

ORIGINAL ARTICLE
VASCULAR SECTION

Long-term outcomes of endovascular aortic repair with flared iliac limb endografts in patients with abdominal aortic aneurysm and aneurysmal common iliac arteries

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ABSTRACT

BACKGROUND: The aim of this study was to evaluate the long-term outcomes of endovascular aneurysm repair with flared iliac limb grafts in patients with abdominal aortic aneurysm (AAA) and aneurysmal common iliac arteries (CIAs).

METHODS: This is a multicenter, retrospective, observational cohort study that involves four tertiary referral hospitals between May 1, 2005, and April 30, 2019. Primary outcomes were freedom from aneurysm-related mortality (ARM), and freedom from iliac-related reintervention.

RESULTS: We studied 995 aneurysmal iliac limbs in 795 (85.2%) patients who met the inclusion criteria. Median AAA diameter was 55mm (IQR: 51-60). Early mortality occurred in 3 (0.4%) patients. The median of follow-up time was 52 months (IQR: 26-88). Estimated freedom from ARM was 99±0.002% (95% CI: 99-99.9) at 1 year, and 99±0.004% (95% CI: 97.9-99.6) at 5-years. Chronic obstructive pulmonary disease (HR=6.4, 95% CI: 1.7-24.0, P=0.006), chronic kidney disease (HR=5.5, 95% CI: 1.4-21.9, P=0.016), and the presence of an aneurysmal left CIA (HR=5.3, 95% CI: 1.0-5-27.4, P=0.044) was associated with ARM. There were 42 (7.3%) late iliac-related events (limb occlusion, N.=5; iliac-related endoleaks, N.=37). Estimated freedom from iliac-related reintervention was 98±0.003% (95% CI: 97-99) at 1 year, and 95±0.01% (95% CI: 92.7-96.7) at 5-years, which was associated with an aneurysmal right CIA (HR=2.2, 95% CI: 1.3-3.9; P=0.005), and age ≥78 years (HR=1.9, 95% CI: 1.01-1.3; P=0.039).

CONCLUSIONS: EVAR flared iliac limb grafts showed a high rate of freedom from ARM and a low reintervention rate. Owing to these results, it can be a durable and stable alternative for patients aged >78 years.

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KEY WORDS: Iliac artery; Endoleak; Endovascular procedures.

Efficacy and long-term durability of endovascular abdominal aortic aneurysm repair (EVAR) are dependent on suitable anatomies, mainly based on stable endograft (EG) fixation and sealing zones.¹⁻³ The use of flared iliac limb grafts during EVAR for aorto-iliac aneurysms, have been proposed to seal endovascularly ecstatic or aneurysmal

common iliac arteries (CIAs) and to preserve direct inflow to the hypogastric artery, in order to avoid more complex and expensive procedures like branched endografting.^{4, 5} Currently, although most manufacturers are providing operators with distally flared iliac limb grafts to seal aneurysmal CIAs, literature reports contradictory results.⁶⁻¹⁰

The aim of the present study was to evaluate mid-to-long term results of the use of flared iliac limb grafts during EVAR for elective abdominal aortic aneurysm (AAA) with aneurysmal CIA.

Materials and methods

Study cohort

This is a multicenter, retrospective, observational cohort study that involves four tertiary referral hospitals. Checklist of items followed the STROBE statement.¹¹ Clinical data were collected in a prospective manner at each center; once merged in a single database, all data were recorded and tabulated in a dedicated database and analyzed retrospectively. For this study, only those treated with flared iliac limb grafts between May 1, 2005, and April 30, 2019, were identified. Medical records for all cases were reviewed between January 2020 and November 2020 by three senior surgeons (NR, CZ, MB). Information collected includes demographics, comorbidities, sizing of the CIAs, type of antithrombotic therapy at intervention, the type of EG, as well as postoperative events (death, endoleaks, reintervention) during hospitalization and follow-up.

For the final analysis, we used the following entry criteria: 1) at least, 100 cases with the same EG; 2) at least, flared iliac limb graft on one CIA; and 3) at least, 6-months of follow-up.

Owing to the retrospective nature of the present study based on anonymized data, approval was not necessary.

Indication for interventions

Informed consent for data recording and intervention was signed by each patient. Indications for the use of flared iliac limb graft were always recommended in agreement with the guidelines of the Italian Society for Vascular and Endovascular Surgery (SICVE), that are in accordance with the most recent position statements of the European Society for Vascular Surgery (ESVS).^{12, 13} The type of EG was left at the surgeons' judgment. The distal landing zone was considered suitable for flared iliac limb graft when there was a straight segment of CIA of at least of 10 mm with a diameter ≤ 25 mm, allowing for an oversizing of 15% of the iliac component. Otherwise, aneurysmal CIA ≥ 25 mm was excluded from this type of technical strategy. The follow-up protocol included computed tomography-angiography (CT-A) at 30 days and at 1 year at least, for all patients at each center. Echo-Color-Doppler was used for intermediate and long-term imaging follow-up. Generally,

institutional indications for reintervention after EVAR are also aligned with clinical practice guidelines, for the following conditions: type 1 and 3 endoleaks, EG infection, and symptomatic EG-limb occlusion. Type 2 endoleak was treated in the presence of sac enlargement (≥ 1 cm from the preoperative diameter), and/or if persisting >12 months or causing symptoms. Different types of EGs have been used throughout the entire experience: Zenith Flex™/Alpha™ (Cook Medical, Bloomington, IN, USA), Endurant™/Endurant™ II (Medtronic Endovascular, Santa Rosa, CA, USA), Gore® Excluder®/Gore® C3® (W.L. Gore and Associates Inc, Flagstaff, AZ, USA), E-tegra® (CryoLife/Jotec, Hechingen, Germany), AFX® 2/Ovation® (Endologix, Irvine, CA, USA), TREO® (Terumo Aortic, Inchinnan, UK), In-craft™ (Cardinal Health, Buckinghamshire, UK). We opted to include in the final cohort only EG with >100 cases to make the analysis much stronger and the subgroups more comparable and homogeneous in terms of number of cases.

Definition and primary outcomes

In agreement with the most recent guidelines of the ESVS, a CIA ≥ 18 mm in men and ≥ 15 mm in women was considered aneurysmal.¹³ Medical comorbidity grading system and operative outcomes were described according to the Society for Vascular Surgery (SVS).¹³ Absolute indications for operative reintervention, with open and/or endovascular treatments, was determined for the following conditions: type 1 and 3 endoleaks, EG infection, limb occlusion, sac enlargement due to endotension, ≥ 1 cm migration. Type 2 endoleak was treated in the presence of sac enlargement (≥ 1 cm from the preoperative diameter), and/or if persisting >12 months. According to SVS reporting standards, we classified aneurysm-related mortality (ARM) as all deaths due to aortic rupture, or due to the consequences of both primary and secondary procedures, or open surgical conversion.¹⁴ Through December 2020, information on aneurysm-related reintervention, vital status and date of death of individual patients were validated by death certificate, electronic charts managed by the regional health care system, General Practitioner or certified data from Emergency Department admission. For this study, primary outcomes of interest were freedom from aneurysm-related mortality (ARM), and freedom from iliac-related reintervention. Freedom from iliac-related reintervention was also stratified by age with a specific cut-off at 78 years. This cut-off was arbitrarily created considering the most recent life expectancy estimate in Italy of 83.3 years,¹⁵ and a follow-up evaluation of up to 5 years which may be considered as a minimum requirement to verify the durability of a treatment.

Statistical analysis

Clinical data were recorded and tabulated in Microsoft Excel (Microsoft Corp, Redmond, WA, USA) database: statistical analysis was performed by means of SPSS 26.0 for Windows (IBM, Armonk, NY, USA). Considering the reported median 15% rate of reintervention due to flared iliac limb grafts, an α cut-off of 0.05 and a power of 90%, for a 11% expected reintervention rate our cohort would have enrolled a total of 757 patients. Categorical variables were presented using frequencies and percentages. Continuous variables were presented with mean±standard deviation (SD), or median with interquartile range (IQR) and ranges, based on data distribution. Categorical variables were analyzed with the χ^2 test, and Fisher's Exact Test when appropriate. Continuous variables were tested for normal distribution by the Shapiro-Wilk's Test and compared between groups with unpaired Student's *t*-test for normally distributed values; otherwise, the Mann-Whitney *U* Test was used. Kruskal-Wallis Honest Significance Test was used as single-step multiple comparisons to find significant difference among medians. Univariate analysis was used to identify potential predictors of ARM and iliac-related reintervention during the follow-up. Associations that yielded a *P* value <0.20 on univariate screen were then included in a Cox's regression analysis using the Wald's forward stepwise model. The strength of the association of variables with ARM and iliac-related reintervention was estimated by calculating the hazard ratio (HR) and 95% confidence intervals ([95% CI]: significance criteria 0.20 for entry, 0.05 for removal). Model discrimination was evaluated by using the area under the receiver operating characteristic (AUC) curve, with ≥ 0.7 being considered significantly accurate. All survival analyses were estimated with the Kaplan-Meier test and reported as percentage±standard error (SE) with 95% CI, and log-rank test for comparison. Additionally, to assess which covariate were associated with ARM, a proportional hazards model was implemented, to properly consider the presence of competitive risks. All reported *P* values were two-sided; *P* value <0.05 was considered significant.¹⁶

Results

Study population

Consort diagram indicating all patients who underwent EVAR with flared iliac limb grafts during the period of study, including the whole cohort from which this final study population according to the inclusion criteria was derived is reported in Figure 1. We studied 995 aneurysmal

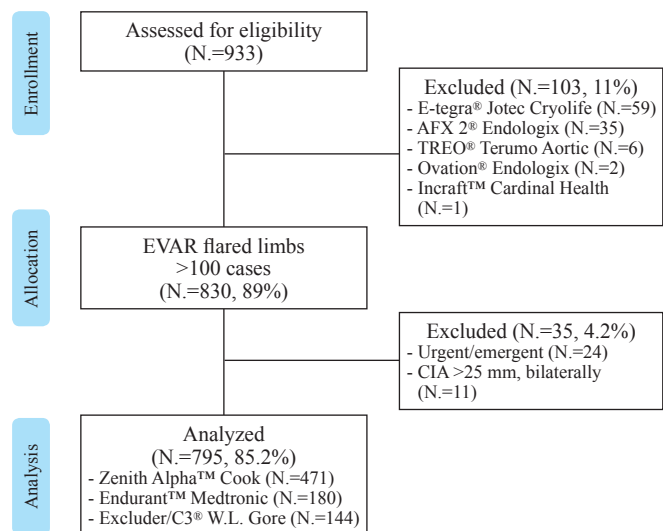


Figure 1.—Consort diagram of EVAR with flared iliac limb grafts during the study period (May 1, 2005, and April 30, 2019). N.: number; EVAR: endovascular aortic repair; CIA: common iliac artery.

iliac limbs in 795 (85.2%) patients who met the inclusion criteria: 751 (94.5%) were male and 44 (5.5%) females. There were 471 (59.2%) patients treated with the Cook EG (group A), 180 (22.6%) with the Medtronic EG (group B), and 144 (18.1%) with the Gore EG (group C). Median age of patients was 75 years (IQR: 69-80). Median AAA diameter was 55 mm (IQR: 51-60): 200 (25.1%) patients had bilateral aneurysmal CIA. Demographic data and comorbidities of the entire cohort, as well as sizing of the AAA and CIAs, are shown in Table I.

Early (<30 days) clinical outcomes and iliac-related complications

Mortality occurred in 3 (0.4%) patients. We observed 18 (1.8%) iliac-related failures: there were 9 (0.9%) cases of type 1_B endoleak, 8 (0.8%) cases of limb occlusion, and 1 (0.1%) case of type 3 endoleak. There was no difference among the EGs in terms of iliac-related failure rate (2.3% vs. 2.2% vs. 2.1%; *P*=0.983), or iliac-related reintervention rate (1.7% vs. 1.1% vs. 1.4%; *P*=0.852). At 30 days, we performed 22 (2.8%) reinterventions that are reported in Table II along with late reintervention discussed later in this section.

Late survival

The median of follow-up time was 52 months (IQR: 26-88). During the follow-up, 381 (48.1%) patients died. Estimated overall survival of 93±0.009% (95% CI: 90.7-94.3)

TABLE I.—Demographic data, comorbidities and risk factors of the entire cohort (N.=795).

Covariate	Cohort, N. (%)
Demographics	
Gender, (M:F ratio)	751:44
Age, median (IQR)	75 (69-80)
Comorbidity	
Hypertension	599 (75.3)
Active smoker	387 (48.7)
Coronary artery disease	311 (39.1)
Dyslipidemia	287 (36.1)
Diabetes	162 (20.4)
Chronic kidney disease	136 (17.1)
Chronic obstructive pulmonary disease	136 (17.1)
Peripheral arterial occlusive disease	135 (17.0)
Stroke	124 (15.6)
Sizing, (mm)	
AAA, median (IQR)	55 (51-60)
Right CIA, median (IQR)	16 (13-20)
Left CIA, median (IQR)	16 (12-19)
RCIA aneurysmal (N., %)	314 (39.4)
LCIA aneurysmal (N., %)	283 (35.6)
Bilateral aneurysmal CIA (N., %)	200 (25.1)

M: Male; F: female; N.: number; IQR: interquartile; AAA: abdominal aortic aneurysm; CIA: common iliac artery.

at 1 year, and 62±0.02% (95% CI: 58.1-65.5) at 5 years were found. Estimated overall survival was associated with dyslipidemia (HR=1.2, 95% CI: 1.05-1.56, P=0.013), and the presence of PAOD (HR=1.3, 95% CI: 1.03-1.72, P=0.027). Estimated freedom from ARM was 99±0.002% (95% CI: 99-99.9) at 1 year, and 99±0.004% (95% CI: 97.9-99.6) at 5-years. Both survival analyses are represented in Figure 2. Cox's regression analysis identified that ARM was associated only with chronic obstructive disease (HR=6.4, 95% CI: 1.7-24.0, P=0.006), chronic kidney disease (HR=5.5, 95% CI: 1.4-21.9, P=0.016), and the presence of an aneurysmal left CIA (HR=5.3, 95% CI: 1.05-27.4, P=0.044). The AUC of this multivariable model was 0.71 (95% CI: 0.55-0.87): in particular, a preoperative left CIA of at least 20 mm in diameter yielded a 67% sensitivity and 72% specificity of association with ARM.

Late iliac-related events

There were 42 (7.3%) iliac-related events. Limb occlusion occurred in 5 (0.5%) cases, which were successfully resolved with femoro-femoral bypass (N.=4), or thrombectomy with additional balloon angioplasty at the distal edge of the occluded iliac limb (N.=1). Late iliac-related endoleaks were detected in 37 (4.7%) patients: 35 (3.5%) cases of new type 1_B endoleak, and only 2 (0.2%) new cases of type 3 endoleak. Specifically, to type 1_B, there was no difference between those with type 1_B endoleak

TABLE II.—Early and late causes of reintervention and type of procedure performed during the follow-up.

Variables	Causes of reintervention and type of reintervention, (N.)			
	Early		Late	
Endoleaks	T1 _A	4	T1 _A	10
	EG explant*	2	Proximal aortic cuff	7
	AUI+FF bypass	1	Embolization	1
	Endoanchors	1	Endoanchors	1
			Unfit for redo	1
	T1 _B	9	T1 _B	35
	Iliac limb extender cuff	3	Iliac limb extender cuff	28
			Iliac branch device	3
			Semiconversion	2
			Explant	1
			AUI+FF bypass	1
	T2	4	T2	29
	Embolization	1	Embolization	26
			Semiconversion	2
			Saccotomy	1
	T3	1	T3	2
	Iliac limb extender cuff	1	Iliac limb extender cuff	2
EG thrombosis	Iliac limb thrombosis	8	Iliac limb thrombosis	5
	FF bypass	7	FF bypass	4
	Iliac thrombectomy + UK	1	Iliac thrombectomy + UK	1
Miscellaneous	Unplanned RA coverage	2		
	Stenting	2		
	Wound infection	1		
	Re-exploration	1		
	EIA rupture	1		
	Stent-graft	1		
	Femoral dissection	1		
	Endarterectomy + patch	1		

*Endograft collapse causing both T1A endoleak and bilateral iliac thrombosis. AUI+FF: Aorto-uni-iliac + femoro-femoral bypass; T: type; EG: endograft; EIA: external iliac artery; RA: renal artery; UK: loco-regional intra-arterial thrombolysis with urokinase.

and those without type 1_B endoleak in terms of length of follow-up (67±39 vs. 58±38, P=0.117) and median distribution (P=0.185). There was no difference among the different EGs in terms of freedom from limb occlusion (Log-rank $\chi^2=0.34$, P=0.843), and freedom from iliac-related endoleak (Log-rank $\chi^2=5.7$, P=0.060) (Figure 3). At the last follow-up available, estimated freedom from iliac-related reintervention was 98±0.003% (95% CI: 97-99) at 1 year, and 95±0.01% (95% CI: 92.7-96.7) at 5-years. Cox's regression analysis showed that iliac-related reintervention was associated with the presence of an aneurysmal right CIA (HR=2.2, 95% CI: 1.3-3.9; P=0.005), and age ≥78 years (HR=1.9, 95% CI: 1.01-1.3; P=0.039). The AUROC of this multivariable model was 0.59 (95% CI: 0.51-0.67): a preoperative right CIA of at least 20 mm in diameter yielded a 31% sensitivity and 81% specificity of association with reintervention. At 5-year follow-up, iliac-related reintervention was not significantly different when

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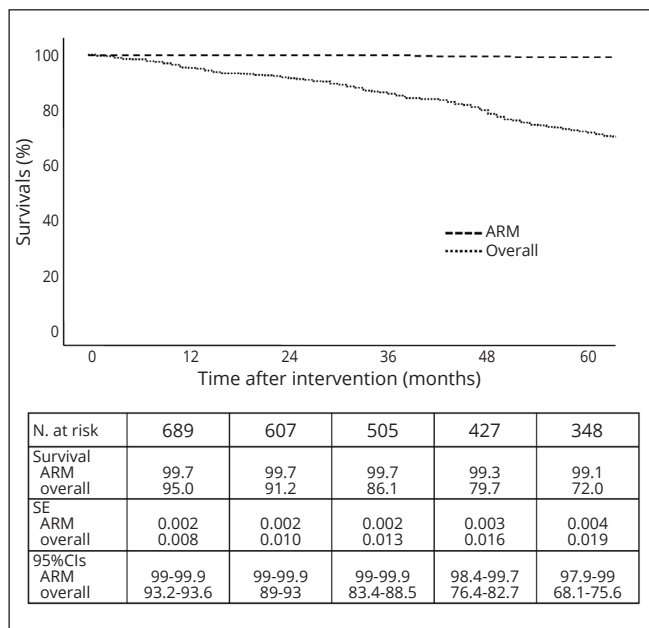


Figure 2.—Survival analyses by Kaplan-Meier estimates.

stratified by age ≥ 78 years (Log-rank $\chi^2=0.4$, $P=0.547$) as reported in Figure 3. There was no difference among the different EGs in terms of freedom from limb occlusion (Log-rank $\chi^2=0.34$, $P=0.843$), freedom from iliac-related endoleak (Log-rank $\chi^2=5.7$, $P=0.060$), and freedom from iliac-related intervention (Log-rank $\chi^2=5.1$, $P=0.080$) (Table III).

Discussion

The analysis of our cohort, that is the largest and with the longest follow-up available according to our knowledge, shows that EVAR with flared iliac limb grafts is a safe treatment option especially in elderly (≥ 78 -year-old) patients.

Safety and durability have been considered to be crucial to establish EVAR effectiveness.¹⁷ While these features have been already ascertained, randomized clinical trials, instead, questioned the durability of EVAR.¹⁸ This is an even more debated pending matter when EVAR is performed in the presence of aneurysmal iliac arteries because, regardless of technique used, these patients have been associated with higher iliac-related re-intervention rate in comparison with patients with non-aneurysmal iliac arteries.^{7-9, 19-21} Our experience shows that ARM after EVAR is estimated to be acceptably low at 99% at 5-years of follow-up. Also, not neglecting the use of alternative

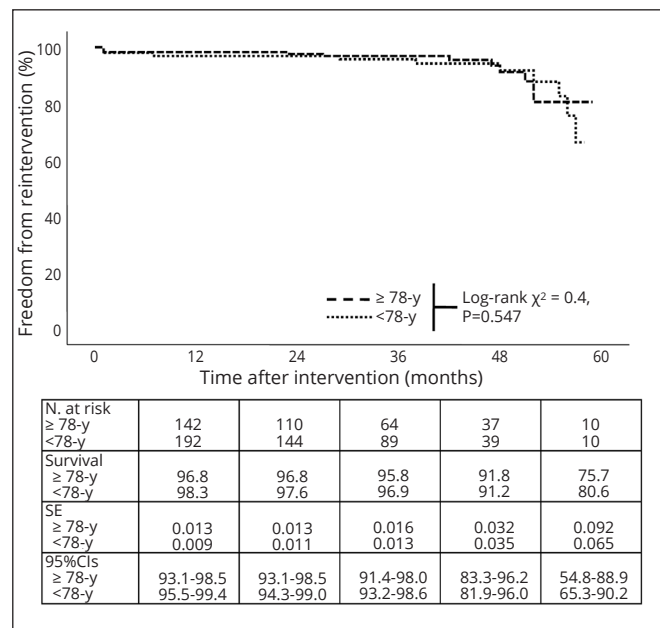


Figure 3.—Kaplan-Meier estimates of freedom from iliac-related reintervention stratified by age.

TABLE III.—Univariate screen and multivariate analysis of aneurysm-related mortality and freedom from iliac-related reintervention.

Covariate	Univariate		Multivariate		
	Log-rank	P	HR	95% CI	P
Aorta-related mortality					
Gender (F)	5.4	0.020			
Chronic obstructive pulmonary disease	10.6	0.001	6.4	1.7-24	0.006
Chronic kidney disease	12.3	0.001	5.5	1.4-21.9	0.016
Peripheral arterial occlusive disease	1.8	0.180			
Enlarged RCIA	7.2	0.007			
Enlarged LCIA	9.5	0.003	5.3	1.0-27.4	0.044
Bilateral CIA enlargement	9.5	0.002			
Iliac-related reintervention					
Dyslipidemia		0.086	2.9		
Enlarged RCIA		0.006	7.7	2.2 1.3-3.9	0.005
Enlarged LCIA		0.027	4.9		
Bilateral CIA enlargement		0.028	4.8		

HR: hazard ratio; CI: confidence interval; CIA: common iliac artery.

techniques, the use of flared iliac limb grafts played a key role in our cohort of selected patients: we are satisfied by observing that the estimated 95% freedom from iliac-related reintervention rate at 5-years compares favorably with the 90% reported risk with the use of iliac branch devices in other studies.^{22, 23} Not only branch technology is not applicable for all anatomic configurations, but follow-

up period in our cohort was quite longer.²² Further, it was satisfactory to observe that the iliac-related reintervention rate in our cohort was identical when stratified for patients younger or older than 78-years of age. This cut-off that was created considering the most recent life expectancy estimate in Italy of 83.3 years, and a follow-up evaluation of up to 5-years which may be considered as a minimum requirement to verify the durability of a treatment. Based on our data, we believe that EVAR with flared iliac limb grafts may no longer be considered a “second-class” technique. Rather it proved to be a safe and stable alternative also with low ARM especially for patients who belong to the most advanced group of age.^{22, 23}

One of the most consolidated aspects regarding the use of EVAR with flared iliac limb grafts is the fact that an aneurysmal CIA used as sealing zone could increase the risk of type I_B endoleak.^{6-10, 19, 24, 25} More specifically, ≥ 20 mm in diameter has been the most frequently reported the cut-off associated with increased risk of late iliac complications in EVAR with flared iliac limb grafts.^{6, 7, 19} Even in our experience these data have not been disregarded: the presence of CIA ≥ 20 mm was associated with late adverse outcomes. In contrast, the emerging data from our case series, as well as new in the literature, is that there was a specific correlation between the affected side and the type of predicted outcome. While an aneurysmal left CIA was associated solely with ARM, an aneurysmal right CIA was most frequently associated with late iliac-related technical reintervention. These specific data have not been previously reported; therefore, it is difficult to give a concrete explanation for this observation. However, it is reasonable that this may lie in the anatomical characteristics of the vessel.²⁶ We could hypothesized that the shorter length, and the correlated greater and rapid tapering in the presence of a dilation can make it a non-ideal target in comparison to the longer and more curvilinear left CIA. According to our results, this data may have a surgical implication in favoring a direct overstenting with embolization of the hypogastric artery to avoid late reinterventions especially in case an iliac branch device is not applicable.²⁴

Being a pure technical aspect of standard EVAR, one last comment should be reserved for a technological observation. Most of the experiences reported data on a variety of different brands with flared limbs; the peculiarity of our cohort lies in the fact that we centered our analysis on the three major brands used in the whole cohort. Despite there was a trend towards a better freedom from iliac-related endoleaks and freedom from iliac-related reintervention favoring the Gore EG, Literature reports only one previous

experience analyzing the results of this technique in correlation to the different EGs used: Wang *et al.*²⁷ observed a difference among three types of EG, but mainly correlated to sac enlargement and iliac artery aneurysm rupture. Similarly, our analysis revealed a trend in favor of the Gore EG towards a better freedom from iliac-related endoleak as well as iliac-related reintervention rate. That said, the pre-operative characteristics of the aorto-iliac anatomy were different among the different EGs. Despite the presence of morphological bias, an observation that would deserve a propensity matched score analysis, it may serve as proof of concept underlying how safe and effective could be this technique coupled with the most recent technology.

Limitations of the study

This study has several limitations. First, the analysis is essentially retrospective in nature as well as there is sampling bias as patients undergoing different types of repairs were not included for comparison. Large databases rely solely on accurate site reporting; thus, it is possible that investigators might have not identified all morphologic variables correlated to the aorto-iliac anatomy. However, missing data were not defaulted to negative, and denominators reflect only reported cases, and the cohort may have potential high value due to the large sample size. Moreover, multiple review auditing was performed by the leading author at each center to limit major inconsistencies. The few adverse events due to the good outcomes with EVAR, did not allow for meaningful multivariate analysis as well as subgroup analyses thus making not possible a “generalizability” of our findings. The absence of core laboratory adjudication should be considered as a possible limitation; however, periodical review auditing was performed by the leading authors (SB, FV, GP, GPi) to limit major inconsistencies. All these limitations may not allow for generalizability of our findings, nevertheless our data compares well with the available literature owing to the consistency of follow-up data validated by official health documents.

Conclusions

In our experience, EVAR with flared iliac limb grafts proved to be safe with a low early mortality rate. Although it cannot be considered as the reference technique, it showed a high rate of freedom from ARM and an acceptably low reintervention rate. According to these results, EVAR with flared iliac limb grafts can be proposed for advanced age patients especially if iliac branch endografting is not applicable.

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