

Original Research Article

Comparing endovascular and open reconstruction for TASC-II D aortoiliac disease: a propensity score analysis

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ABSTRACT

Background: Aortoiliac disease management remains a subject of ongoing debate, with a shift in focus toward endovascular techniques, even in complex cases. This study aimed to evaluate and compare the safety and results of open surgery with endovascular surgery for treating TASC-II D aortoiliac lesions.

Methods: From January 2013 to February 2021, the clinical data of 89 patients revascularized with symptomatic TASC II D AID were analyzed in a prospective cohort study. The patients were divided into two groups: open repair (61 patients) and endovascular treatment (28 patients). Baseline characteristics, preoperative and postoperative imaging, operation procedure reports and follow-up were reviewed and analyzed. Kaplan-Meier survival analysis, multivariate Cox regression, and a Propensity Score Matching (PSM) analysis were used to evaluate the relevance between risk factors and surgical technique.

Results: Open repair had a higher technical success rate (100% vs. 73.7%, $p=0.01$). 30-day major adverse cardiovascular (MACE) and limb (MALE) events showed no differences between both groups (PSM: 1 (4.8%) vs. 0, $p=0.462$ and 1 (4.8%) vs. 2 (13.3), $p=0.235$, respectively). Cox multivariable regression proportional hazard ratio showed no significant differences in terms of MALE between open and endovascular revascularization at 36 months (hazard ratio, HR 1.31 95% CI 0.56-3.06, $p=0.54$), even after PSM (HR 1.63 95% CI 0.58-4.55, $p=0.35$). Moreover, MACE and all-cause mortality also didn't show a statistically significant difference between groups (HR 0.77 95% CI 0.22-2.64, $p=0.67$ and HR 0.97 95% CI 0.27-3.46, $p=0.96$).

Conclusions: Open and endovascular techniques are safe and effective treatments for complex AIOD. It is expected to have a higher technical success rate with open repair; however, there are no significant differences in MACE or MALE between these two approaches.

Keywords: Peripheral artery disease, Aortobifemoral bypass, Aortoiliac stenting, Major adverse cardiovascular events, Preoperative care, Survival analysis

INTRODUCTION

Open surgical repair with Aortobifemoral Bypass (ABF) remains the treatment of choice in many vascular centers in patients with lifestyle-limiting intermittent claudication (IC) and chronic limb-threatening ischemia due to extensive Aortoiliac atherosclerotic Disease (AID), particularly in Trans-Atlantic Inter-Society Consensus II (TASC-II) type D lesions.¹

The ABF procedure has proven safe, effective, and durable, particularly considering its high long-term patency rates (85%-90% at five years and 75%-80% at ten years) despite its significant early postoperative associated morbidity.¹ On the other hand, endovascular treatment (EVT) offers an attractive alternative with durable results (four- and five-year primary and secondary patency rates ranging from 60% to 86% and 80% to 98%, respectively), especially in less extensive AID, combined with low perioperative morbidity, making it generally preferable for patients with more severe comorbid conditions.^{2,3} Thus, surgical approaches to extensive AID have changed considerably over the last years, primarily due to increased EVT, particularly with bare aortoiliac stenting (AIS).

The advancement of endovascular techniques has led to many trials suggesting that endovascular management of TASC II C and D lesions is a potential alternative treatment to open strategies mainly in the subset of patients with high surgical risk, given the substantially less perioperative morbidity and mortality compared to ABF.⁴⁻⁶

Aim and objectives

This study aimed to compare the long-term results of EVT *versus* ABF grafting in patients presenting with complex AID lesions, classified as TASC II D.

METHODS

Study population

Data of patients from a tertiary care (Centro Hospitalar do Tâmega e o Sousa, EPE) and a referral center (Centro Hospitalar Universitário de São João, EPE), who underwent elective aortoiliac TASC D lesions revascularization were collected between January 2013 and February 2021 for a prospective cohort study. Consecutive patients were included. Patient's demographics, cardiovascular risk factors, clinical presentation, procedural, and lesion-specific details were obtained from a detailed review of the clinical records of the patients kept in an ongoing vascular registry.⁷ Preoperative arteriography and computed tomography angiography images were retrieved and reviewed by two independent and experienced observers (JRN and APN) to assess TASC classification. TASC II classification was used to categorize disease patterns.⁸ Only type D

aortoiliac lesions were included. In conformity with the referred classification system, type D lesions include infra-renal aortoiliac occlusions, a diffuse disease involving the aorta and both iliac arteries, bilateral occlusions of external iliac artery, diffuse multiple stenosis involving the unilateral common iliac artery and external iliac artery.⁸ Patients with concomitant aortoiliac aneurysm disease were excluded. The present work follows the Strengthening the Reporting Of Cohort Studies in Surgery (STROCSS) criteria.⁹ The study protocol respects the Declaration of Helsinki and is under the European union general data protection regulation (GDPR).

Surgical technique

Revascularization technique, either endovascular or open surgical, was chosen considering the surgeon's and the institution's experience and preferences, with the patient involved in the decision-making process. Technical success was defined as patency at 24 hours post-procedure. Postoperative surveillance consisted of clinical evaluation and non-invasive Doppler arterial study with Doppler ultrasound and ankle-brachial index (ABI) measurements. The ABI measurements were performed at 1 and 12 months, followed by biannual or annual clinical follow-up. Vascular surgeons performed all endovascular procedures under local or regional anesthesia and bare metal stents were employed on these patients, as detailed elsewhere.⁷

After stent deployment, aspirin (100 mg/day) and clopidogrel (75 mg/day) were prescribed for one to three months. Thereafter single anti-aggregation was recommended for lifelong use. Transperitoneal aortobifemoral bypass surgeries were performed in an operating room under general anesthesia. A double-woven Dacron graft was used for all the bilateral aortoiliac surgical reconstructions. All patients were at least 24 hours under continuous surveillance in an Intensive Care Unit (ICU). Patients submitted to endovascular procedures seldomly needed intensive care.

Definitions

Patency was defined according to reporting standards.¹⁰ MALE was defined as the loss of primary patency (interventions for assisted primary patency, secondary patency or loss of patency without reintervention), and major amputation.¹⁰ MACE was defined as a composite outcome of myocardial infarction, coronary reintervention, acute heart failure, and all-cause mortality.

Statistical analysis

All statistical calculations were obtained using SPSS (IBM Corp., released 2022. IBM SPSS Statistics for Windows, version 29.0, Armonk, NY, USA). For univariate purposes, χ^2 and Fisher exact tests were used to measure the association between categorical variables,

Student's t test for continuous variables, and Mann Whitney U test for continuous variables with non-normal distribution. The significance threshold was set to $p < 0.05$. Demographics and other comorbidities were compared between patients submitted to ABF and AIS (Table 1). Binary logistic regression was subsequently performed for the multivariable analysis; variables with $p < 0.2$ were included, resorting to the dimension reduction method to exclude confounding factors. Since the two subgroups significantly differed concerning many clinical characteristics (Table 2), a propensity score matching (PSM) analysis using the preoperative demographic parameters was additionally used to reduce confounding factors between categories. In this procedure, patients were paired using 1:1 nearest-neighbor matching with a ± 0.05 caliper and without replacement. A standardized mean difference higher than 0.2 was considered an imbalance. Survival analysis was also assessed using the Kaplan-Meier estimator and lifetable method. The log-rank estimator was applied to compare time-dependent variables.

RESULTS

Demographic and comorbidity data

The sample consisted of a total of 89 patients, divided into two groups, according to the surgical treatment they were submitted: The ABF group, including 61 patients (95,1% male) with a mean age of 61.0 ± 7.46 years, and the AIS group, including 28 patients (92,9% male) with a mean age of 65.9 ± 12.7 years (Table 1). The median follow-up was 77 months (CI 95% 57.2-96.8). There were no significant differences in demographic characteristics and comorbidities between the two groups, except for age ($p = 0.026$), smoking history ($p = 0.039$) and CHF ($p = 0.031$). The results for age or smoking were not consistent in the multivariable analysis but approved for CHF (aOR: 3.60; 1.109-11.690, $p = 0.033$), which was significantly higher in the endovascular group. PSM analysis nullified any significance between groups, and any imbalance superior to 20% was found regarding demographic and comorbidities characteristics between the two groups (Table 1).

Table 1: Patients demographics and comorbidities.

Characteristics	Univariate analysis before PSM			Multivariable	Post PSM		
	Aortobifemoral bypass (N=61) Frequency (%)	Aortoiliac stenting (N=28) Frequency (%)	P value		Aortobifemoral bypass (N=21) Frequency (%)	Aortoiliac stenting (N=21) Frequency (%)	P value
Age, years	61.0±7.46	65.9±12.7	0.026	NC	61.7±7.56	61.52±7.85	0.970
Sex, male	58 (95.1)	26 (92.9)	0.672	-	21 (100)	21 (100)	1
Hypertension	41 (67.2)	16 (57.1)	0.358	-	15 (71.4)	13 (61.9)	0.513
Smoking history	57 (93.4)	22 (78.6)	0.039	NC	21 (100)	20 (95.2)	0.311
Diabetes	17 (27.9)	9 (32.1)	0.681	-	7 (33.3)	7 (33.3)	1
Dyslipidemia	39 (63.9)	19 (67.6)	0.753	-	12 (57.1)	14 (66.7)	0.525
CKD	8 (12.1)	8 (20.5)	0.078	-	1 (4.8)	2 (9.5)	0.549
CAD	17 (27.9)	9 (32.1)	0.681	-	5 (23.8)	6 (28.6)	0.726
COPD	7 (11.5)	3 (10.7)	0.916	-	0	1 (4.8)	0.311
CHF	5 (8.2)	7 (25)	0.031	HR=3.60 (1.109-11.690) (p=0.033)	1 (4.8)	2 (9.5)	0.549
ASA							
2	21 (34.4)	9 (33.3)	0.851		7 (33.3)	11 (52.4)	0.226
3	36 (59.0)	18 (69.3)			14 (66.7)	9 (42.9)	
4	4 (6.6)	1 (3.7)			0	1 (4.8)	
SFA disease,	33 (55.9)	19 (67.9)	0.289		15 (71.4)	13 (65)	0.658
Rutherford classification preoperative							
3	21 (34.4)	6 (21.4)	0.363		8 (38.1)	6 (28.6)	0.655
4	23 (35.9)	9 (32.1)			7 (33.3)	8 (38.1)	
5	17 (28.1)	10 (35.7)			6 (28.6)	5 (23.8)	
6	0	3 (10.7)			0	1 (4.8)	
CLTI	40 (62.5)	26 (66.7)	0.669		12 (57.1)	13 (61.9)	0.753
Preoperative ABI	0.30±0.136	0.32±0.134	0.737		0.32±0.13	0.33±0.14	0.742

ABI-Ankle Brachial Index; ASA-American Society of Anesthesiologists; CAD-Coronary artery disease; CHF-Cardiac heart failure; CKD - Chronic kidney disease (creatinine > 1.5 mg/dl); CLTI-Chronic Limb-Threatening ischemia; COPD-Chronic obstructive pulmonary disease; HR-Hazard Ratio; NC-Not Confirmed; PSM-Propensity score match; SFA-Superficial Femoral Artery.

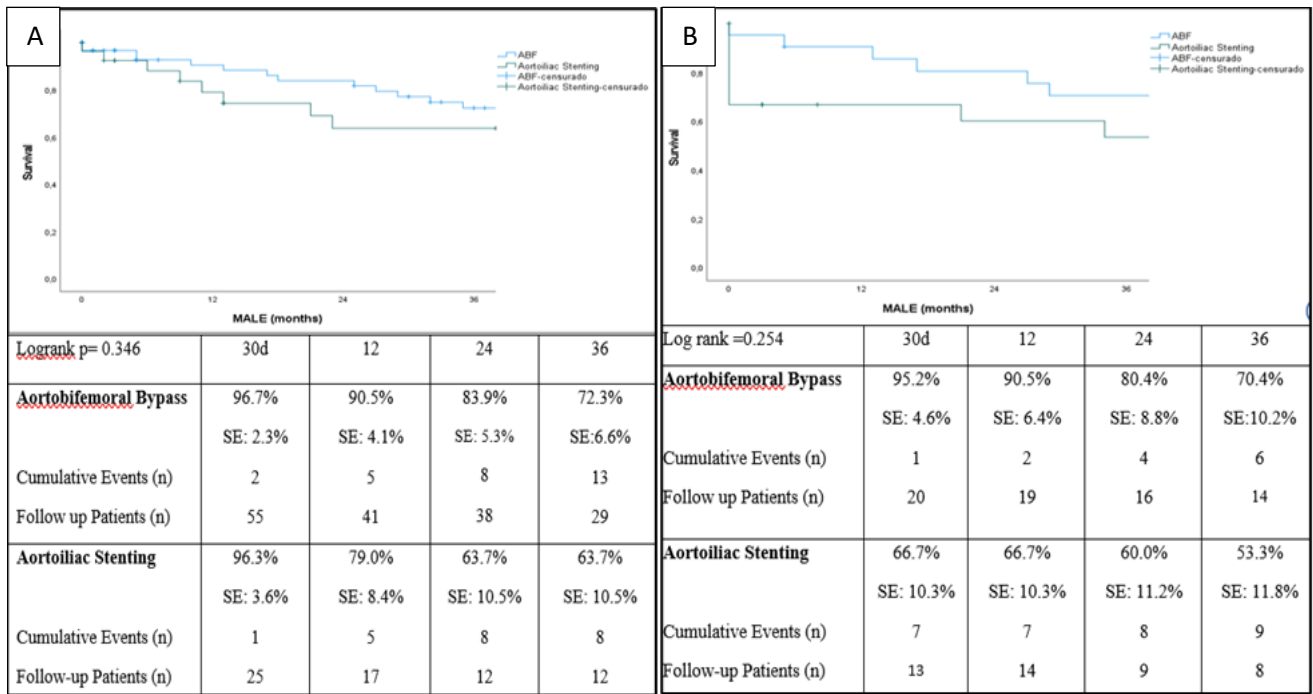


Figure 1: Survival plots; Three-year follow-up Kaplan Meier survival plots for different clinical events post elective aortoiliac revascularization, aortobifemoral bypass vs. aortoiliac stenting, Pre PSM; A) Kaplan-Meier curves of freedom from major adverse limb events after aortoiliac revascularization according to revascularization procedure, Pre PSM, B) Kaplan-Meier curves of freedom from major adverse limb events after aortoiliac revascularization according to revascularization procedure, after Propensity score matching.

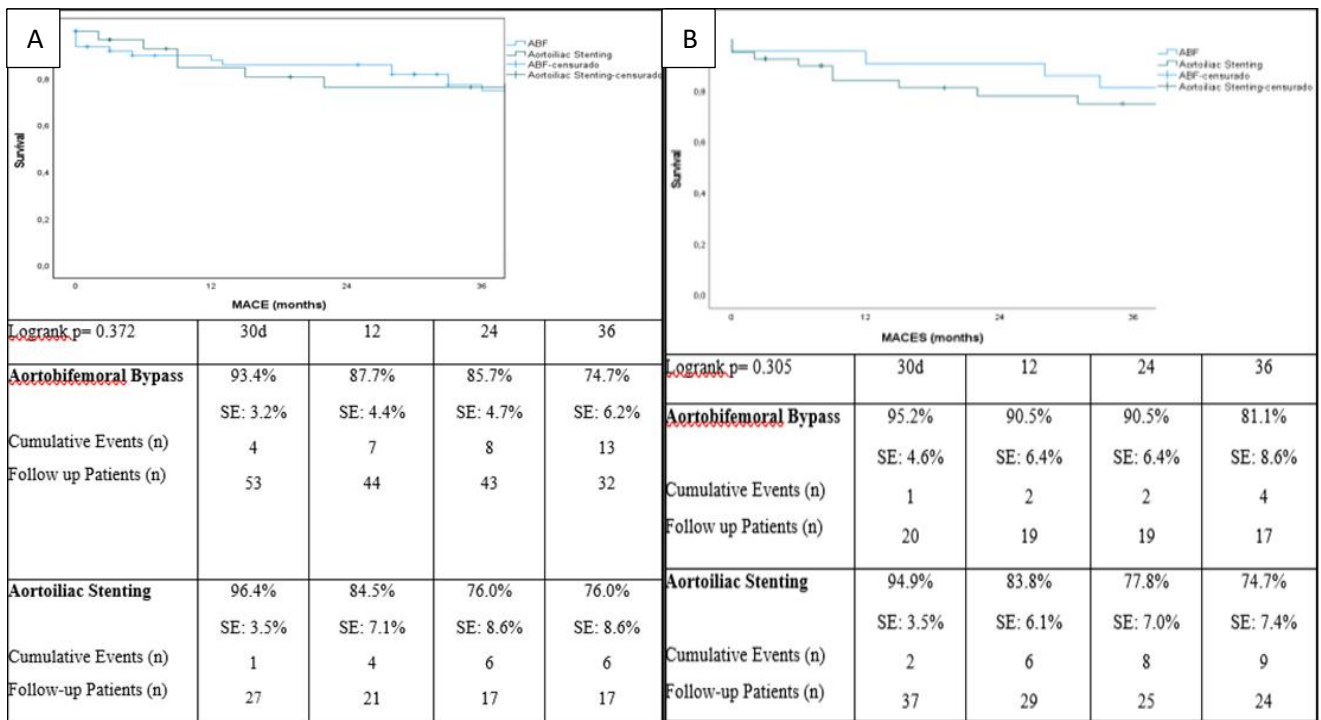


Figure 2: Survival plots. After PSM, three-year follow-up Kaplan Meier survival plots for major adverse cardiovascular events post elective aortoiliac revascularization, aortobifemoral bypass vs. aortoiliac stenting; A) Kaplan-Meier curves of freedom from Major Adverse Cardiovascular Events after aortoiliac revascularization according to revascularization procedure, B) Kaplan-Meier curves of freedom from Major Adverse Cardiovascular Events after aortoiliac revascularization according to revascularization procedure, after Propensity score matching.

Table 2: Patients’ thirty-day outcomes according to surgical technique.

30-day’s	Univariate analysis before PSM			Post PSM analysis		
	Aortobifemoral bypass (N=61) Frequency (%)	Aortoiliac stenting (N=28) Frequency (%)	P value	Aortobifemoral bypass (N=21) Frequency (%)	Aortoiliac stenting (N=21) Frequency (%)	P value
Technical success	61 (100)	28/36 (73.7)	0.01	21 (100)	21 (100)	1
Infringuinal femoro popliteal revascularization	13 (21.3)	14 (50)	0.007	6 (28.6)	4 (26.6)	0.652
Rutherford classification postoperative						
1	33 (62.3)	13 (48.1)	0.184	11 (55)	10 (55.5)	0.264
2	15 (28.3)	8 (29.6)		7 (35)	4 (22.2)	
3	0	4 (14.8)		0	2 (11.1)	
4	1 (1.9)	0		2 (10)	0	
5	4 (7.5)	2 (7.4)		0	0	
Postoperative ABI	0.78±0.214	0.71±0.25	0.172	0.79±0.20	0.66±0.26	0.141
ABI Δ	0.46±0.22	0.34±0.22	0.081	0.46±0.20	0.34±0.23	0.149
MACE	3 (4.9)	1 (3.6)	0.776	1 (4.8)	0	0.462
MALE	2/55 (96.7)	1/25 (96.3)	0.435	1 (4.8)	2 (13.3)	0.235
ICU (days) (median, IQR)	3 (2-4)	0 (0-0)	0.001*	3 (2-4)	0 (0-0)	0.005
Hospital (days) (median, IQR)	9 (4-19)	7 (2-21.5)	0.256*	14 (6-25)	7 (2-36)	0.194
Prosthesis infection (1Y)	4 (6.7)	0	0.170	2 (9.5)	0	0.313

ABI Δ-Postoperative Ankle Brachial Index-Preoperative Ankle Brachial Index; ICU-intensive care unit postoperative care duration; IQR- Interquartile Range (25-75%); MACE-Major adverse cardiovascular events; MALE-Major Adverse Limb Events; Prosthesis Infection (1Y)-One-year incidence of prosthesis infection; PSM-Propensity score match; *Mann-Whitney U

Table 3: Cox multivariable regression proportional hazard ratio for each outcome.

Parameters	Before PSM			Post PSM		
	Non-adjusted hazard ratios	95% Confidence interval	P value	Non-adjusted hazard ratios	95% Confidence interval	P value
MACE	1.209	0.618-2.365	0.579	0.765	0.222-2.635	0.672
MALE	1.306	0.557-3.062	0.539	1.628	0.582-4.552	0.353
All-cause mortality	1.341	0.660-2.723	0.417	0.965	0.269-3.456	0.956

Thirty-day surgical outcomes

Regarding 30-day surgical outcomes, the technical success rate was significantly higher in the ABF group (100% vs. 73.7%, p=0.01) before PSM. To evaluate the 30-day surgical outcomes, the procedures were only considered with technical success. Thus, there were 61 (100%) patients with ABF bypasses and 28 (73.7%) in the AIS group. The median ICU stay was significantly higher in the ABF group (p=0.005), as expected, however there were no statistically significant difference in hospital length stay between groups (p=0.256). Infringuinal femoropopliteal revascularization was higher in the endovascular group (p=0.007) a result not supported after PSM (p=0.652). Moreover, the clinical

results evaluated at 30-days postoperative were not statistically different between groups, either by measuring them through postoperative Rutherford’s Classification (p=0.184), ABI change (p=0.081) or even major outcomes as MACE (0.776) and MALE (0.435) (Table 2).

Long-term outcomes

There were no significant differences in MACE survival at 36 months between the groups (PSM: ABF: 81.1%; AIS: 74.7%, p=0.305). For MALE in the PSM subgroup, the ABF group displayed a survival rate of 70.4%, and in the AIS group, the survival rate was 53.3% (p=0.254). Univariate analysis cox-proportional hazards

showed no significant differences in terms of MALE between open and endovascular revascularization ((hazard ratio, HR 1.31 95% CI 0.56-3.06, $p=0.54$), even after PSM (HR 1.63 95% CI 0.58-4.55, $p=0.35$) (Table 3). Moreover, both MACE and all-cause mortality also did not demonstrate a statistically significant difference between groups.

DISCUSSION

These findings suggest that both open and endovascular approaches are safe and viable treatment options for this patient population. Both before and after PSM this analysis failed to identify any statistically significant differences in terms of MALE, MACE and all-cause mortality either at 30-day postoperative or in the survival analysis conducted up to 36 months postoperatively. Even though the endovascular approach displayed comparatively lower rates of technical success, it is also observed that patients subjected to open surgical procedures experienced prolonged stays in the Intensive Care Unit (ICU). The TASC-II type D AIOD standard of care remains controversial.¹¹ While experts opinions vary, shifting trends are noticeable due to advancements in endovascular techniques and the escalating morbidity and mortality rates associated with open procedures.¹² This has prompted an increased inclination toward an endovascular-first approach, even in cases involving complex lesions. This outcome could be attributed to the surgeons' relative early learning curve in endovascular techniques. Recent device developments and increased experience of interventionists have prompted the utilization of endovascular therapy for extensive AID. While endovascular therapy offers notable progress in the field of vascular interventions, it still exhibits lower primary patency rates in comparison to surgical revascularization.^{2,7} This discrepancy is due, in part, to the technical difficulties associated with complex AID cases. Lesions with extensive involvement and the need for precise deployment of endovascular devices can pose considerable challenges during the procedure. These technical complexities can lead to lower primary patency rates and necessitate the use of reinterventions. Nevertheless, a notable advantage of endovascular therapy is the ability to perform reinterventions percutaneously, which can result in secondary patency rates similar to those achieved with surgical repair.^{2,13} The technical failures associated with endovascular treatments highlight the importance of continuous advancements and improvements in this field to address these challenges effectively.

Demographic and comorbidity data revealed a high degree of comparability between the ABF and AIS group across various parameters. However, distinctions were noticeable, particularly in the older age of patients and a higher prevalence of smoking history and CHF within the AIS group. These factors collectively indicate a potential physiological fragility among AIS patients, which likely influenced the surgeon's choice to opt for a less invasive

procedure, considering the inherent risks associated with open surgery, particularly in patients with CHF. Patients with CHF have been described with a heightened risk during aortic cross-clamping and anesthesia, making the utilization of endovascular repair and local anesthesia an attractive alternative to mitigate additional risks. Furthermore, there is evidence that patients with CHF are also at increased risk of developing complications during anesthesia in peripheral artery disease, meaning that endovascular repair, allows for the use of local anesthesia, mitigating additional risks associated with general anesthesia.^{14,15} Patients characterized by frailty are also associated with increased vulnerability to postoperative complications and subsequent discharge to nursing homes following vascular surgery, as shown by Visser et al in a prospective cohort study, analyzing 1201 patients.¹⁶ The surgeon's decision-making process may have been influenced by the patient's frailty, potentially leading to the selection of a less invasive procedure for patients with CHF.¹⁵

Considering that anatomical characteristics not comprehensively represented in the TASC classification, such as severe artery calcification, a porcelain aorta, and similar factors, might influence the assistant surgeon's inclination towards the ostensibly less risky endovascular option. Notably, these observations align with existing literature, which has consistently indicated that open surgical procedures tend to achieve higher technical success rates within this specific anatomical sector.¹⁷ Several factors could contribute to this outcome. It is plausible that the surgeons' relatively early learning curve in endovascular techniques plays a role. Furthermore, the inherent complexity of TASC II D lesions, characterized by extensive calcification or other challenging anatomical discrepancies, can pose technical challenges during the endovascular procedures, potentially leading to less favorable outcomes.

However, clinical results at 30 days, the two groups had no significant differences regarding limb salvage, adverse events, prosthesis infection, or hospital stay. The results suggest that both surgical techniques effectively achieved comparable short-term outcomes regarding morbidity, limb salvage and overall clinical improvement. One crucial consideration highlighted by the study is the difference in ICU stay between the two groups.^{18,19} Aortoiliac revascularization procedures impose significant physiological stress, as evidenced by the elevated incidence of myocardial injury following non-cardiac surgical interventions.^{2,12}

Regarding infrainguinal femoropopliteal revascularization, the results show no substantial difference in the rate between the two treatment groups after adjusting for potential confounding factors through PSM (ABF: 28.6% vs. AIS: 26.6%) ($p=0.652$). This suggests that both ABF and AIS may be similarly effective approaches for concomitant infrainguinal femoropopliteal revascularization in the studied population, as there was no clear

evidence of one procedure being consistently preferred or providing better results over the other, based on the available data.²⁰ A systematic review and meta-analysis by Salem et al with 9319 patients, one of the most extensive analyses of contemporary and historical studies, encompassing various treatment modalities, also demonstrated similar primary patency rates when comparing EVT with 86% rate and OS (Open bypass surgery) with 94.8% rate at 1 year and 80 vs. 86% at 3 years.²¹ The study conclusively demonstrates that endovascular intervention exhibits better 30-day morbidity and mortality outcomes compared to open surgical repair for individuals with extensive AID. Moreover, the research advocates for widespread availability and utilization of endovascular treatment options for all symptomatic patients classified under TASC II C/D disease whenever clinically viable. These results are supported by those reported by Mayor et al. retrospectively analyzing 75 patients with TASC II D, revealing high technical success rate and fewer in-hospital systemic complications in the EVT although with a cost of higher re-intervention rates.¹⁹

This study's strengths include its long-term follow-up, two-center design, and the use of PSM to minimize confounding factors and enhance the reliability of the comparison. While this study provides valuable insights, it is essential to acknowledge some limitations. First was the lack of randomization for endovascular versus open surgery selection, as the criteria were left to the surgeon discretion. This may have introduced potential inherent selection bias, particularly if there was a leaning towards employing ABF in instances involving more complex aortic lesions or the selection of frailty patients for the EVT. Although the results were comparable with previous reports, due to the severity of the lesions selected and ongoing preference for open procedures in TASC-D patients as the established standard of care, this study presented a small sample, particularly in the EVT group, which may limit the generalizability of the findings. The low prevalence of female patients in the sample could also mask the gender potential role as a determinant of outcome in this sector. There is also a possible selection bias since patients with more comorbidities and worse clinical condition possibly not tangible in our variables, may have been selected for less invasive procedures or even excluded from revascularization as exemplified by age and CHF. These limitations could be overcome by the implementation of further studies with larger sample sizes and longer follow-up period.

CONCLUSION

Although open surgery showed higher rates of technical success when compared to the endovascular approach, the short-term outcomes in terms of patency, limb salvage, and postoperative Rutherford Classification were found to be comparable between the two procedures, a result maintained in the long-term analysis. It is worth

noting that the endovascular method is significantly less invasive and leads to shorter ICU stays, making it a compelling option for AID treatment. To further advance our understanding and enhance the overall management of extensive AID, there is a clear need for additional high volume multicenter prospective studies. These studies can help us gain insights into strategies for reducing complications and re-intervention rates, maintaining long-term patency, and refining the clinical and imagiologic selection criteria for endovascular procedures in patients with extensive AID.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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