risk of intraoperative iliac rupture (0% vs 3.5%; $P = .013$), and better primary patency for those with moderate or severe iliac calcifications (100% vs 89% ± 9%; $P = .048$). Age (hazard ratio, 0.93; $P = .03$) and stent diameter ≥8 mm (hazard ratio, 0.25; $P = .03$) were significantly associated with patency, independently of the stent type used.
- **Take Home Message:** In endovascular treatment with kissing stents of obstructive lesions involving the aortic bifurcation, covered stents might be advantageous for calcified vessels and provide a lower risk of rupture and greater ankle-brachial index improvement compared with bare metal stents.

## METHODS

**Study design.** A retrospective, multicenter, observational cohort registry collected data from 1306 patients who had undergone endovascular treatment of aortoiliac arterial obstructive disease from 2015 to 2019. The details regarding the registry's characteristics and the original cohort of patients have been previously reported.[18] The registry is voluntary, collecting data from prospectively maintained institutional databases of 15 participating Italian centers. Delegates from each center were responsible for entering the anatomic, clinical, diagnostic, and technical variables into a dedicated database, and a single merged database was created from each center's entries. Data from all consecutive patients undergoing endovascular iliac procedures in each center were entered in the database on an intention-to-treat basis. One center (Division of Vascular Surgery, Department of Medicine and Surgery, ASST Settelaghi University Teaching Hospital, University of Insubria School of Medicine, Varese, Italy) was responsible for merging the data provided by each participating institution, checking the quality of the imputed data, and requiring audits, as needed. Regular updates were provided every 3 months. The included patients provided written informed consent, and each center's institutional review board approved the present study in accordance with the national policy on the retrospective analysis of anonymized data and the Italian privacy act.

**Patients.** Only patients with TASC C or D obstructive lesions involving the aortic bifurcation who had undergone bilateral iliac stenting with the kissing stent technique were included in the present analysis. The stent configuration was considered "kissing" if both right and left iliac stents protruded into the distal aorta with a parallel conformation and completely covering the aortic bifurcation. Patients receiving bilateral iliac stenting without a kissing conformation were not included. Patients treated using the covered endovascular reconstruction of the aortic bifurcation technique[19] or with insufficient information regarding stent conformation were excluded. Patients who had undergone concomitant endovascular procedures on the EIA or hybrid interventions with common femoral artery (CFA) endarterectomy were included.

The baseline characteristics, early (30-day) medical and surgical complication rates, and primary patency, secondary patency, and limb salvage rates were compared between the patients receiving kissing CSs vs BMSs.

**Definitions.** The patients' demographics, cardiovascular risk factors, and symptoms at presentation were evaluated. The indications for surgery included lifestyle limiting claudication, rest pain, and ischemic tissue loss. The decisions regarding the indication for treatment, surgical technique, stent type, and perioperative patient management were left to each participating center. However, these generally followed the international guidelines on the treatment of peripheral arterial disease.[1,20,21]

The diagnosis was determined from the physical examination findings, continuous wave Doppler ultrasound findings with ankle-brachial index (ABI) assessment, duplex ultrasound findings, and computed tomography angiography (CTA) findings of the aortoiliac segment bilaterally. Data on the TransAtlantic Inter-Society Consensus (TASC) classification, disease extension into the abdominal aorta or EIA, the presence of chronic total occlusion, and calcification grade were obtained from the CTA scans. The severity of calcification was categorized as none, mild (<25% circumference), moderate (25%-50%), or severe (>50%).[22]

Technical success was defined on an intention-to-treat basis as the successful recanalization and deployment of both kissing stents to reestablish vessel patency with residual stenosis of <30%. Early (30-day) medical complications included death, myocardial infarction, dysrhythmia, respiratory failure, and acute renal insufficiency (>50% decrease in the estimated glomerular filtration rate or new-onset dialysis). Surgical complications included arterial access complications, bowel ischemia (requiring surgical resection or intensive medical care), embolization, thrombosis, and wound complications occurring intraoperatively or within 30 days after the primary procedure. Intraoperative iliac ruptures were also recorded.

The follow-up and surveillance protocol included clinical examination with ABI assessment and duplex ultrasonography at 1, 6, and 12 months and then annually. During the 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 the ultrasound findings in the case of symptom recurrence. Primary patency, secondary patency, and limb salvage were defined according to the current reporting standards.[22]

**Treatment.** All interventions were performed by vascular surgeons. Local anesthesia with intravenous sedation or analgesia was usually preferred. Locoregional or general anesthesia was adopted for more complex or hybrid interventions. Bilateral CFA access was always obtained. The access was percutaneous if the CFA was free from significant stenosis, with a noncalcified anterior wall. The preferred access site for iliac recanalization was the ipsilateral CFA. In the case of unsuccessful recanalization from this site, a femoral contralateral or brachial approach was used. Intraluminal recanalization was always attempted, with subintimal recanalization reserved for cases of unsuccessful intraluminal recanalization. After bilateral iliac recanalization, two stents with the same diameter were simultaneously deployed from the distal aorta to the CIAs using ipsilateral femoral access. Balloon-expandable stents were preferentially used for focal and ostial lesions involving only the aortic bifurcation, with self-expanding stents preferred for cases of disease extension into the EIA, especially in the presence of tortuous vessels. BMSs were favored for focal noncalcified stenosis, and CSs were mostly used for long or severely calcified lesions, in presence of thrombus, or after subintimal recanalization.[18] The same type of stent (CS or BMS) was used bilaterally in all cases. The extension of coverage into the infrarenal aorta or EIAs varied according to the disease extension. In general, healthy-to-healthy artery coverage was performed. In the case of concomitant CFA stenosis >50%, CFA endarterectomy with great saphenous or synthetic patch closure was performed. Dual antiplatelet therapy was recommended after the intervention for ≥1 month, followed by long-term single antiplatelet therapy.[1]

**Statistical analysis.** Continuous data are presented as the mean ± standard deviation and median and range and categorical data as the frequencies and percentages. Continuous variables were compared using the Wilcoxon rank sum test or *t* test, as appropriate. The Pearson $\chi^2$ and Fisher exact tests were used for analysis of the categorical variables. The propensity score was estimated using logistic regression. The baseline demographics and anatomic data (ie, occlusion vs stenosis, disease extension into the abdominal aorta or EIA, calcification grade, TASC classification) and center performing the procedure were considered in the initial model. The TASC classification, presence of iliac occlusion, aortic involvement, chronic obstructive pulmonary disease, center performing the procedure, and calcification score were included in the final model and used to create propensity score-matched CS and BMS cohorts (Supplementary Fig 1, online only). The C statistic for this model was 0.925 (95% confidence interval [CI], 0.896-0.954) and yielded a matched cohort of 110 patients treated with kissing CSs and 110 with kissing BMSs.

The primary patency, secondary patency, and limb salvage rates were estimated using Kaplan-Meier curves, and the log-rank test was used to compare the two groups. Univariable and multivariable Cox proportional hazards models were used to assess the association of the covariates with primary patency in both unmatched and matched cohorts. The most parsimonious multivariable model with inclusion of the primary variable of interest (stent type: CS vs BMS) and confounders was selected as the final multivariable model. Also, a subgroup analysis was performed to assess the clinical effects of CSs vs BMSs for particular subsets of "complex" lesions, such as TASC class D, lesions with EIA involvement, total occlusions, and lesions with moderate or severe calcification. The R, version 3.5.2, software (R Foundation for Statistical Computing, Vienna, Austria) with the MatchIt package was used for analysis, and $P < .05$ (two-tailed) was considered statistically significant.

## RESULTS

A total of 336 patients were treated with iliac kissing stents for TASC C or D lesions, 201 (60%) with CSs and 135 (40%) with BMSs. The demographics and risk factors are presented in Table I. The CS group was more likely than the BMS group to have critical limb ischemia (41% vs 30%; *P* = .038), a lower ABI at presentation (0.45 ± 0.15 vs 0.49 ± 0.14; *P* = .014), TASC class D lesions (90% vs 56%; *P* = .006), disease extension into the distal aorta (23% vs 7%; *P* < .001), iliac occlusion (59% vs 44%; *P* = .005), and more advanced iliac calcifications (*P* = .027; Table II). After propensity score matching, 220 patients were selected (110 with CSs and 110 with BMSs), without differences in the clinical presentation (critical limb ischemia, 41% vs 33%; *P* = .167), TASC classification (TASC D, 66% vs 60%; *P* = .211), lesion type (occlusion, 48% vs 49%; *P* = .893), aortic involvement (11% vs 6%; *P* = .230), or grade of iliac calcifications (*P* = .195).

Percutaneous access was used for most patients (unmatched, 69% vs 75%, *P* = .260; matched, 68% vs 74%; *P* = .296). Overall, femoral surgical access was performed for concomitant endarterectomy in 77 patients (80%) and unsuitable percutaneous access in 19 (20%). The preferred access site was the CFA, and patients treated with CSs had more frequently required brachial access for recanalization in the unmatched cohort (unmatched, 16% vs 5%, *P* = .003; matched, 10% vs 5%, *P* = .193; Table III).

Patients in the CS group more often received self-expanding stents than balloon-expandable stents (unmatched, 72% vs 59%, *P* = .018; matched, 74% vs 58%, *P* = .016) and required subintimal iliac recanalization (unmatched, 26% vs 12%, *P* = .002; matched, 25% vs 14%, *P* = .040). The stent diameter (unmatched, 8.3 ± 1.4 mm vs 8.3 ± 1.2 mm, *P* = .844; matched, 8.3 ± 1.5 mm vs 8.4 ± 1.3 mm, *P* = .742), length of coverage (right side, unmatched, 9.9 ± 4.9 cm vs 9.3 ± 4.9 cm, *P* = .230; right side, matched, 9.7 ± 4.9 cm vs 9.3 ± 5.1 cm, *P* = .541; left side, unmatched, 9.9 ± 5.5 vs 9.0 ± 4.4, *P* = .124; matched, 9.5 ± 5.6 vs 8.9 ± 4.4, *P* = .380), and the necessity for associated thrombolysis or CFA endarterectomy were similar between the two groups.

The technical success rate was 99% (unmatched, 100% vs 99%, *P* = .083; matched, 100% vs 100%, *P* = 1.00) and the 30-day mortality was 0% (Table IV). Five intraoperative iliac ruptures (2.9%) occurred after subintimal recanalization (n = 1) or BMS implantation (n = 4), all of which were managed with deployment of kissing CSs. On an intention-to-treat basis, arterial rupture was more frequent after the use of BMSs (0% vs 3.5%; *P* = .013). The early medical (unmatched, 5% vs 4%, *P* = 1.00; matched, 5% vs 4%, *P* = .748) and surgical (unmatched, 5% vs 5%, *P* = 1.00; matched, 5% vs 3%, *P* = .721) complication rates were similar between the CS and BMS groups. Most surgical complications were access artery dissection (unmatched, 2% vs 3%, *P* = .712; matched, 2% vs 1%, *P* = 1.00) or pseudoaneurysm (unmatched, 2% vs 1%, *P* = .737; matched, 3% vs 1%; *P* = .622). Two cases of intraoperative embolization occurred (one to the hypogastric artery and one to the lower limb) in the BMS group. The postoperative ABI (unmatched, 0.86 ± 0.17 vs 0.84 ± 0.16, *P* = .279; matched, 0.88 ± 0.17 vs 0.83 ± 0.15, *P* = .022) and ABI improvement (unmatched, 0.40 ± 0.29 vs 0.34 ± 0.25, *P* = .048; matched, 0.43 ± 0.22 vs 0.36 ± 0.24, *P* = .025) were significantly greater after deployment of CSs compared with BMSs.

The mean follow-up was 16 ± 11 months. The overall primary patency rate was 89% ± 7% in the unmatched cohort and 92% ± 6% in the matched cohort after 36 months. The 3-year estimated primary patency (unmatched, 91% ± 6% vs 93% ± 6%, *P* = .29; matched, 92% ± 7% vs 92% ± 8%, *P* = .38; Fig 1), secondary patency (unmatched, 99% ± 2% vs 98% ± 4%, *P* = .30; matched, 98% ± 3% vs 98% ± 4%, *P* = .50), and limb salvage (unmatched, 95% ± 5% vs 97% ± 4%, *P* = .20; matched, 93% ± 9% vs 97% ± 5%, *P* = .20) rates were similar between the CS and BMS groups. The subgroup analyses found no significant differences in the primary patency rates in the subset of TASC D lesions (unmatched, 90% ± 8% vs 92% ± 8%, *P* = .48; matched, 94% ± 6% vs 92% ± 9%, *P* = .67; Fig 2, *A* and *B*), lesions with aortic (unmatched, 89% ± 15% vs 100% ± 0%, *P* = .60; matched, 92% ± 14% vs 100% ± 0%, *P* = .40) or EIA (unmatched, 94% ± 9% vs 89% ± 11%, *P* = .50; matched, 92% ± 14% vs 88% ± 11%, *P* = .60) involvement, and iliac occlusion (unmatched, 89% ± 8% vs 95% ± 8%, *P* = .30; matched, 91% ± 7% vs 95% ± 8%, *P* = .30). For patients with moderate or severe iliac calcifications, CSs showed better results after propensity-score matching (unmatched, 93% ± 8% vs 91% ± 9%, *P* = .81; matched, 100% vs 89% ± 9%, *P* = .048; Fig 2, *C* and *D*).

Active smoking (hazard ratio [HR], 4.18; 95% CI, 1.33-13.19; *P* = .014), dialysis (HR, 12.01; 95% CI, 1.48-97.06; *P* = .020), aortic thrombosis (HR, 7.21; 95% CI, 1.00-55.26; *P* = .049), subintimal recanalization (HR, 3.13; 95% CI, 1.13-8.67; *P* = .028), and length of coverage (HR, 1.13; 95% CI, 1.04-1.23, *P* = .007) were significantly associated with a loss of patency in the unmatched cohort (Supplementary Table I, online only). Increasing age (HR, 0.94; 95% CI, 0.89-0.98; *P* = .014), hypertension (HR, 0.30; 95% CI, 0.11-0.89; *P* = .024), and larger kissing stent diameter (HR, 0.67; 95% CI, 0.10-0.72; *P* = .039) were protective from loss of patency. The use of a stent diameter of ≥8 mm

**Table I.** Baseline demographics and risk factors in matched and unmatched cohorts (N = 336)

| | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| Variable | CS (n = 201) | BMS (n = 135) | *P* value | BMS (n = 110) | CS (n = 110) | *P* value |
| Male sex | 145 (72.1) | 96 (71.1) | .837 | 76 (69.1) | 78 (70.9) | .769 |
| Age, years | | | .663 | | | .662 |
| Mean ± SD | 68.2 ± 9.9 | 67.8 ± 9.9 | | 68.7 ± 9.8 | 68.2 ± 9.9 | |
| Range | 39-88 | 41-96 | | 39-88 | 44-96 | |
| Hypertension | 171 (85.1) | 113 (83.7) | .733 | 94 (85.5) | 92 (83.6) | .709 |
| Hyperlipidemia | 149 (74.1) | 99 (73.3) | .871 | 80 (72.7) | 85 (77.3) | .436 |
| Diabetes | 48 (23.9) | 45 (33.3) | .058 | 31(28.2) | 39 (35.5) | .247 |
| CAD | 64 (31.8) | 51 (37.8) | .261 | 32 (29.1) | 42 (38.2) | .154 |
| COPD | 64 (31.8) | 65 (48.1) | **.003** | 34 (30.9) | 46 (41.8) | .123 |
| Active smoke | 88 (43.8) | 55 (40.7) | .581 | 43 (39.1) | 45 (40.9) | .783 |
| CKD | | | **.036** | | | .192 |
| No | 183 (91.0) | 110 (81.5) | | 100 (90.9) | 91 (82.7) | |
| Yes | 16 (8.0) | 22 (16.3) | | 8 (7.3) | 16 (14.5) | |
| Dialysis | 2 (1.0) | 3 (2.2) | | 2 (1.8) | 3 (2.7) | |

*BMS,* Bare metal stent; *CAD,* coronary artery disease; *CKD,* chronic kidney disease; *COPD,* chronic obstructive pulmonary disease; *CS,* covered stent; *SD,* standard deviation.
Data presented as number (%), unless otherwise noted. Boldface *P* values represent statistical significance.

was protective (HR, 0.26; 95% CI, 0.10-0.72; *P* = .010) against stent failure during follow-up. Older age (HR, 0.97; 95% CI, 0.88-0.99; *P* = .042), dialysis (HR, 12.51; 95% CI, 1.43-108.8; *P* = .022), active smoking (HR, 1.17; 95% CI, 1.05-1.30; *P* = .005), length of coverage (HR, 1.13; 95% CI, 1.01-1.26; *P* = .028) were also significantly associated with primary patency in the matched cohort, as was a stent diameter of ≥8 mm (HR, 0.26; 95% CI, 0.08-0.90; *P* = .033).

The multivariable Cox regression analysis (Table V) in the propensity-matched cohort showed that older age (HR, 0.93; 95% CI, 0.87-0.99; *P* = .33) and stent diameter of ≥8 mm (HR, 0.25; 95% CI, 0.07-0.90; *P* = .034) were significant predictors of primary patency, independent of the type of stent (HR, 1.67; 95% CI, 0.44-6.41; *P* = .449). Multivariate analysis also showed that the stent type had no significant effects on secondary patency (HR, 1.60; 95% CI, 0.13-18.73; *P* = .707) or limb salvage (HR, 1.93; 95% CI, 0.18-20.51; *P* = .583; Supplementary Table II, online only).

## DISCUSSION

In recent years, an evolution has occurred in the treatment of aortoiliac obstructive disease, with an increased use of endovascular techniques for more challenging disease and more frequent use of CSs. Similar to others' experience,[2-6] previous data from the same multicenter registry[18] have confirmed this tendency, showing that the complexity of the treated pathology has increased throughout the years and that more complex aortoiliac lesions were predominately treated with CSs. Although this strategy appears reasonable from the clinical standpoint and reflects a worldwide tendency, it could also represent a selection bias, limiting a fair comparisons between CSs and BMSs in contemporary nonrandomized series. Therefore, we performed a propensity score-matched comparison of CSs vs BMSs to account for different baseline characteristics. This led to balanced groups in terms of the preoperative clinical and anatomic characteristics. Some procedural differences persisted in the matched cohort. However, these likely reflected the different approaches to the procedure with CS use, which depends on the specific device characteristics (profile, diameter, and length; availability of specific CS types at each center) and operator preference for specific intraoperative circumstances (ie, subintimal recanalization). The results from the present study showed no significant differences between the use of CSs and BMSs in the early complication rate. However, the postoperative ABI (*P* = .022) and hemodynamic improvement (*P* = .025) were significantly better in the CS group, in line with a recent meta-analysis of CSs vs BMSs.[23] Although it might not be considered clinically significant, this difference might be the sign of a higher grade of subclinical residual stenosis after the use of BMSs, likely a consequence of more aggressive stent dilatation with a reduced risk of rupture when a CS is used. An additional consistent observation in the present series was that iliac rupture was significantly less frequent after the use of CSs (*P* = .013). The low number of events did not allow for further analysis of this aspect; however, it could be of particular importance in presence of heavily

**Table II.** Clinical presentation and anatomic factors in matched and unmatched cohorts (N = 336)

| Variable | Unmatched cohort CS (n = 201) | Unmatched cohort BMS (n = 135) | Unmatched cohort *P* value | Matched cohort BMS (n = 110) | Matched cohort CS (n = 110) | Matched cohort *P* value |
|---|---|---|---|---|---|---|
| Clinical characteristics | | | | | | |
| Rutherford category | | | .178 | | | .505 |
| 3 | 119 (59.2) | 95 (70.4) | | 65 (59.1) | 74 (67.3) | |
| 4 | 57 (28.4) | 25 (18.5) | | 26 (23.6) | 23 (20.9) | |
| 5-6 | 25 (10.5) | 15 (11.1) | | 19 (17.3) | 13 (11.8) | |
| Preoperative ABI | | | **.014** | | | .307 |
| Mean ± SD | 0.45 ± 0.15 | 0.49 ± 0.14 | | 0.45 ± 0.14 | 0.47 ± 0.15 | |
| Range | 0-0.8 | 0-0.8 | | 0-0.8 | 0-0.8 | |
| Previous iliac treatment | 25 (12.4) | 9 (6.7) | .085 | 12 (10.9) | 7 (6.4) | .230 |
| Anatomic factors | | | | | | |
| TASC II classification | | | **.006** | | | .211 |
| C | 60 (29.9) | 60 (44.4) | | 37 (33.6) | 44 (40.0) | |
| D | 141 (90.1) | 75 (55.6) | | 73 (66.4) | 66 (60.0) | |
| Aortic involvement | 47 (23.4) | 9 (6.7) | **<.001** | 12 (10.9) | 7 (6.4) | .230 |
| EIA involvement | 97 (48.3) | 57 (42.2) | .276 | 51 (46.4) | 52 (47.3) | .893 |
| Aortic thrombosis | 5 (2.5) | 0 (0) | .085 | 1 (0.9) | 0 (0) | .316 |
| Iliac occlusion | 119 (59.2) | 59 (43.7) | **.005** | 53 (48.2) | 54 (49.1) | .893 |
| Calcification grade | | | **.027** | | | .195 |
| None | 17 (8.5) | 4 (3.0) | | 8 (7.3) | 4 (3.6) | |
| Mild | 77 (38.3) | 52 (38.5) | | 40 (36.4) | 46 (41.8) | |
| Moderate | 56 (27.9) | 54 (40.0) | | 33 (30.0) | 41 (37.3) | |
| Severe | 51 (25.4) | 25 (18.5) | | 29 (26.4) | 19 (17.2) | |

*ABI*, Ankle-brachial index; *BMS*, bare metal stent; *CS*, covered stent; *EIA*, external iliac artery; *SD*, standard deviation; *TASC*, TransAtlantic Inter-Society Consensus (classification).
Data presented as number (%), unless otherwise noted. Boldface *P* values represent statistical significance.

calcified or small vessels, supporting the commonly adopted strategy of using CSs for these types of lesions.

In the present real-word registry study, excellent 36-month primary patency (89% ± 7%), secondary patency (98% ± 2%), and limb salvage (96% ± 3%) rates were achieved in the overall cohort. These results are similar to those from the largest series of open surgical reconstruction with aortobifemoral bypass, reporting 86% primary patency at 3 years and 76% to 82% primary patency at 5 years.[24,25] The overall primary patency was not significantly different between the CS and BMS groups. This outcome was maintained in the subset of patients with more complex lesions, such as TASC D lesions, chronic occlusions, or aortic involvement. The high flow, large arterial diameter, relatively straight anatomy, and lower mechanical stress related to hip movement can be protective from restenosis in this anatomic area compared with the CIAs and EIAs.[26,27] However, CSs showed significantly better primary patency ($P = .048$) in iliac lesions with moderate or severe calcifications.

Overall, these results seem to support the use of kissing CSs for more advanced iliac lesions of the aortic bifurcation. CSs allow for more efficient dilatation, without the risk of intraoperative rupture, thus eliminating noncritical residual stenosis that could be still the cause of a loss of patency during follow-up owing to disease progression. However, given the generally higher costs and higher device profile compared with BMSs, the routine use of CSs should not be recommended, with their use reserved for lesions with moderate to severe calcifications. Although this represents a specific disease subset, data from our real-word registry showed that these disease characteristics are present in >50% of TASC C and D lesions involving the aortic bifurcation. Furthermore, in our clinical practice, we have routinely used CSs after subintimal recanalization. Also, we have always used a self-expanding CS when coverage of the EIA is required. In particular, in the case of extensive disease involving the aortic bifurcation and the entire iliac axis, a possibly advantageous conformation that has recently been described consists of the use of kissing new-generation balloon-expandable CSs to treat the aortic bifurcation, followed by deployment of a self-expandable stent in the EIA.[28]

Another important factor to consider is the stent diameter, which was associated with both primary and secondary patency in the present study. In particular, our

**Table III.** Procedural factors in matched and unmatched cohorts (N = 336)

| | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| Variable | CS (n = 201) | BMS (n = 135) | *P* value | BMS (n = 110) | CS (n = 110) | *P* value |
| Access for recanalization | | | **<.001** | | | **<.001** |
| Femoral, ipsilateral | 120 (59.7) | 58 (42.9) | | 77 (70) | 47 (42.7) | |
| Femoral, contralateral | 49 (24.4) | 70 (51.9) | | 22 (20.0) | 58 (52.7) | |
| Brachial | 32 (15.9) | 7 (5.2) | | 11 (10.0) | 5 (4.5) | |
| Surgical access | 62 (30.8) | 34 (25.2) | .260 | 35 (31.8) | 28 (25.5) | .296 |
| Self-expanding stent | 144 (71.6) | 80 (59.3) | **.018** | 81 (73.6) | 64 (58.2) | **.016** |
| Stent diameter, mm | | | .844 | | | .742 |
| Mean ± SD | 8.3 ± 1.4 | 8.3 ± 1.2 | | 8.3 ± 1.5 | 8.4 ± 1.3 | |
| Range | 6-13 | 6-13 | | 6-13 | 6-13 | |
| Stent diameter <8 mm | 51 (25.4) | 31 (23.0) | .679 | 28 (25.5) | 25 (22.3) | .753 |
| Length of coverage, cm | | | | | | |
| Right | | | .230 | | | .541 |
| Mean ± SD | 9.9 ± 4.9 | 9.3 ± 4.9 | | 9.7 ± 4.9 | 9.3 ± 5.1 | |
| Range | 3.7-25 | 2.6-26 | | 3.7-25 | 3-25 | |
| Left | | | .124 | | | .380 |
| Mean ± SD | 9.9 ± 5.5 | 9.0 ± 4.4 | | 9.5 ± 5.6 | 8.9 ± 4.4 | |
| Range | 3.7-25 | 2.6-26 | | 3.7-25 | 3-25 | |
| Subintimal recanalization | 52 (25.9) | 16 (11.9) | **.002** | 27 (24.5) | 15 (13.6) | **.040** |
| Associated procedures | | | | | | |
| CFA endarterectomy | 49 (24.4) | 28 (20.7) | .508 | 29 (26.4) | 25 (22.7) | .638 |
| Thrombolysis | 5 (2.5) | 4 (3.0) | .791 | 2 (1.8) | 3 (2.7) | .651 |

*ABI,* Ankle-brachial index; *BMS,* bare metal stent; *CFA,* common femoral artery; *CS,* covered stent; *SD,* standard deviation.
Data presented as number (%), unless otherwise noted. Boldface *P* values represent statistical significance.

analysis highlighted that a minimum 8-mm diameter has a protective role against occlusion and restenosis and, therefore, should be preferred whenever possible, including cases of narrow aortic bifurcation. In these cases, the use of covered kissing stents could also be advantageous to avoid the risk of rupture and achieve optimal dilatation. Consistent results have been previously reported for endovascular interventions of the CIA and EIA.[26]

Although the general results of kissing stent revascularization have been good, some anatomic situations deserve particular attention. The presence of aortic thrombus extending toward the renal arteries represents an unfavorable scenario compared with simple atherosclerotic disease involving the aortic bifurcation. This might be associated with a substantial risk of embolization and renal function deterioration when treated using endovascular methods[29]; thus, open aortobifemoral bypass should be preferred as the first-line approach. Only five cases with aortic thrombosis were treated in the present series, indicating that open surgery or other alternative endovascular options (covered endovascular reconstruction of the aortic bifurcation technique or the use of low-profile endografts) were the treatment of choice in the participating centers. However, it was interesting to note that the loss of patency had occurred in four of the five cases (HR, 7.21; $P = .049$), discouraging the use of the kissing stent technique in this situation.

Also, age was an important variable associated with patency on multivariable analysis, in the matched and unmatched cohorts both. This result was consistent with the findings from a meta-analysis by Groot Jebbink et al[8] of 605 patients from 22 different studies treated with iliac kissing stents. Similar results were also described in large series that had included other types of iliac endovascular procedures.[30-32] One possible explanation is that older patients will typically have a shorter life expectancy; therefore, death for unrelated reasons will usually occur before any stent complications have developed. Also, atherosclerotic disease presenting in young patients could be more aggressive and lead to a greater risk of stent thrombosis or restenosis.[31] However, we believe this finding should not be interpreted as a reason to exclude young patients from the benefits of endovascular treatment if an endovascular approach will not compromise future open surgical options. Also, good early and midterm outcomes have been reported for young and low-risk patients.[33]

**Table IV.** Early (30-day) outcomes in matched and unmatched cohorts (N = 336)

| Outcome | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| | CS (n = 201) | BMS (n = 135) | *P* value | BMS (n = 110) | CS (n = 110) | *P* value |
| Technical success | 201 (100) | 133 (98.5) | .083 | 110 (100) | 110 (100) | 1.00 |
| Postoperative ABI | | | .279 | | | **.022** |
| Mean ± SD | 0.86 ± 0.17 | 0.84 ± 0.16 | | 0.88 ± 0.17 | 0.83 ± 0.15 | |
| Range | 0.4-1 | 0.3-1.1 | | 0.4-1 | 0.3-1.1 | |
| ABI increase | | | **.048** | | | **.025** |
| Mean ± SD | 0.40 ± 0.29 | 0.34 ± 0.25 | | 0.43 ± 0.22 | 0.36 ± 0.24 | |
| Range | 0-1 | 0-1 | | 0-1 | 0-1 | |
| Mortality | 0 (0) | 0 (0) | 1.00 | 0 (0) | 0 (0) | 1.00 |
| Early thrombosis | 3 (1.5) | 1 (0.7) | .527 | 1 (0.9) | 1 (0.9) | 1.00 |
| Early amputation | 1 (0.5) | 1 (0.7) | .782 | 0 (0) | 0 (0) | 1.00 |
| Surgical complications | 11 (5.4) | 7 (5.2) | 1.00 | 5 (4.5) | 3 (2.7) | .721 |
| Pseudoaneurysm | 5 (2.4) | 1 (0.7) | .407 | 3 (2.7) | 1 (0.9) | .622 |
| Artery dissection | 4 (1.9) | 4 (2.9) | .712 | 2 (1.8) | 1 (0.9) | 1.00 |
| Embolization | 0 (0) | 2 (1.5) | .160 | 0 (0) | 1 (0.9) | 1.00 |
| Wound dehiscence | 2 (0.9) | 0 (0) | .518 | 0 (0) | 0 (0) | 1.00 |
| Systemic complications | 10 (4.9) | 6 (4.4) | 1.00 | 6 (5.4) | 4 (3.6) | .748 |
| Respiratory insufficiency | 2 (0.9) | 1 (0.7) | 1.00 | 1 (0.9) | 1 (0.9) | 1.00 |
| Renal failure | 4 (1.9) | 3 (2.2) | 1.00 | 2 (1.8) | 2 (1.8) | 1.00 |
| Myocardial infarction | 2 (0.9) | 1 (0.7) | 1.00 | 1 (0.9) | 1 (0.9) | 1.00 |
| Dysrhythmia | 2 (0.9) | 1 (0.7) | 1.00 | 1 (0.9) | 0 (0) | 1.00 |

*ABI,* Ankle-brachial index; *BMS,* bare metal stent; *CS,* covered stent; *SD,* standard deviation.
Data presented as number (%), unless otherwise noted. Boldface *P* values represent statistical significance.

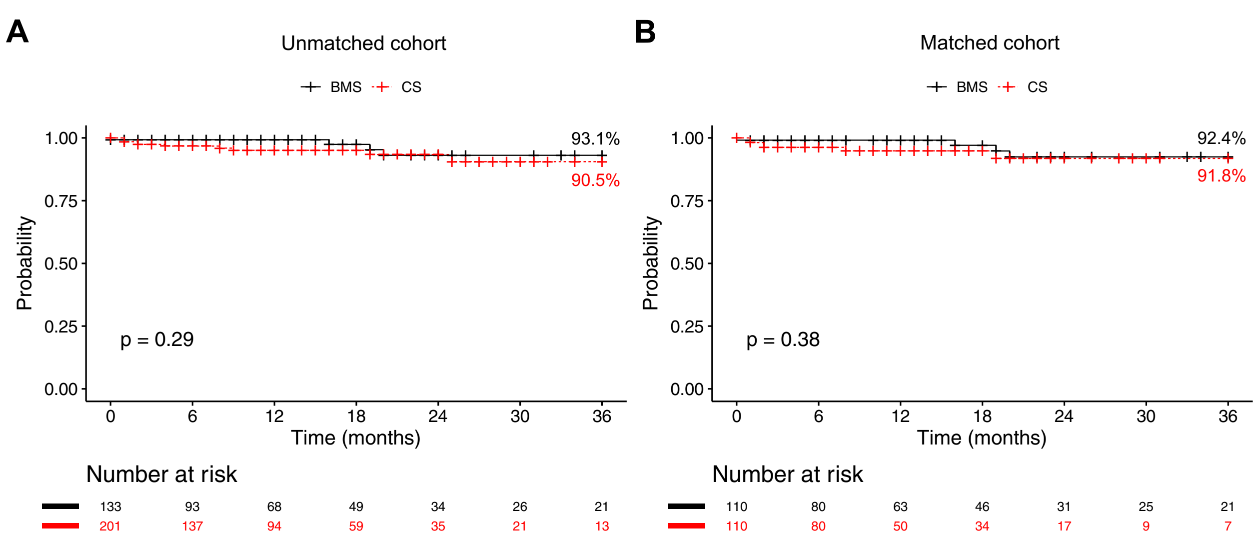


**Fig 1. A,** Overall Kaplan-Meier estimates of primary patency at 3 years in the unmatched cohort of patients receiving kissing covered stents (*CSs*) or bare metal stents (*BMSs*). Standard error <10%. **B,** Overall Kaplan-Meier estimates of primary patency at 3 years in the matched cohort of patients receiving kissing CSs or BMSs. Standard error <10%.

The present study had some notable limitations. The study was retrospective, with a limited follow-up period. Also, the decisions regarding the indication for surgery, surgical technique, materials, and perioperative patient management were not standardized but differed among the treating surgeons and centers. Detailed

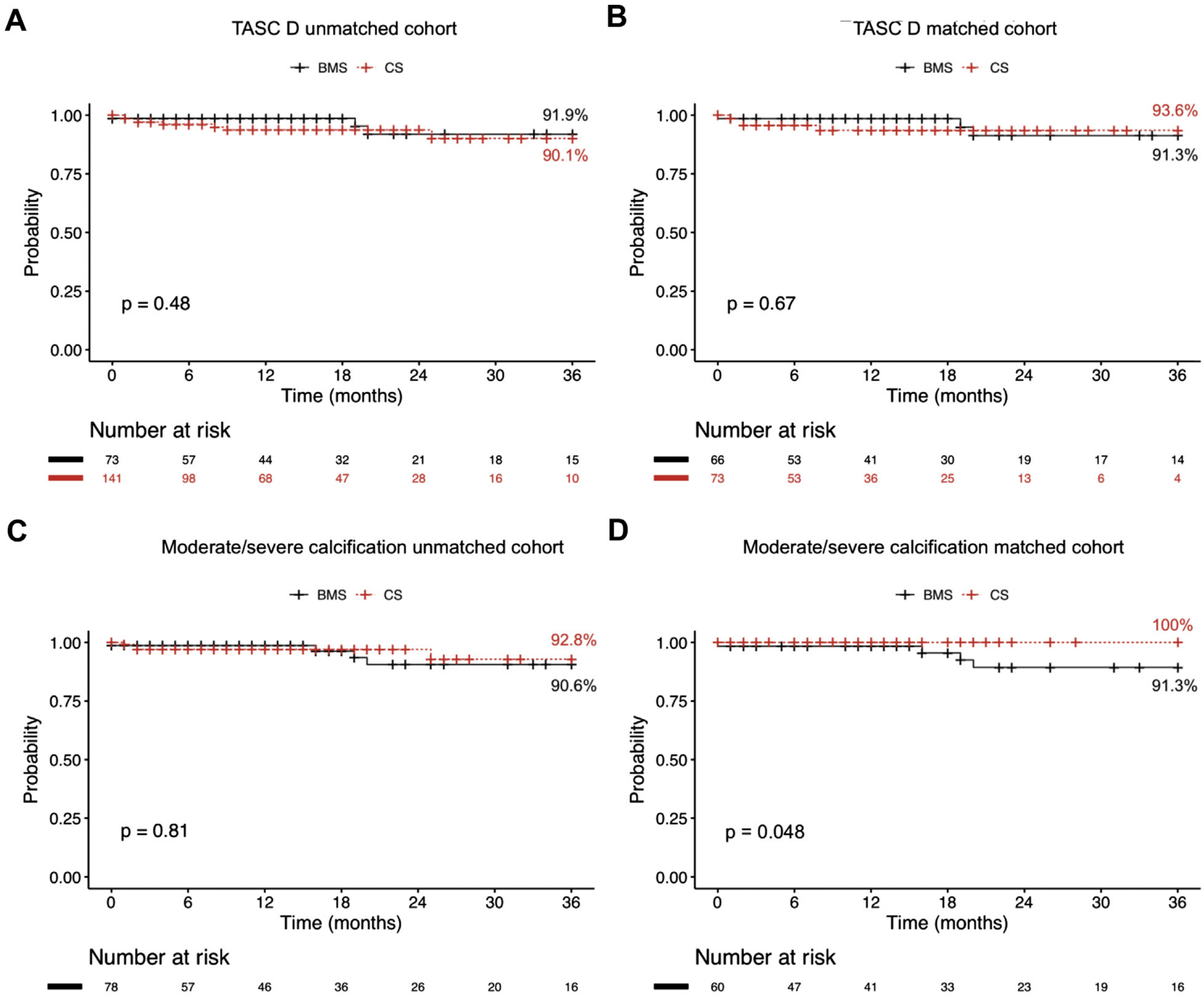


**Fig 2. A,** Kaplan-Meier estimates of primary patency at 3 years in the unmatched cohort of patients with TransAtlantic Inter-Society Consensus (*TASC*) D lesions receiving kissing covered stent (*CSs*) or bare metal stent (*BMSs*). Standard error <10%. **B,** Kaplan-Meier estimates of primary patency at 3 years in the matched cohort of patients with TASC D lesions receiving kissing CSs or BMSs. Standard error <10%. **C,** Kaplan-Meier estimates of primary patency at 3 years in the unmatched cohort of patients with moderate or severe iliac calcifications receiving kissing CSs or BMSs. Standard error <10%. **D,** Kaplan-Meier estimates of primary patency at 3 years in the matched cohort of patients with moderate or severe iliac calcifications receiving kissing CSs or BMSs. Standard error <10%.

technical and geometric data on the kissing stent configuration, which could have affected the patency rates, were not available. Also, information on the level of aortic disease in relation to the renal arteries was not collected. Even if the baseline differences between the CS and BMS groups in disease severity reflected real-word practice, these acted as confounders, limiting the statistical analysis, because CSs were predominantly used for those with more advanced disease. Some of these differences could have persisted after matching and not have been evident because of the smaller sample size. Also, some unmeasured confounders could have been present. Thus, our results might have underestimated the benefit of CSs compared with BMS. Also, the results found in the matched cohort might not be fully generalizable to the general population. However, the propensity scores were effectively balanced between the two groups. Also, we have provided the results for the unmatched and matched cohorts both to allow for a clearer interpretation. It was possible to perform a multivariate analysis of the matched populations to adjust for confounders that could have persisted after matching. The study was also strengthened by the multicenter design, prospective data collection, and large number of patients, representing, to the best of our knowledge, the largest contemporary series of aortoiliac obstructive disease treated with kissing stents.

**Table V.** Final multivariable models of Cox proportional hazards for primary patency in matched and unmatched cohorts (N = 336)

| | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| Variable | HR | 95% CI | *P* value | HR | 95% CI | *P* value |
| Covered stent | 2.81 | 0.80-9.84 | .106 | 1.67 | 0.44-6.41 | .449 |
| Age, years | 0.93 | 0.88-0.98 | **.005** | 0.93 | 0.87-0.99 | **.033** |
| Aortic involvement | 0.45 | 0.11-1.85 | .110 | NA | NA | NA |
| Stent diameter ≥8 mm | 0.25 | 0.08-0.73 | **.001** | 0.25 | 0.07-0.90 | **.034** |

*CI,* Confidence interval; *HR,* hazard ratio; *NA,* not applicable.
Boldface *P* values represent statistical significance.

## CONCLUSIONS

In the present multicenter registry, the use of kissing stents for the treatment of the aortic bifurcation provided good early and midterm results. CSs were preferred for more complex lesions, were protective against iliac rupture, and allowed for greater postoperative hemodynamic improvement. After propensity score matching, the 3-year patency rates were similar overall between the kissing CSs and BMSs. However, the CSs showed improved outcomes in the presence of moderate or severe iliac calcifications. Younger age and the use of a kissing stent diameter <8 mm were associated with loss of patency, independently of the type of stent. Further studies with more comparable baseline populations might be required to investigate the role of stent type in the outcomes of aortoiliac revascularization with kissing stents.

## AUTHOR CONTRIBUTIONS

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

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## APPENDIX (online only).

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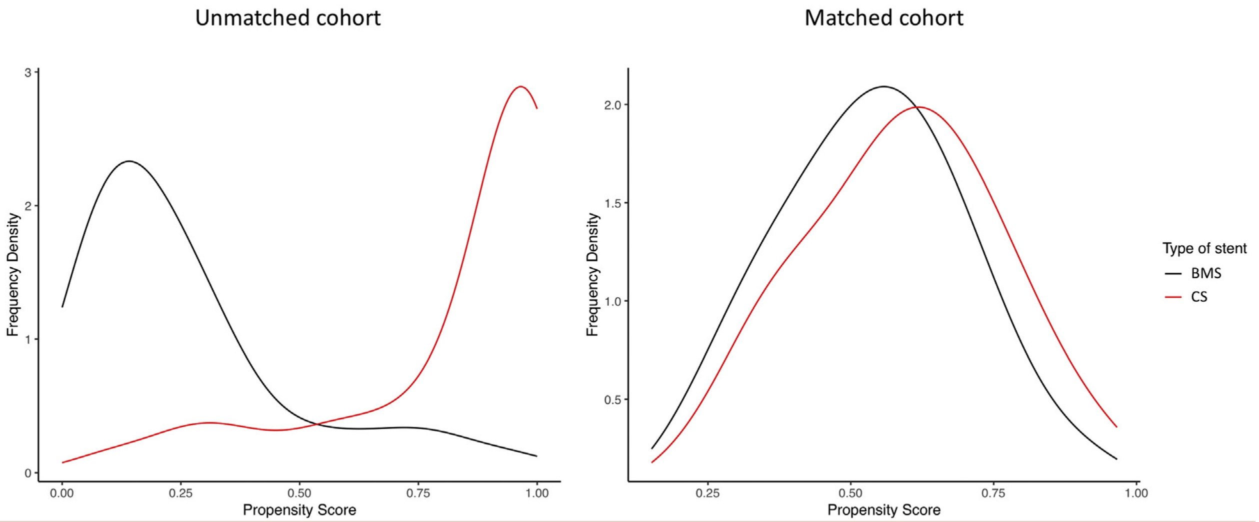


**Supplementary Fig 1 (online only).** Frequency density distribution of the propensity scores in the unmatched and matched populations. Note the apparent improvement of the overlap between the covered stent (*CS*) and bare metal stent (*BMS*) groups in the matched cohort.

**Supplementary Table I (online only).** Univariate Cox proportional hazards for primary patency in matched and unmatched cohorts (n = 336)

| | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| | HR | 95% CI | *P* value | HR | 95% CI | *P* value |
| Clinical factors | | | | | | |
| Year of treatment | 1.04 | 0.57-1.87 | .908 | 1.07 | 0.55-2.08 | .356 |
| Age | 0.94 | 0.89-0.98 | **.014** | 0.97 | 0.88-0.99 | **.042** |
| Female sex | 0.38 | 0.09-1.72 | .212 | 0.58 | 0.12-2.74 | .154 |
| Hypertension | 0.30 | 0.11-0.86 | **.024** | 0.43 | 0.12-1.47 | .224 |
| Hyperlipidemia | 0.45 | 0.16-1.26 | .109 | 0.20 | 0.06-0.71 | **.012** |
| CKD | 0.45 | 0.07-3.43 | .441 | 0.67 | 0.09-5.27 | .701 |
| Dialysis | 12.01 | 1.48-97.06 | **.020** | 12.51 | 1.43-108.8 | **.022** |
| COPD | 1.13 | 0.41-3.21 | .805 | 1.77 | 0.51-6.12 | .365 |
| Active smoker | 4.18 | 1.33-13.19 | **.014** | 1.17 | 1.05-1.30 | **.005** |
| Former smoker | 0.70 | 0.22-2.21 | .544 | 1.11 | 0.31-3.93 | .875 |
| Diabetes | 0.19 | 0.03-1.44 | .109 | 0.25 | 0.04-1.97 | .189 |
| CAD | 0.47 | 0.14-1.69 | .253 | 0.51 | 0.11-2.44 | .406 |
| Rutherford 5/6 | 0.61 | 0.08-4.63 | .630 | 0.70 | 0.08-5.52 | .734 |
| Previous iliac treatment | 0.57 | 0.07-4.32 | .583 | 0.00 | NA | NA |
| Anatomic factors | | | | | | |
| Aortic thrombosis | 7.21 | 1.00-55.26 | **.049** | 0.00 | NA | NA |
| TASC D | 1.88 | 0.53-6.69 | .328 | 1.19 | 0.31-4.62 | .803 |
| Aortic involvement | 1.15 | 0.32-4.02 | .829 | 1.11 | 0.14-8.78 | .921 |
| EIA involvement | 0.63 | 0.22-1.86 | .408 | 0.79 | 0.22-2.81 | .720 |
| Iliac occlusion | 1.90 | 0.59-6.06 | .277 | 1.24 | 0.35-4.43 | .745 |
| Severe calcification | 0.67 | 0.23-1.88 | .451 | 1.27 | 0.32-4.98 | .736 |
| Procedural factors | | | | | | |
| Covered stent | 2.19 | 0.69-6.98 | .181 | 1.75 | 0.49-6.23 | .386 |
| Self-expanding stent | 1.19 | 0.37-3.74 | .765 | 2.05 | 0.44-9.64 | .365 |
| Length of coverage | 1.13 | 1.04-1.23 | **.007** | 1.13 | 1.01-1.26 | **.028** |
| Stent diameter | 0.67 | 0.46-0.98 | **.039** | 0.68 | 0.38-1.20 | .183 |
| Stent diameter ≥8 mm | 0.26 | 0.10-0.72 | **.010** | 0.26 | 0.08-0.90 | **.033** |
| Subintimal recanalization | 3.13 | 1.13-8.67 | **.028** | 1.58 | 0.41-6.12 | .509 |
| CFA endarterectomy | 0.42 | 0.09-1.87 | .254 | 0.69 | 0.15-3.27 | .646 |
| Associated thrombolysis | 1.99 | 0.25-15.44 | .508 | 0.00 | NA | NA |

*CAD,* Coronary artery disease; *CFA,* common femoral artery; *CI,* confidence interval; *CKD,* chronic kidney disease; *COPD,* chronic obstructive pulmonary disease; *EIA,* external iliac artery; *HR,* hazard ratio; *NA,* not applicable; *SD,* standard deviation; *TASC,* TransAtlantic Inter-Society Consensus (classification).
Data presented as number (%), unless otherwise noted. Boldface *P* values represent statistical significance.

**Supplementary Table II (online only).** Final multivariate Cox proportional hazards models for secondary patency and limb loss in matched and unmatched cohorts (n = 336)

| Variable | Unmatched cohort | | | Matched cohort | | |
|---|---|---|---|---|---|---|
| | HR | 95% CI | *P* value | HR | 95% CI | *P* value |
| Secondary patency | | | | | | |
| Covered stent | 1.68 | 0.15-19.79 | .672 | 1.60 | 0.13-18.73 | .707 |
| Aortic involvement | 0.46 | 0.04-5.99 | .539 | NA | NA | NA |
| Stent diameter ≥8 mm | 0.12 | 0.01-0.99 | **.048** | 0.14 | 0.01-1.68 | .122 |
| Limb loss | | | | | | |
| Covered stent | 3.12 | 0.36-26.81 | .299 | 1.93 | 0.18-20.51 | .583 |
| Rutherford 5/6 | 13.16 | 2.74-63.10 | **.001** | 27.7 | 2.60-294.9 | **.006** |
| Aortic involvement | 3.49 | 0.72-16.92 | .119 | 8.36 | 1.04-66.82 | **.045** |

*CI*, Confidence interval; *HR*, hazard ratio; *NA*, not applicable.
Boldface *P* values represent statistical significance.