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Impact of aortic bifurcation in iliac limb patency in the endovascular repair of aortoiliac aneurysms

Influencia de la bifurcación aórtica en la permeabilidad de las ramas ilíacas en el tratamiento endovascular de aneurismas aortoilíacos

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Abstract

Introduction and objective: iliac limb thrombosis in endovascular aorto-iliac aneurysm repair (EVAR) has an incidence rate of 6 % to 7 %, leading in these cases to a high reintervention rate. Aortic bifurcation diameter has been studied as a risk factor. The aim of this study was to analyze the impact of aortic bifurcation anatomy in aorto-iliac aneurysm treated with EVAR.

Methods: we conducted a single-center retrospective study in patients treated with bifurcated EVAR (2011-2020). We analyzed the demographic, anatomical, surgical and clinical variables. Narrow aortic bifurcation (NAB) was defined as diameters < 20 mm and regular aortic bifurcation (RAB) ≥ 20 mm. Primary endpoint: iliac limb primary patency during follow-up. Secondary endpoints: EVAR limb stenosis or kinking requiring further intraoperative treatment (percutaneous transluminal angioplasty (PTA) and/or stenting) and freedom from device-related reintervention.

Results: 205 patients (410 iliac limbs) were included; 47 patients with NAB (18.1 ± 1.24 mm) and 94 iliac limbs (23 %) and 158 RAB with 316 iliac limbs (77 %) were included. During follow-up (mean follow-up of 40.5 months) occlusion rate was 1.6 % in RAB and 0 % in NAB ($p = 0.593$). The NAB group showed a 3.2 % rate of limb stenosis which required further intraoperative treatment vs a 1.3 % rate from the control group ($p = 0.2$). The rates of freedom from device-related reintervention at 1 month, 1, 5 and 10 years were 98.1 %, 92.9 %, 83.4 %, and 79.1 % in RAB, and 100 %, 100 %, 94.7 %, and 94.7 % in NAB, respectively ($p = 0.013$).

Conclusions: EVAR seems to be feasible, safe and effective in the managemenf of narrow aortic bifurcations with current devices, achieving high patency rates, without requiring additional intraoperative measures.

Keywords:
Aortic aneurysm. Endovascular aneurysm repair. Graft occlusion.

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Resumen

Introducción y objetivo: la trombosis de las ramas ilíacas en el tratamiento endovascular de aneurismas aortoilíacos (EVAR) tiene una incidencia entre el 6-7 %, que conlleva, en estos casos, una elevada tasa de reintervención. El diámetro de la bifurcación aórtica se ha estudiado como factor de riesgo. Analizamos su relación con la permeabilidad de las ramas ilíacas.

Material y métodos: estudio retrospectivo y unicéntrico en pacientes tratados con EVAR bifurcado (2011-2020). Analizamos variables demográficas, anatómicas, quirúrgicas y resultados clínicos. Bifurcación aórtica estrecha (BAE) se definió como diámetro < 20 mm y bifurcación aórtica regular (BAR) ≥ 20 mm. Variables principal: permeabilidad primaria de las ramas ilíacas. Variables secundarias: estenosis intraoperatoria que precisa de procedimientos adyuvantes (angioplastia transluminal percutánea o *stent*) y supervivencia libre de reintervención asociada al dispositivo.

Resultados: se incluyó a 205 pacientes (410 ramas ilíacas); 47 pacientes presentaron BAE (18,1 ± 1,24 mm), con 94 ramas a estudio (23 %) y 158 BAR que aportaron 316 ramas al estudio (77 %). Durante el seguimiento (media de 40,5 meses) presentaron trombosis el 1,6 % de las ramas en BAR y el 0 % en BAE (p = 0,593). En el grupo BAE se halló estenosis intraoperatoria que precisó procedimientos adyuvantes en el 3,2 % de las ramas del grupo a estudio y 1,3 % del grupo control (p = 0,2). La supervivencia libre de reintervención a 1 mes, 1, 5 y 10 años fue del 98,1 %, 92,9 %, 83,4 % y 79,1 % en BAR y 100 %, 100 %, 94,7 % y 94,7 % en BAE, respectivamente (p = 0,013).

Conclusiones: el uso del EVAR parece ser seguro y efectivo en el tratamiento de pacientes con BAE con los dispositivos actuales, que mantienen una permeabilidad adecuada de las ramas ilíacas, sin precisar de un mayor número de procedimientos intraoperatorios adicionales ni conllevar un aumento en la tasa de reintervención.

Palabras clave:
Aneurisma de aorta. Tratamiento endovascular. Oclusión de prótesis.

INTRODUCTION

Endovascular repair of abdominal aortic aneurysms (EVAR) is associated with lower perioperative morbidity and short-term mortality vs open surgery (1,2). EVAR significantly reduces surgical time, the length of stay, blood loss, and the need for transfusion (3), benefits that stem from its minimally invasive nature. However, in the mid-to-long-term follow-up, the benefits in terms of overall and aneurysm-related mortality are lost (3,4), with reinterventions in EVAR being higher compared to open surgery (1).

The third most frequent complication of EVAR is iliac branch thrombosis, with incidence rates between 6 % and 7 % (5,6), which increases the rate of reintervention, risk of infection, and limb loss (7-9).

The diameter and tortuosity of the iliac arteries and a narrow and/or narrow aortic bifurcation (NAB) have been associated with this complication (10,11). However, few studies have compared the outcomes between NAB and regular aortic bifurcation (RAB) (12-16), achieving iliac patency rates > 90 % at the cost of increased intraoperative adjunctive procedures (12,13).

Our objective was to analyze the influence of the aortic bifurcation diameter (ABD) in EVAR, assessing the risk of intraoperative stenosis, the need for intraoperative adjunctive procedures, and postoperative thrombosis in patients with NAB.

MATERIALS AND METHODS

We conducted a retrospective observational study, and patients were obtained from our high-volume center in Spain. We consecutively selected patients undergoing bifurcated primary EVAR for aortoiliac aneurysms, both elective and urgent, from January 2011 through December 2020.

Anastomotic, infectious aneurysms, non-standard EVAR (fenestrated, branched, or branch iliacs), discontinued devices, and patients with perioperative multiple organ failure were excluded. Patients without available preoperative or postoperative computed tomography (CT) were also excluded.

Demographic, comorbidity, and operative data were collected from the patients' physical and/or electronic health records.

Anatomical measurements were taken independently by 2 vascular surgeons using the Endosize software (Therenva, Rennes, France). Preoperative and follow-up CT scans were analyzed using center-line image reconstructions. Diameters were measured from adventitia to adventitia. Measurements included the diameter and length of the proximal neck and the maximum diameter of the aneurysm. For the bifurcation, the ABD, mean diameter of the common and external iliac arteries, and the characteristics of the iliac components were recorded, including the sum of the iliac branch diameters (IBD) and the ratio between this sum and the ABD (IBD/ABD). Significant presence of thrombus in the bifurcation and/or calcification affecting > 50 % of its circumference was considered.

Characteristics of the stent-graft s and surgical details were collected from preoperative planning and surgical protocols. Device selection was based on the lead surgeon's preference, considering anatomical criteria and personal experience.

After deploying the stent-graft, ballooning was performed at the proximal neck, overlap zones, and iliac branches in all cases using a Reliant® balloon catheter (Medtronic Cardiovascular) to achieve proper arterial wall sealing.

During the study period, the follow-up protocol after stent-graft implantation included performing a CT at 30 days, 6 months, and 1 year, with annual checks thereafter. However, in selected patients with low risk of complications or impaired renal function, CT was replaced by color Doppler ultrasound or non-contrast CT. In case of adverse results, CT was performed to rule out any complications.

Intraoperative stenosis or kinking of the iliac branches requiring adjunctive procedures during stent-graft implantation (stenosis > 30 % seen in 2 different projections by arteriography) were documented, noting the type of procedure performed. During follow-up, thrombosis or occlusion of the iliac branches was diagnosed by CT. The time from intervention to thrombosis was calculated, and the event type of presentation and treatment were recorded.

Stratification by groups

Patients were stratified into 2 groups based on the ABD. The study group included patients with ABD < 20 mm (NAB). The control group consisted of those with ABD ≥ 20 mm (RAB).

Endpoints

The primary endpoint was the patency of the iliac branches during follow-up. Secondary endpoints studied included > 50 % stenosis or kinking of the iliac branches requiring intraoperative adjunctive procedures (percutaneous transluminal angioplasty (PTA) or stent) and device-related reintervention-free survival.

Statistical analysis

For this study, the Statistical Package for the Social Sciences 25.0 (IBM Corp, Armonk, NY, United States) was used. A descriptive analysis of qualitative variables was performed using n and percentage, while quantitative variables were expressed as mean and standard deviation. In the analytical phase, a bivariate analysis was included using the chi-square test or Fisher's exact test for qualitative variables and Student's t test or Mann-Whitney U test for quantitative variables depending on normality tests (Kolmogorov-Smirnov test). Afterwards, and depending on the results obtained in the bivariate analysis, a multivariable analysis was performed using linear regression (quantitative dependent variables) and logistic regression (categorical dependent variables), including variables that had a $p < 0.2$ on the univariate analysis. A significance level of $p < 0.05$ was considered. The Kaplan-Meier method with the log-rank test was used to evaluate event-free survival rates.

RESULTS

Between 2011 and 2020, a total of 321 bifurcated EVARs were performed at our center. We excluded 2 anastomotic aneurysms, 5 infectious aneurysms, 75 non-standard EVAR, 9 patients with discontinued devices, 9 with perioperative multiple organ failure, and 16 without preoperative or postoperative CT.

A total of 205 patients met the inclusion criteria, contributing 410 iliac branches to this study. Forty-seven patients (23 %) belonged to the study group, and 158 patients (77 %) to the control group. Table I analyzes the demographic and comorbidity data of our series. No statistically significant differences were found between the groups in any of the factors studied.

Specific details of aortic anatomy are documented in table II. As expected, the NAB group showed a smaller ABD, 18.1 ± 1.25 mm vs 28.3 ± 6.35 mm ($p < 0.001$). Additionally, NABs showed greater calcification > 50 % at the bifurcation (38.3 % vs 10.8 %; $p < 0.001$). No statistically significant differences were found in the diameter of the proximal neck, maximum aortic diameter, or presence of thrombus at the bifurcation. The common and external iliac arteries were significantly smaller in the NAB group.

Table I. Baseline characteristics and comorbidity by groups (*n* = 205)

Characteristics	Total (*n* = 205)	NAB (*n* = 47)	RAB (*n* = 158)	*p**
Age, mean (SD), years	73.7 (7.23)	74 (7.04)	73.6 (7.31)	0.799
Male gender	200 (97.6)	46 (97.9)	154 (97.5)	1§§
Comorbidity				
Hypertension†	159 (77.6)	37 (78.7)	122 (77.2)	0.828
Diabetes *mellitus*‡	48 (23.4)	13 (27.7)	35 (22.2)	0.434
Hipercolesterolemia§	150 (73.2)	37 (78.7)	113 (71.5)	0.328
Coronary artery disease‖	51 (24.9)	11 (23.4)	40 (25.3)	0.790
COPD¶	60 (29.3)	12 (25.5)	48 (30.4)	0.521
Chronic kidney disease**	40 (19.5)	9 (19.1)	31 (19.6)	0.943
Smoking††	150 (73.2)	35 (68.6)	115 (74.7)	0.398
Peripheral arterial disease‡‡	32 (15.6)	7 (14.9)	25 (15.8)	0.878

COPD: chronic obstructive pulmonary disease; NAB: narrow aortic bifurcation; RAB: regular aortic bifurcation. Continuous variables are expressed as mean (standard deviation) and categorical variables as n *(percentage). *Comparison between NAB and RAB cohorts. †Systolic blood pressure > 140 mmHg, diastolic > 80 mmHg, or on antihypertensive treatment. ‡Hemoglobin A1c > 6.5 % or active treatment with oral hypoglycemic agents or insulin. §Total cholesterol concentration documented > 200 mg/dl, low-density lipoprotein concentration > 130 mg/dL, or active treatment with statins. ‖Disease documented by coronary angiography or diagnosed by a cardiologist. ¶Diagnosed by spirometry with forced expiratory volume in 1 second < 80 %. **Diagnosis of chronic kidney disease stage 3 or higher (glomerular filtration rate < 60 ml/min/1.73 m^2). ††History of past or current active smoking. ‡‡Defined as an ankle-brachial index < 0.90. §§Fisher's exact test.*

Table II. Anatomical characteristics

	Total (*n* = 205)	NAB (*n* = 47)	RAB (*n* = 158)	*p**
Proximal neck diameter (mm), mean (SD)	23.6 (3.08)	22.9 (2.67)	23.8 (3.17)	0.091†
Maximum AAA diameter (mm), mean (SD)	62.5 (10.9)	59.9 (8.88)	63.3 (11.30)	0.130†
ABD, mean (SD) (mm)	29.4 (6.5)	18.1 (1.25)	28.3 (6.35)	< 0.001†
Thrombus at bifurcation	89 (43.4)	19 (40.4)	70 (44.3)	0.638
Calcification > 50 % at bifurcation	35 (17.1)	18 (38.3)	17 (10.8)	< 0.001
Right CIA diameter (mm), mean (SD)	16.3 (8.74)	13.79 (6.89)	17.09 (9.11)	< 0.001†
Left CIA diameter (mm), mean (SD)	16.3 (5.41)	11.94 (1.86)	15.90 (5.78)	< 0.001†
Right EIA diameter (mm), mean (SD)	9.39 (1.71)	8.55 (1.18)	9.65 (1.76)	< 0.001
Left EIA diameter (mm), mean (SD)	9.39 (1.71)	8.53 (1.29)	9.65 (1.74)	0.026†

CIA: common iliac artery; EIA: external iliac artery; NAB: narrow aortic bifurcation; RAB: regular aortic bifurcation. Continuous variables are expressed as mean (standard deviation) and categorical variables as n *(percentage). *Comparison between NAB and RAB cohorts. †Mann-Whitney U test.*

The characteristics of the stent-grafts are shown in Table III. Differences were found in the type of device used ($p = 0.033$), as well as in the DRI ($p < 0.001$) and the IBD/ABD ratio ($p < 0.001$).

When analyzing the stent-grafts individually, the ABD was 26.8 ± 7 mm in the Endurant®, 23.8 ± 6.1 mm in the Excluder®, and 24.3 ± 6 mm in the Ovation® ($p = 0.03$), and regarding the IBD/ABD ratio, we obtained figures of 1.26 ± 0.32 in Endurant®, 1.2 ± 0.27 in Excluder®, and 1.36 ± 0.5 in Ovation® ($p = 0.348$).

The primary and secondary endpoints are analyzed in Table IV. With a mean follow-up of 40.5 months (0.5-124 months), iliac patency was analyzed in 420 branches (94 NABs and 316 RABs), with a thrombosis rate of 0 % in NABs and 1.6 % in RABs ($p = 0.593$). One patient presented with gluteal claudication at long distances due to left iliac branch occlusion and was treated conservatively. The other 4 patients presented with acute ischemia symptoms; 3 underwent femoral-femoral bypass while the fourth patients underwent an axillofemoral bypass. The median time to thrombosis was 16 days (4 days-76 months). Considering each stent graft, the thrombosis-free survival of iliac branches was 100 % during follow-up for both the Excluder® and the Ovation® in both groups. In the case of the Endurant®, thrombosis-free survival at 1, 3, and 5 years was 100 %, 100 %, and 100 %, respectively, in NABs, and 98.8 %, 98.1 %, and 98.11 %, respectively, for NABs (log rank = 0.33), with graphs shown in figure 1.

No inter-group differences were ever found regarding intraoperative stenosis or kinking requiring adjunctive procedures (3.2 % vs 1.3 % in NAB and RAB, respectively; $p = 0.200$). In the NAB group, 1 isolated branch stenosis (ABD, 14.6 mm) and 1 bilateral branch stenosis (ABD, 18.4 mm) were reported, both treated with a kissing-balloon technique.

In the RAB group, 4 unilateral stenoses were observed, all treated with PTA (ABD, 21.1 mm, 23 mm, 29.8 mm, and 38.3 mm).

Device-related reintervention-free survival (Fig. 2) at 1 month, 1, 5, and 10 years was 98.1 %, 92.9 %, 83.4 %, and 79.1 % in RAB, and 100 %, 100 %, 94.7 %, and 94.7 % in NAB, respectively (log rank $p = 0.013$).

In the univariate study, an OR of 1.07 (95 % CI, 1.02-1.13; $p = 0.004$) was observed for the diameter of the

Table III. Characteristics of the stent-graft

	Total Patients ($n = 205$)	NAB ($n = 47$)	RAB ($n = 158$)	p*
Device				0.033
Endurant®	148 (72.2)	27 (57.4)	121 (76.6)	
Excluder®	50 (24.4)	18 (38.3)	32 (20.3)	
Ovation®	7 (3.4)	2 (4.3)	5 (3.2)	
IBD (mm), mean (SD)	31.2 (6.51)	27.49 (4.38)	32.27 (6.65)	< 0.001
IBD/ABD, mean (SD)	1.25 (0.321)	1.52 (0.245)	1.17 (0.3)	< 0.001

*NAB: narrow aortic bifurcation; RAB: regular aortic bifurcation; IBD: iliac branch diameter; ABD: aortic bifurcation diameter. Continuous variables are expressed as mean (standard deviation) and categorical variables as n (percentage). *Comparison between NAB and RAB cohorts.*

Table IV. Primary and secondary endpoints

	Total iliac branches ($n = 410$)	NAB iliac branches ($n = 94$)	RAB iliac branches ($n = 316$)	p*
Branch thrombosis	5 (1.2)	0 (0)	5 (1.6)	0.593†
Intraoperative stenosis	7 (1.7)	3 (3.2)	4 (1.3)	0.200†

NAB: narrow aortic bifurcation; RAB: regular aortic bifurcation. Categorical variables are expressed as n *(percentage). *Comparison between NAB and RAB cohorts. †Fisher's exact test.*

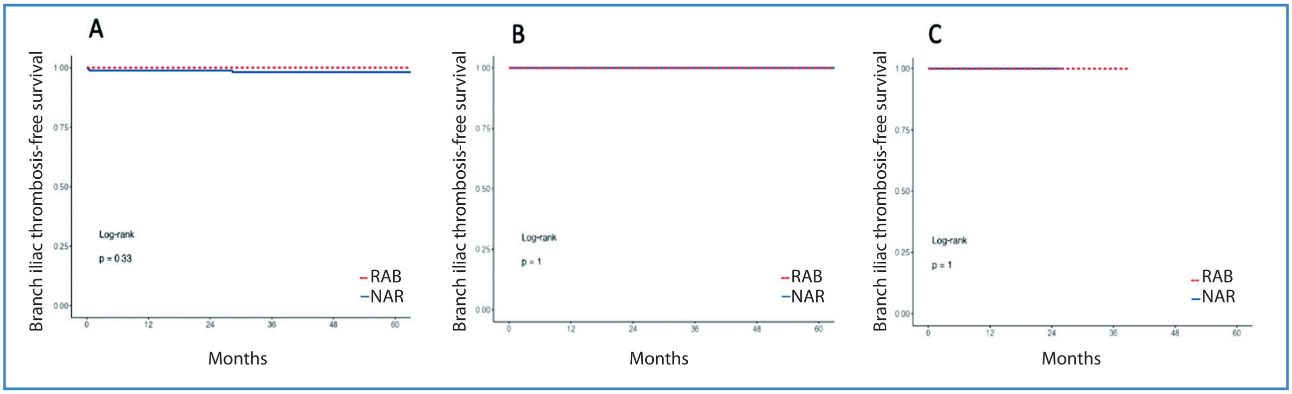

Figure 1. *Iliac branch thrombosis-free survival by type of stent graft. A. Endurant®. B. Excluder®. C. Ovation®.*

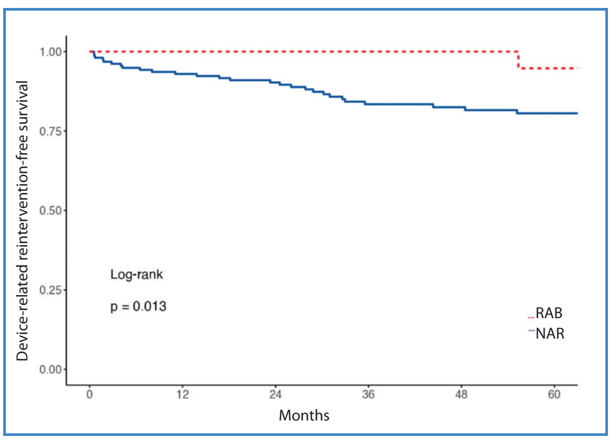

Figure 2. *Device-related reintervention-free survival.*

common iliac artery. After performing the multivariable analysis, this variable lost statistical significance, and no risk factors for branch thrombosis were found.

DISCUSSION

Our series, which includes 410 iliac branches with a mean follow-up of 40.5 months, has shown 0 % iliac thrombosis during follow-up in patients with NAB, without an increased need for additional intraoperative procedures to facilitate their patency.

Few studies in the literature have made similar comparisons; in several cases, there is a need for a greater number of intraoperative procedures in patients with NAB, performing PTA or even placing stents prophylactically.

Troisi et al. (13) studied a total of 87 patients implanted with the Endurant® (Medtronic, Santa Rosa, CA, United States), comparing NAB (ABD < 20 mm) with RAB. While they found no inter-group differences in primary patency and reintervention-free survival in the short- and mid-term, this study used prophylactic primary stenting if a residual stenosis > 50 % was observed, being implanted in almost 50 % of patients with NAB and almost 25 % of patients with RAB. Veraldi et al. (12) obtained similar results. In this case, they analyzed the Gore Excluder/C3® stent-graft, with reintervention-free survival and iliac thrombosis similar between the groups, but with very high rates of intraoperative stenosis requiring adjunctive procedures, up to 40 % in NAB and 12 % in RAB. These two series offer a very high percentage of adjunctive procedures vs other series (14,15).

Orrico et al. (14) showed no statistically significant differences in the number of intraoperative stenoses (2.1 % in RAB and 3.2 % in NAB), which is consistent with our results, despite setting a much lower cutoff point for NAB (16 mm). They also do not document any differences in iliac branch occlusion (3.2 % NAB vs 2 % RAB).

These results, along with ours, support the study published by Marqués de Marino et al. (15). They reported their 10-year experience with the Gore Excluder/C3® stent-graft in patients with ABD < 20 mm. Only 6 % of all NABs required intraoperative PTA for stenosis > 50 %. Regarding RAB, it was 1 %, with non-significant statistical differences being reported between the groups nor thrombosis during follow-up.

Briggs et al. (16) also studied the patency of iliac branches with the same device; it is the only article that does not document intraoperative stenoses. It shows no differences at 1 year in terms of reintervention-free survival and branch occlusion.

Finally, in 2021, Galanakis et al. (17) published a meta-analysis that included these studies and concluded that NAB is associated with an increased risk of intraoperative stenosis or kinking during EVAR, requiring a greater number of adjunctive procedures vs RAB. However, it did not seem to influence branch occlusion or reintervention during follow-up.

Intraoperative stenosis treatment is considered important as it has been documented as a prognostic factor for branch thrombosis during follow-up (18). Therefore, the importance of the role of post-dilation as a technical strategy to optimize cases with NAB, favoring iliac patency, has been investigated. Strajina et al. (11) analyzed 112 patients with an ABD < 18 mm and reported high rates of intraoperative adjunctive maneuvers, using kissing-balloon in 75 % of patients and kissing-stent in 20 % to achieve a primary patency of 98 % and secondary of 100 %.

Intraoperative stenosis has also been associated with the presence of NAB (19), 14.5 % of patients required prophylactic stent implantation for residual stenosis > 50 %, with no occlusions seen during 33 months of follow-up.

Marqués de Marino et al. (20) documented stenosis during follow-up and found an increased risk in NAB, although no association with branch thrombosis was ever found. The IBD/ABD ratio was the most important independent risk factor for branch stenosis during follow-up, with a hazard ratio (HR) of 29. These results are consistent with those obtained by Bianchoni Massoni (19), who showed that a significant disparity between the diameter of the iliac branches and the aortic bifurcation (IBD/ABD ratio > 1.4) was the only intraoperative risk factor for branch stenosis, increasing the risk of occlusion during follow-up.

We report an IBD/ABD ratio of 1.17 in RAB and 1.52 in NAB; this could justify a higher percentage of stenosis in NAB (3.2 % vs 1.3 %), although no statistically significant differences were ever reached. The placement of excessively large branches in a NAB could be why extremely high rates of intraoperative adjunctive procedures are reported in the initial studies mentioned (12,13), although we do not have this data.

Overall, these studies use variable cutoff points to define NAB, depending on the author (16 mm to 20 mm). We chose 20 mm because in published articles stipulating NAB as a risk factor for iliac thrombosis, 20 mm being the point from which this risk increases (21,22).

Another limitation of these studies is that they evaluate one stent-graft, making it difficult to apply these results to the routine clinical practice. In our case, we included the 3 most widely used devices in our center and showed differences in their use depending on the ABD. As shown by the smaller ABD in patients with the Excluder® stent-graft and the higher proportion of this stent-graft in patients from the NAB group, the reasoning behind our unit natural tendency to place the Excluder® stent-graft in patients with NAB—as long as the rest of the aortic anatomy characteristics allow it—is that the stent-graft that has shown the lowest annual incidence rate of iliac occlusion (23,24). This may be due to its material (expanded polytetrafluoroethylene and nitinol), which forms an iliac branch that is both flexible and rigid, allowing it to withstand complicated anatomies. The thinner material of the prosthesis and its conformability facilitate this adaptation.

Currently, there is no limit in the ABD contraindicating the use of bifurcated stent-grafts. In our study, the minimum ABD was 14.6 mm, and other series has reported ABDs < 13 mm (14,17), without documenting iliac branch occlusions in these patients. Therefore, currently, we could not set a limit based on the ABD for placing bifurcated stent-grafts. Considering this data, our results combined with those from former studies can help change attitudes in those patients who previously underwent aorto-uni-iliac stent-graft placement along with a femoral-femoral bypass for the exclusion of AAA in NAB. This technique increases the risk of infection, pseudoaneurysms, hematomas, stenosis, and bypass obstruction (25). We suggest reserving this technique for highly selected patients in whom placing a bifurcated stent-graft is complicated, such as cases of occluded iliac axes.

One of the difficulties we may encounter when implanting a bifurcated stent-graft in a NAB is the increased complexity of cannulating the contralateral branch due to the narrow bifurcation size and the short maneuvering distance possible with the guides and catheters. If the branch cannot be catheterized, the use of tools such as using a snare or a humeral approach is advised

The main limitation of this study is its retrospective nature, although the information was obtained from a prospectively formed database. Additionally, we are limited by the lack of follow-up > 40 months in most patients and its basis on the experience of a single center. Furthermore, there are differences in sample sizes, which could lead to type II errors, and the determination of the NAB cutoff as < 20 mm could be a conditioning factor for the results.

CONCLUSIONS

EVAR seems to be feasible, safe, and effective in treating NAB with current devices without requiring additional intraoperative measures, except for cases with severe branch stenosis identified in intraoperative arteriography.

New parameters should be studied to help us establish preoperative and postoperative strategies that favor the patency of iliac branches. Larger studies with longer follow-ups and more patients are needed to confirm these results.

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