

Comparative outcomes of aortobifemoral bypass with or without previous endovascular kissing stenting of the aortoiliac bifurcation

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ABSTRACT

Objective: The aim of this multicenter national study was to compare the outcomes of primary open surgery by aorto-bifemoral bypass (ABFB) with those performed after a failed endovascular treatment (EVT) by kissing stent technique for complex aortoiliac occlusive disease (AIOD) lesions (TransAtlantic Inter-Society Consensus [TASC] II C and D).

Methods: All consecutive ABFB cases carried out at 12 vascular surgery centers between 2016 and 2021 were retrospectively collected and analyzed. Data included patients' baseline demographics and clinical characteristics, procedural details, perioperative outcomes, and follow-up results (survival, patency, amputation). The study cohort was divided into two groups based on indications for ABFB: primary treatment vs secondary treatment after EVT failure.

Results: Overall, 329 patients underwent ABFB during the study period (71% males; mean age, 64 years), of which 285 were primary treatment and 44 were after prior EVT. At baseline, no significant differences were found between study groups in demographics and clinical characteristics. TASC C and D lesions were similarly represented in the study groups (TASC C: 22% vs 78%; TASC D: 16% vs 84%). No major differences were found between study groups in terms of procedural details, early mortality, and perioperative complications. At 5 years, primary patency rates were significantly higher for primary ABFB (88%; 95% confidence interval [CI], 93.2%-84%) as compared with ABFB after prior EVT (69%; 95% CI 84.9%-55%; log rank *P* value < .001); however, the 5-year rates of secondary patency (100% vs 95%; 95% CI, 100%-86%) and limb salvage (97%; 95% CI, 99%-96 vs 97%; 95% CI, 100%-94%) were similar between study groups.

Conclusions: Surgical treatment of TASC C/D AIOD with ABFB seems to be equally safe and effective when performed after prior EVT, although primary ABFB seemed to have higher primary patency rates. Despite the need for more frequent reinterventions, secondary patency and limb salvage rates were similar. However, future large prospective trials are required to confirm these findings. (*J Vasc Surg* 2024;80:451-8.)

Keywords: Aorto-bifemoral bypass; Aortoiliac disease; Kissing stent; Multicenter

Extensive aortoiliac occlusive disease (AIOD), like TransAtlantic Inter-Society Consensus (TASC) II C and D lesions,¹ may present significant challenges both in open

surgery (OS) and in endovascular treatment (EVT). When the TASC classification first appeared, indication to treatment for C and D lesions was mainly OS by

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aorto-bifemoral bypass (ABFB). However, with the increasing experience, the evolution of techniques and materials, the support of the patients for a less invasive approach, EVT has progressively replaced OS both in simple and complex AIOD lesions. This has led to a paradigm shift in the management of aortoiliac disease that favors less-invasive endovascular/hybrid procedures, with a resultant progressive decrease in total number of OS procedures for extensive AIOD.^{2,3} However, the long-term results of ABFB have remained superior to EVT, at the cost of higher perioperative morbidity and mortality.⁴ Recent international guidelines^{5,6} have issued recommendations for an endovascular-first approach also in complex AIOD, as long as EVT does not compromise a possible future surgical approach, if EVT would fail. However, such recommendations were mainly based on common practice and expert consensus since no specific studies were published.

A large regional cohort study on outcomes of infringuinal bypass has shown that patients with a prior failed endovascular intervention are at higher risk for major adverse limb events and decreased survival after open bypass.⁷ However, a few studies⁸⁻¹⁰ have recently examined the effect of prior aortoiliac endovascular intervention on outcomes after ABFB, with several limitations.

Prior literature has found that femoro-popliteal bypass performed after failure of EVT may show inferior outcomes to first-line surgical therapy; however, whether the same concept may hold true in the aorto-iliac district remains mostly unanswered. Therefore, the aim of this multicenter national study is to provide more evidence to this issue and evaluate whether the outcomes of primary aortoiliac open bypass are different than those after a failed EVT by kissing stent (KS) for complex AIOD lesions (TASC II C and D).

METHODS

Data sources and study design. Between January 2012 and December 2021, all consecutive patients undergoing ABFB for TASC II C and D lesions at 12 Vascular Surgery centers in Italy were retrospectively retrieved. All collected data were merged in a dedicated database for the purpose of all subsequent analyses. All centers applied their own protocols for pre-, intra-, and postoperative evaluation. However, all centers performed at least one follow-up visit within the first 2 months after the index interventions and one follow-up visit with duplex ultrasound examination within the first 2 years after the index intervention. No strict indications were established for perioperative medical care, and the study did not alter local pattern of care. The study cohort was divided according to whether ABFB was performed as the first treatment (group 1) or secondarily after a failed prior KS (group 2). Patients were not included in the present study if one of the following criteria were true: major amputation at index presentation, extra-anatomic

ARTICLE HIGHLIGHTS

- **Type of Research:** Retrospective analysis of collected registry data from a multicenter national database on severe aortoiliac occlusive disease
- **Key Findings:** Aorto-bifemoral bypass surgery was performed in 329 patients, 285 primarily (group 1) and 44 after a failed endovascular treatment (group 2). At 5 years, the primary patency was significantly higher in group 1 vs group 2, although the secondary patency and limb salvage were similar in the two groups.
- **Take Home Message:** An endovascular-first approach for severe aortoiliac occlusive disease may be justified, considering the requirement for more frequent reinterventions in the follow-up and provided a secondary aorto-bifemoral bypass can be later performed if needed.

revascularization, covered endovascular reconstruction of aortic bifurcation or endovascular aneurysm repair before ABFB, and lack of at least 2-year follow-up data after the index operation/intervention (Fig 1). Acute limb ischemia was not considered an exclusion criterion for the present study. Presence of concomitant atherosclerotic disease to the common femoral artery (CFA) and/or profunda femoral artery (PFA) was investigated with preoperative duplex ultrasound and/or computed tomography. All centers applied a similar surgical approach (ie, ensuring good outflow through the CFA/PFA without any significant [75% or more] stenosis). In such cases, concomitant CFA endarterectomy with or without profundoplasty was performed. In cases of mild to moderate CFA/PFA disease, the choice to perform additional distal procedures was left to the operating surgeon's discretion. Approval from the Institutional Ethics Committee as well as patients' informed consent was not needed because of the retrospective design and minimal risk nature of the study.

Study definitions and statistical analysis. The information included demographics, preoperative risk factors, clinical and diagnostic assessments, intraoperative features, and follow-up data. Continuous data were expressed as the mean \pm standard deviation or median with interquartile range (IQR) values if not normally distributed. Categorical data were expressed as percentages. Early (30 days) results in terms of technical success, major adverse event, limb salvage, and mortality were assessed. Early outcomes were analyzed and compared between the two groups with the χ^2 test or Fisher exact test. When necessary, the mean independent-samples *t*-test was used to compare means. The life-table analysis (Kaplan-Meier test with standard error <0.10) was used to evaluate the following

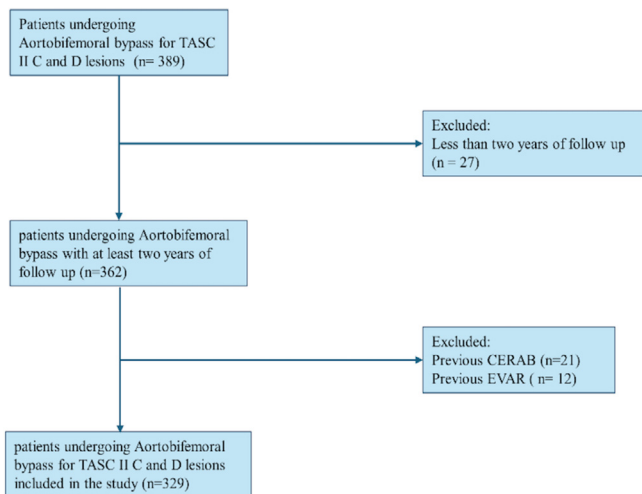


Fig 1. Flowchart of study design. CERAB, Covered endovascular reconstruction of aortic bifurcation; EVAR, endovascular aneurysm repair; TASC, TransAtlantic Inter-Society Consensus.

outcomes: survival, primary patency (defined as no evidence of restenosis, peak systolic velocity ratio ≥ 2.5 , or occlusion based on color-coded duplex sonography), secondary patency (defined as patency maintained by repeat intervention after complete occlusion of the stents or bypass), and limb salvage (defined as absence of major amputation). The two groups were compared with the log-rank test. Estimates were given with the 95% confidence intervals (CIs). In the whole study population, associations of procedure variables with primary patency rates were sought based on a multivariate Cox regression analysis. Results of the regression analysis were presented as the hazard ratio (HR) with the 95% CI. Statistical analysis was performed using SPSS software (version 24.0 for Apple; IBM Corporation).

RESULTS

During the study period, a total of 329 patients underwent ABFB (group 1, $n = 285$; group 2, $n = 44$) (Supplementary Fig 1, online only). The median number of cases per center was 20 (IQR, 13-25). At baseline, no statistically significant differences were observed between groups in age (mean, 65 vs 64 years; $P = .48$), gender distribution (males 71% vs 73%; $P = .91$), and smoking habits (39% vs 50%; $P = .38$). Similarly, most preoperative characteristics did not show any significant differences between groups, as shown in Table I. However, patients in group 1 were significantly less likely to have received an urgent operation as compared with those in group 2 (14% vs 27%; $P = .03$).

The median time from endovascular treatment to surgical regrafting was 20 months (IQR, 12:37) (Supplementary Fig 2, online only). As shown in Table II, the majority of patients presented TASC II D lesions (77% in group 1 and 84% in group 2; $P = .41$) without

any statistically significant differences between the groups in both TASC II C and D lesions. Supra-renal clamping was required in 25% of group 1 and in 34% of group 2 ($P = .17$). Technical success was achieved in 99% of group 1 (4 perioperative limb occlusions) and 100% of group 2.

Table III shows postoperative and follow-up outcomes. Postoperative mortality was very low in both groups (1.5% in group 1 vs 2.3% in group 2; $P = .66$). No statistically significant differences were detected in postoperative surgical or medical complications. The mean follow-up time was 65 months for group 1 vs 68 months for group 2 ($P = .61$).

Kaplan-Meier survival estimates showed no significant differences at 5 years between groups, as shown in Fig 2 (group 1: 91%; 95% CI, 94%-86.6% vs group 2: 91.5%; 95% CI, 98%-83%; $P = .91$) However, primary patency at 5 years was significantly higher in group 1 (88%; 95% CI, 93.2%-84%) as compared with group 2 (69%; 95% CI, 84.9%-55%; $P < .001$) (Fig 3). The Cox proportional hazard model confirmed the association between prior endovascular treatment and loss of primary patency (HR, 2.7; 95% CI, 1.39-5.14; $P < .001$) (Table IV). Nonetheless, no significant differences were observed in 5-year estimates of secondary patency (100% in group 1 vs 95%; 95% CI, 100%-86% in group 2; $P = .51$) (Fig 4) and limb salvage (97%; 95% CI, 99%-96% in group 1 vs 97%; 95% CI, 100%-94%; $P = .37$) (Fig 5). The overall follow-up index was 0.88.

DISCUSSION

Although there are several studies that have cross-compared the outcomes of endovascular management vs OS for treatment of AIOD, only a few⁸⁻¹⁰ have examined in detail the potential effect of prior aortoiliac endovascular intervention (AIEI) on outcomes after ABFB, and none of these have specifically included only the KS technique. The complexity of the present cohort is illustrated by the fact that TASC D AOID was present in 77% and 84% patients in group 1 (no prior KS) and group 2 (prior KS), respectively, and iliac occlusion was present in 79% of group 1 and 84% of group 2, respectively. Moreover, a suprarenal clamp was required in 25% and 34% of group 1 and group 2, respectively, a finding that can be reasonably linked to the extensive atherosclerotic burden at the aortic level. Nonetheless, the 30-day mortality in this cohort was remarkably low (1.4% in group 1 and 2.3% in group 2, respectively): lower than a recently published data¹⁰ from the Vascular Quality Initiative (VQI) database (reported as high as 2.9%), and significantly lower than historical series from 20 to 50 years ago, in which ABF bypass carried a 4.0% to 4.4% operative mortality.^{11,12}

In the present multicenter study, postoperative major adverse event rates were 28.7% in group 1 and 20.4% in group 2, whereas the reintervention rate was 10.5% in

Table I. Demographic characteristics of patients

Variable	Overall (N = 329)	Primary procedure (n = 285)	Secondary procedure (n = 44)	P value
Demographics				
Male gender	235 (71.1)	203 (71)	32 (72.7)	.91
Age, years	64 ± 8	65 ± 8	64 ± 8	.48
Age >79 years	9 (2.7)	9 (3.2)	0 (0)	.23
Body mass index, kg/m ²	25±3	25±3	25±3	.96
Obesity	45 (13.7)	38 (13.3)	7 (15.9)	.64
Smoking habits	82 (24.9)	72 (25.3)	10 (22.7)	.38
No	113 (34.3)	101 (35.4)	12 (27.3)	
Previous ongoing	134 (40.7)	112 (39.3)	22 (50)	
Dislipidemia	200 (60.8)	169 (59.3)	31 (70.5)	.15
Diabetes	90 (27.4)	80 (28.1)	10 (22.7)	.46
Hypoalbuminemia	50 (15.2)	41 (14.4)	9 (20.5)	.29
Anemia	89 (27.1)	80 (28.1)	9 (20.5)	.29
SVS score	0.7±0.4	0.7±0.5	0.7±0.4	.62
Urgent setting	53 (16.1)	41 (14.4)	12 (27.3)	.03
Indication				.59
Claudication	181 (55)	155 (54.4)	26 (59.1)	
Rest pain	111 (33.7)	96 (33.7)	15 (34.1)	
Tissue loss	37 (11.2)	34 (11.9)	3 (6.8)	
Medications				
Acetylsalicylic acid	232 (70.5)	199 (69.8)	33 (75)	.49
Clopidogrel	66 (20.1)	53 (18.6)	13 (29.5)	.09
Warfarin	26 (7.9)	23 (8.1)	3 (6.8)	.77
Direct oral anticoagulants	8 (2.4)	6 (2.1)	2 (4.5)	.32
Statins	195 (59.3)	164 (57.5)	31 (70.5)	.10

SVS, Society for Vascular Surgery.
Data are presented as number (%) or mean ± standard deviation.
Boldface P values indicate statistical significance.

group 1 and 11.4% in group 2. A small percentage of patients were lost to follow-up (only 4.6% in group 1), and the mean follow-up time was longer than 5 years in both groups, therefore making estimates of long-term durability clinically reliable.

Conflicting results are reported in the few available studies analyzing the effect of previous aortoiliac endovascular intervention on outcomes of subsequent ABFB. In a single center 30-year experience of 359 ABFB patients, comparing the results of the historical cohort (1995-1999) with the contemporary cohort (2000-2015), Sharma et al⁸ found that contemporary cohort, decreasing age, prior aortic surgery, and decreasing graft diameter were significant independent predictors of loss of primary patency after adjustment, and not prior endovascular interventions. In another

Table II. Anatomical and procedural characteristics of patients

Variable	Overall (N = 329)	Primary procedure (n = 285)	Secondary procedure (n = 44)	P value
Anatomical characteristics				
TASC				
C	71 (21.5)	64 (22.4)	7 (15.9)	.41
D	258 (78.4)	221 (77.5)	37 (84.1)	
Iliac occlusion	261 (79.3)	224 (78.6)	37 (84.1)	.40
Rutherford classification				.53
3	30 (9.1)	26 (9.1)	4 (9)	
4	229 (69.6)	206 (72.2)	23 (52.2)	
5	49 (14.9)	42 (14.7)	7 (25)	
6	21 (6.3)	17 (5.9)	4 (9)	
CFA stenosis				.19
Mild (<50%)	157 (47.7)	138 (48.4)	19 (43.2)	
Moderate (50%-75%)	77 (23.4)	67 (23.5)	10 (22.7)	
High (75%-99%)	64 (19.5)	57 (20)	7 (15.9)	
Occlusion	31 (9.4)	23 (8.1)	8 (18.2)	
Femoropopliteal occlusive disease	101 (30.7)	85 (29.8)	16 (36.4)	.38
Procedural				
Suprarenal clamping zone	85 (25.8)	70 (24.6)	15 (34.1)	.17
Suprarenal clamping time, minutes	31±11	24±9	36±11	.12
CFA endarterectomy	146 (44.4)	126 (44.2)	20 (45.5)	.87
Additional aortic endarterectomy	47 (14.2)	39 (13.6)	8 (18.1)	.63
Distal endovascular procedure	11 (3.3)	10 (3.5)	1 (2.3)	.67
Operative time, minutes	265±93	259±89	270±127	.48
Amount of blood loss, mL	2754±276	2610±277	2791±280	.09
Postoperative blood transfusion	141 (42.9)	124 (43.5)	17 (38.6)	.36
Technical success	325 (98.8)	281 (98.6)	44 (100)	.42

CFA, Common femoral artery; SVS, Society for Vascular Surgery; TASC, TransAtlantic Society Classification.
Data are presented as number (%) or mean ± standard deviation.
Boldface P values indicate statistical significance.

single-center analysis (from 2000 to 2017), DeCarlo et al⁹ found that rates of postoperative major complications were high (35.9%), and predictors included prior endovascular intervention, along with malignancy, intraoperative complication, operative blood loss, and aortic

Table III. Outcomes

Variable	Overall (N = 329)	Primary procedure (n = 285)	Secondary procedure (n = 44)	P value
Early outcomes				
Death	5 (1.5)	4 (1.4)	1 (2.3)	.66
Amputation	4 (1.2)	4 (1.4)	0 (0)	.42
Intensive care unit stay >24 hours	210 (63.8)	187 (65.6)	23 (52.3)	.08
Reintervention	35 (10.6)	30 (10.5)	5 (11.4)	.86
Any medical complications				
Myocardial infarction	4 (1.2)	4 (1.4)	0 (0)	
Heart failure	8 (2.4)	8 (2.8)	0 (0)	
Respiratory failure (orotracheal intubation >24 hours, need for reintubation, severe pneumonia, or ARDS)	12 (3.6)	10 (3.5)	2 (4.5)	
Renal insufficiency (as per RIFLE criteria)	17 (5.2)	14 (4.9)	3 (6.8)	
Any surgical complications				
Thrombosis	24 (7.3)	21 (7.4)	3 (6.8)	.48
Hematoma	8 (2.4)	8 (2.8)	0 (0)	
Surgical infection	18 (5.5)	17 (6.0)	1 (2.3)	
Late outcomes				
Median follow-up, months	66±39	65±41	68±36	.61
Lost to follow-up	13 (4.0)	13 (4.6)	0 (0)	.14

ARDS, Acute respiratory distress syndrome; RIFLE, Risk, injury, Failure, Loss, End-stage. Data are presented as number (%) or mean ± standard deviation.

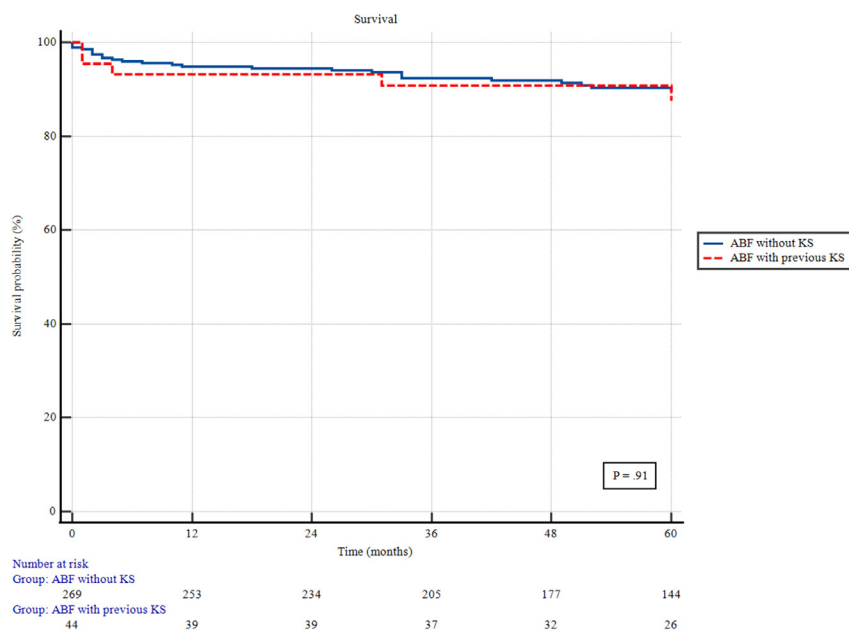


Fig 2. Kaplan-Meier analysis of overall survival in group 1 vs group 2. ABF, Aortobifemoral bypass; KS, kissing stent.

cuff endarterectomy. Primary patency and freedom from reinterventions at 5 years were 76% and 79%, respectively, although predictors of primary patency were not analyzed. In another study, the same author¹⁰ queried the VQI database for all patients who underwent ABFB from 2009 to 2019, with the aim to

determine if prior AIEI was predictive of adverse events after ABF bypass. Among 3056 patients who underwent open surgery, 618 had a prior AIEI. Prior AIEI did not predict any of the primary outcomes in multivariable analysis. In this study, however, data on ABFB patency were not analyzed.

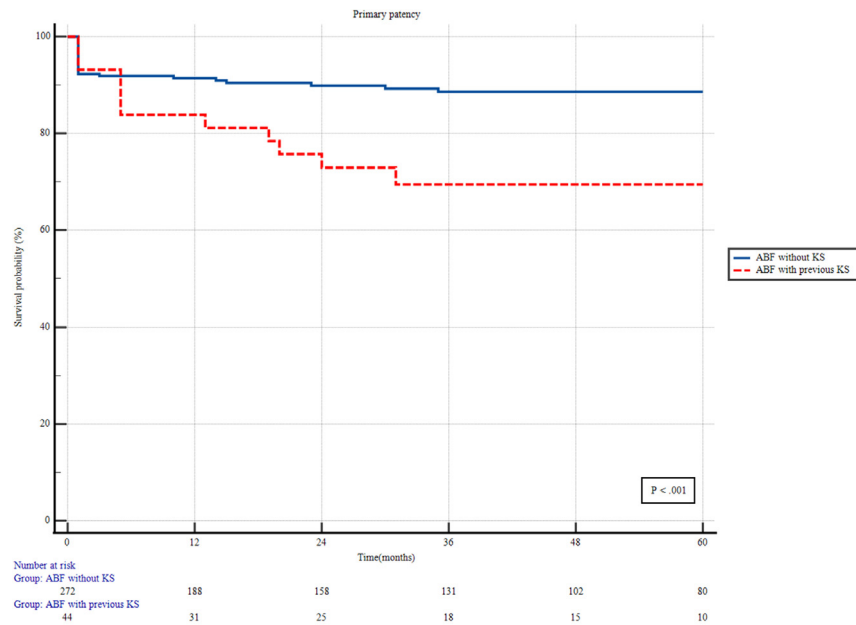


Fig 3. Kaplan-Meier analysis of primary patency in group 1 vs group 2. ABF, Aortobifemoral bypass; KS, kissing stent.

Table IV. Cox regression

Covariate	HR	95% CI of HR	P value
Secondary procedure	2.7	1.39-5.14	<.001
Urgent setting	1.6	0.69-3.27	.29
TASC D	1.2	0.54-2.63	.64
Rutherford class 4-5-6	1.5	0.73-2.99	.27
CFA endarterectomy	1.3	0.72-2.45	.35

CFA, Common femoral artery; CI, confidence interval; HR, hazard ratio; TASC: Trans-Atlantic Society Classification. Boldface P values indicate statistical significance.

In contrast to the study of Sharma et al,⁸ the present analysis showed that primary patency of ABFB was significantly lower in patients with previous KS treatment (88.6% vs 69.5%, respectively). Only failures of KS for extensive AIOD were taken into consideration in the present study, whereas in the other studies,⁸⁻¹⁰ data are not available regarding the prior EVT, so that the exact nature of each intervention, such as balloon angioplasty alone vs stenting or other potential confounders, including the anatomical complexity (ie, TASC classification), is unknown. Nonetheless, the secondary patency of ABFB in our series was remarkably high (99% in group 1 vs 94.3% in group 2) at 5 years, and without any differences between the two groups.

Despite the low mortality of the present cohort, the overall major complication rate in our cohort was not negligible (27.6%), and similar to other studies, like a recent VQI dataset analysis¹⁰ of 3056 patients who underwent ABF surgery from 2009 to 2019 (24.4%). In a recent meta-analysis of direct surgical vs endovascular

revascularization for AIOD including 4030 patients, Premaratne et al¹¹ showed that the overall pooled primary patency at 5 years was significantly better in the direct surgery group (91%) than in the endovascular or hybrid group (80.7%). These results are in line with a previous systematic review⁴ of the endovascular treatment of extensive AIOD, which showed a 5-year primary patency rate of 60% to 86%.

Several single and multicenter studies,¹²⁻¹⁵ mostly retrospective, have been published on the outcomes of KS for AIOD treatment, with encouraging results. A systematic review has been published in 2017 by Jebbink et al¹⁶ on the results of KSs. The pooled data from these studies showed an overall technical success rate of 98.7%, a complication rate of 10.8%, and a primary patency at 12, 24, and 60 months of 89.3%, 78.6%, and 69.0%, respectively. The same authors published in 2019 an individual patient data meta-analysis including 605 (40.9%) of 1480 patients treated with kissing stenting for AIOD, which confirmed an overall primary patency estimate of 81% at 24 months.¹⁷

Study limitations. Findings from this study must be interpreted in the context of some intrinsic limitations. First, the retrospective observational design of the study may entail possible selection or attrition bias, although cases were consecutively queried at participating institutions. Importantly, we could not ascertain the actual percentage of surgical regrafting over the total number of endovascular cases as some of the formers were referred from peripheral hospitals. For similar design-related reasons, some patients were lost to follow-up, although

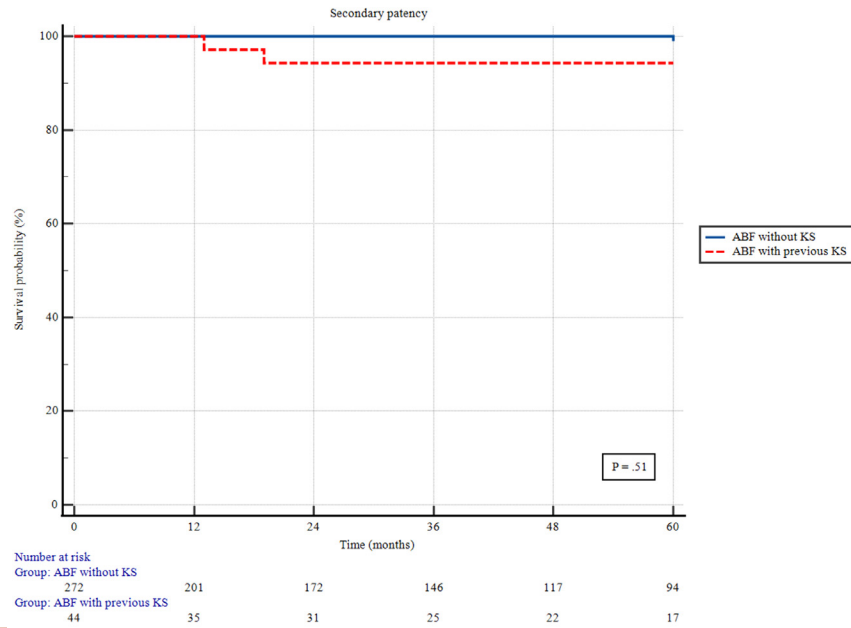


Fig 4. Kaplan-Meier analysis of secondary patency in group 1 vs group 2. *ABF*, Aortobifemoral bypass; *KS*, kissing stent.

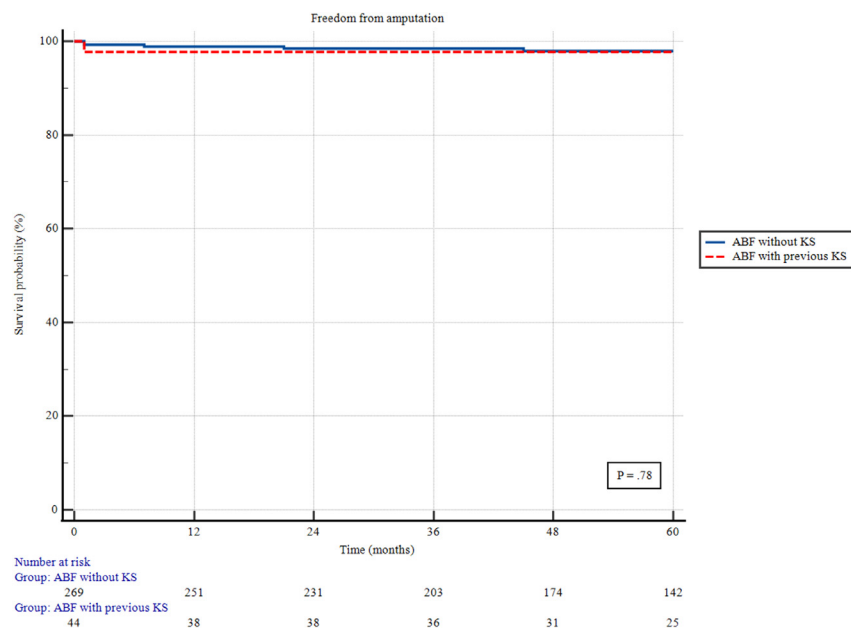


Fig 5. Kaplan-Meier analysis of limb salvage in group 1 vs group 2. *ABF*, Aortobifemoral bypass; *KS*, kissing stent.

this proportion was relatively small (4% of the entire study population). Secondly, the specific strategies for endovascular treatment or open surgery were at the discretion of the treating physicians and alternative approaches may have been chosen for similar patient-related characteristics. Furthermore, the study lacks any core laboratory-based analysis. Finally, a larger cohort of patients may be useful to identify further predictors of procedural failures using multivariate methods.

CONCLUSIONS

Surgical treatment of TASC C/D AIOD with ABFB surgery remains equally safe and effective when performed after prior endovascular treatment, although primary ABFB seemed to have higher primary patency rates. Despite the need for more frequent reinterventions, secondary patency and limb salvage rates were similar. However, future large prospective trials are required to confirm these findings.

AUTHOR CONTRIBUTIONS

Conception and design: SL, MDO

Analysis and interpretation: SL, DM, MA, AK, PF, GP, SB, MG, GFV, RP, NT, ST, RB, MDO

Data collection: SL, DM, MA, AK, PF, GP, SB, MG, GFV, RP, NT, ST, RB, MDO

Writing the article: SL, MDO

Critical revision of the article: SL, DM, MA, AK, PF, GP, SB, MG, GFV, RP, NT, ST, RB, MDO

Final approval of the article: SL, DM, MA, AK, PF, GP, SB, MG, GFV, RP, NT, ST, RB, MDO

Statistical analysis: DM, MDO

Obtained funding: Not applicable

Overall responsibility: SL

DISCLOSURES

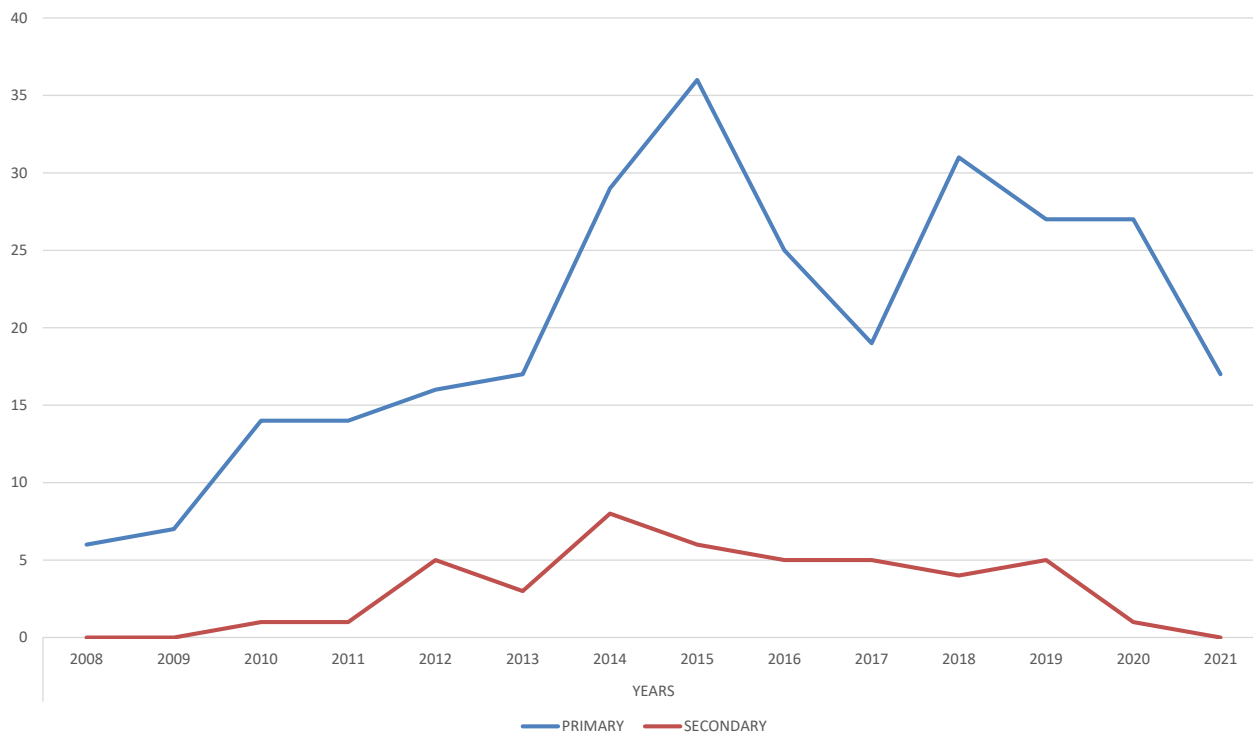
None.

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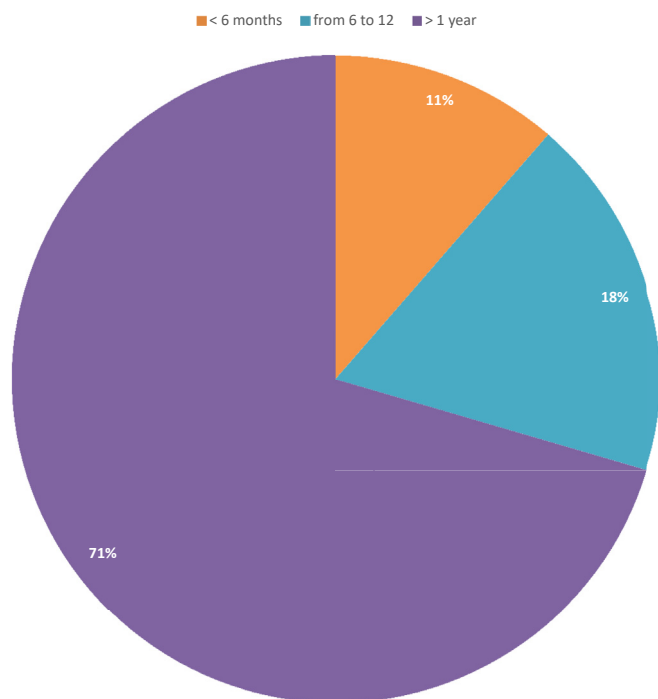
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Supplementary Fig 1 (online only). Line chart with number of cases over time.



Supplementary Fig 2 (online only). Pie chart of time from endovascular treatment to surgical regrafting.