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Incidence and Factors Associated with Aortic SAC Reduction after Evar in Spanish Population

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Authors' contributions

This work was carried out in collaboration between all authors. Authors DRE, MFM and IFF designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Author LRM managed the analyses of the study. Authors RJR and NCR managed the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: This study aimed to know the incidence and factors associated with aneurysmal sac reduction (ASR) after endovascular aneurysm repair (EVAR) at 3 years of follow up in the Spanish population.

Material and Methods: This is a retrospective observational study. We analyzed all patients with abdominal aortic and aortoiliac aneurysms who underwent elective EVAR in our hospital between January 2007 and September 2015. We studied ASR incidence at 3 years of follow-up. ASR was defined as a reduction in sac diameter ≥ 5 mm. Multiple preoperative and postoperative variables were analyzed. We used chi2 and T student tests for statistical analysis. Kaplan-Meier survival analysis and actuarial analysis were performed.

Results: Three hundred one patients underwent EVAR. The majority was men (97.3%) with a mean age of 74 ± 8 years, and 77.4% were at high surgical risk according to the American Society of Anesthesiologists classification (ASA). There was an incidence of 51.6% ASR at 3 years of follow

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up. Patients under chronic anticoagulation had 60% ASR vs 50.5%, $p = 0.489$. An aortic neck > 20 mm in length was associated with 55.3% ASR vs 45.7%, $p = 0.303$. Patients with ASR were younger 71 ± 8 years vs 76 ± 6 years, ($P = 0.001$, 95% CI, -7-1.9). Type II endoleak was associated with lower ASR, 32.4% vs 60, 8%, $p = 0.006$. Overall survival at 6, 12, 24 and 36 months was 90%, 82%, 71% and 61%, respectively. Survival in patients with ASR was better than patients without ASR, $p = 0.008$.

Conclusions: ASR incidence after EVAR was high in our series and was associated with increased survival rate. The overall survival at medium term was good despite the high surgical risk of our series.

Keywords: Aortic aneurysm; endovascular therapy; aortic sac reduction; Endoleak.

1. INTRODUCTION

The prevalence of abdominal aortic aneurysm (AAA) in Spain is approximately 5% in men over 50 years of age, with a male/female ratio of 5:1 [1,2]. The estimated mortality rate due to AAA is 4 per 100,000 persons [2]. Since its introduction in 1991, endovascular aneurysm repair (EVAR) has assumed a preferential role in the treatment of AAA [3,4,5]. The success rate of EVAR depends on the aortic and iliac anatomy, mainly on characteristics of the neck of an aneurysm, which is defined as the non-dilated aortic segment immediately proximal to the AAA [6].

The reduction of the aneurysmal sac after EVAR is one of the best indicators of success in treatment [7,8]. The primary purpose of this study was to know the incidence and factors associated with the aneurysmal sac reduction (ASR) in abdominal aortic and aortoiliac Aneurysms after elective EVAR at 3 years of follow up.

2. MATERIALS AND METHODS

This is a retrospective observational study. All patients with abdominal aortic and aortoiliac aneurysms who underwent elective EVAR between January 2007 and September 2015 were analyzed. Only patients with Medtronic® endoprosthesis (Talent® or Endurant®) were included because it is the device we use for standard EVAR. Patients with ruptured or symptomatic AAA were excluded. A retrospective review of a prospective database was performed. The characteristics of the aneurysms were analyzed by Computed Tomography (CT) in all patients. We studied the aneurysmal sac reduction at 3 years follow-up.

ASR was defined as a reduction ≥ 5 mm in aortic sac diameter; Diameters were measured on the preoperative CT, at 3 years follow-up and the last

CT. The diameters were measured from adventitia to adventitia on axial planes using Osirix Software. We analyzed multiple preoperative and postoperative variables: Cardiovascular risk factors, comorbidities, medication, anatomical characteristics of the aneurysm, mainly the maximum diameter of the sac, diameter and neck length as preoperative variables and the presence of endoleaks in the follow-up. Patients under anticoagulation therapy were taking acenocoumarol with dose adjusted to the international normalized ratio (INR) of 2-2.5. Univariate statistical analysis was performed. For the statistical analysis, Chi square test was used for categorical variables and T student for continuous variables. We performed Kaplan-Meier survival analysis with statistical significance of Log Rank and actuarial analysis. A $p < 0.05$ with a 95% confidence interval was considered statistically significant. Categorical variables are expressed in absolute numbers and percentages. Continuous variables are expressed by the mean, the standard deviation and the maximum and minimum values.

The study was carried out according to instructions and approval by the Ethical Committee for Clinical Research (CEIC) of the University Hospital La Paz according to the HULP code: PI-2330 dated March 31, 2016.

3. RESULTS

In the analyzed period, 301 patients underwent elective EVAR. The majority of the patients were male (97.3%) and the mean age was 74 ± 8 years. Eight patients were lost in follow-up. The surgical risk distribution according to the ASA classification was 0%, 22.6%, 66.8% and 10.6% for ASA I, II, III and IV, respectively. The mean diameter of treated aortic aneurysms was 59.6 ± 14.8 mm and that of the iliac arteries 20.6 ± 10.8 mm. The demographic characteristics of the

sample and the characteristics of the aneurysm are summarized in Table 1.

One hundred and twenty-two patients (40%) had a follow-up ≥ 3 years. In this subgroup of patients, ASR was observed in 63 of them (51.6%). Fifty-nine patients (48.4%) had no sack reduction. In the group of patients with no reduction, 46 (37.7%) remained stable and 13 (10.7%) increased in size (> 5 mm) during follow-up. In those patients who had increased sack size, 3 died because of non-vascular nature and the remaining was intervened. The ASR rate in patients under chronic anticoagulation treatment was higher than patients without anticoagulation, 60% vs 50.5% respectively, $p = 0.489$. In patients with single antiplatelet treatment the ASR was 52.5% vs 50.8%, $p = 0.856$ and with double antiplatelet 53.8% vs 51%, $p = 0.8$.

Patients with an aortic neck > 20 mm in length had an ASR rate of 55.3% vs 45.7%, $p = 0.303$. The mean age in patients with ASR was 71 ± 8 years vs 76 ± 6 years of those who did not have sack reduction ($p = 0.001$, 95% CI, -7-1.9) (Table 2 and 3 summarize the different variables

analyzed). The presence of type II endoleak was associated with aneurysmal sac reduction of 32.4% versus 60.8% for those without endoleak ($p = 0.006$). The incidence of endoleak was 29.6%, of which 7.3% were type I, 22.9% type II and 1% type III. The global reintervention rate due to endoleak was 4%. Overall survival rate at 6, 12, 24 and 36 months was 90%, 82%, 71% and 61%, respectively. Survival in the subgroup of patients with reduction of the aneurysmal sac was greater, $p = 0.008$ (Fig. 1).

4. DISCUSSION

The reduction of the aneurysmal sac is one of the best indicators of success after EVAR. Our study showed a 51.6% incidence of ASR, which is similar to that described in the literature [7]. The demographic characteristics of our series correspond to those expected for AAA patients in our country with the presence of multiple cardiovascular risk factors. This is reflected on the surgical risk, the majority of the patients had a high surgical risk according to the ASA classification, 77.4% were ASA III or IV.

Table 1. Demographic characteristics and cardiovascular risk factors

Variable		N=301
Age (years) media and typical deviation	73.7 \pm 7.8	(53-90)
Sex		
Men	97.3%	293/301
Women	2.7%	8/301
ASA* classification		
ASA I	0%	0/301
ASA II	22.6%	68/301
ASA III	66.8%	201/301
ASA IV	10.6%	32/301
Hypertension	73.1%	220/301
Diabetes Mellitus	21.6%	65/301
Dyslipidemia	62.3%	187/301
Active smoking	25.6%	77/301
Chronic renal failure	15%	45/301
Coronary artery disease	29.9%	90/301
Cerebrovascular disease	10.6%	32/301
Peripheral artery disease	21.3%	64/301
Chronic obstructive pulmonary disease	30.2%	91/301
Antiplatelet therapy.		
Aspirin	59.5%	179/301
Clopidogrel.	15%	45/301
Aspirin + Clopidogrel	3.7%	11/301
Maximun aortic diameter (mm)	59.6 \pm 14.8	
Neck diameter (mm)	25.3 \pm 3.6	
Neck length (mm)	28.5 \pm 14.9	
Iliac artery diameter (mm)	20.6 \pm 10.8	

*ASA: American society of anesthesiologists

Table 2. Associated factors with aneurysmal sac reduction at 3 year follow-up

N=122	Aneurysmal sac reduction >5 mm		Statistical significance (p)
	Presence of variable	Ausence of variable	
Sex: men	62 (51.7%)	1 (50%)	0.963
Hypertension	43(50.0%)	20 (55.6%)	0.575
Diabetes Mellitus	15 (57.7%)	48 (50.0%)	0.486
Active smoking	24 (72.7%)	39 (43.8%)	0.005
Chronic renal failure	9 (47.4%)	54 (52.4%)	0.685
Coronary artery disease	17 (47.2%)	46 (53.5%)	0.528
Cerebrovascular disease	4 (36.4%)	59 (53.2%)	0.288
Peripheral artery disease	13 (52.0%)	50 (51.5%)	0.968
Chronic obstructive pulmonary disease	21 (63.6%)	42 (47.2%)	0.106
Antiplatelet therapy			
Aspirin	32 (52.5%)	31 (50.8%)	0.856
Clopidogrel	14 (53.8%)	49 (51.0%)	0.800
Double therapy	2 (50%)	61 (51.7%)	0.947
Anticoagulants	9 (60.0%)	54 (50.5%)	0.489
Aneurysm diameter <60mm	38 (48.1%)	25 (58.1%)	0.289
Aortic Neck length >20mm	42 (55.3%)	21 (45.7%)	0.303
Endleaks: (global)	15 (35.7%)	48 (60.8%)	0.011
Type I	4(57.1%)	48 (60,8%)	0.005
Type II	11 (32.4%)	48 (60.8%)	0.006
Type III	0 (0%)	0 (0%)	-

Table 3. Associated factors with aneurysmal sac reduction at 3 year follow-up

Factors	Aneurysmal sac reduction	N=122	Media	σ	Statistical significance (p)	Confidence interval (95%)
Age (years)	Yes	63	71.1	7.8	0.001	-7.0 -1.9
	NO	59	75.6	6.2		
Aneurysm diameter (mm)	Yes	63	58.2	11.1	0.724	-4.0 7.5
	NO	59	57.3	15.6		
Neck diameter (mm)	Yes	63	26.1	3.3	0.927	-1.3 1.2
	NO	59	26.2	3.8		
Neck length (mm)	Yes	63	30.3	15.9	0.711	-4.5 6.6
	NO	59	29.3	15.2		

We found no association between comorbidities and ASR, except in smokers (Table 2). The strong association between the onset and progression of AAA and smoking has been amply demonstrated in the literature [3,9,10]. For this reason, we believe that our finding that smoking was associated with increased ASR rate could be an alpha-type statistical error. Patients on chronic anticoagulation therapy had a higher percentage of ASR (60% vs 50.5%), however this finding was not statistically significant. Some authors have found that the use of anticoagulation after EVAR is associated with a higher incidence of reintervention and less reduction of the sac [11]. Other authors have found an association between the use of antiplatelet agents and increased aneurysmal sac after EVAR. However, in our series,

treatment with antiplatelet agents did not appear to have any effect on the size of the aneurysm sac (52.5% vs 50.8%, p = 0.856). We believe that more studies would be needed to clarify the meaning of these contradictory findings.

In the literature an aortic neck > 20 mm in length with little calcification associates higher ASR rates [7,8]. We did not analyze neck calcification. However, we found a higher percentage of ASR in long necks > 20 mm (55.3% vs 45.7%), although it was not statistically significant. In our analysis, the patients with ASR were younger (71 ± 8 years) than those who did not present a reduction (76 ± 6 years), this difference was statistically significant. We found no association between the size of the aneurysm and the ASR rate. In the literature there has been reported

higher percentages of ASR in small aneurysms <60 mm [12]. This discrepancy with other authors could be a Beta-type statistical error or simply that there is no relationship between these two variables.

The most frequent complications in EVAR are endoleaks. Of these, type II endoleak are the most frequent, emerging as a complication in 20% of EVAR. This occurs when increased pressure from the side branches of aorta force blood to leak into the aneurysm sac [13]. Our incidence of type II endoleak was similar to that described in the literature (22.9%). At present there is some controversy regarding the treatment of type II endoleaks, since they sometimes diminish or disappear during follow-up, while in others they are associated with aneurysmal sac expansion and rupture [13,14]. Generally, it is accepted that the intervention of type II endoleaks should be performed only when they condition an increase of the sac size [15]. It is logical to deduce that the presence of endoleaks decreases the ASR rate, as has been the case in our study (endoleak type II 32.4% vs 60.8%).

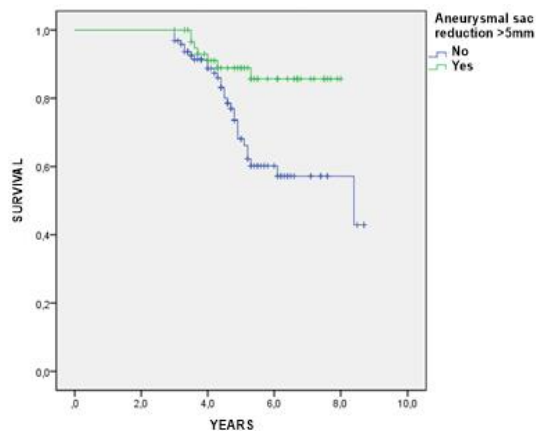


Fig. 1. Kaplan-Meier curves for patients with aneurysmal sac reduction after EVAR vs patients without sac reduction, $p=0.008$

Overall survival at two years was good (71% and 61% at 24 and 36 months respectively), taking into account the high surgical risk and the advanced age of this series. In the subset of patients with a follow-up greater than 3 years (122), we observed a higher survival rate in patients who had ASR (Fig. 1). This difference was statistically significant ($p < 0.05$). We cannot ensure that this increase in survival is due to a lower incidence of death due to a vascular cause

since we could not identify the cause of death in most patients. However, the question of treating all the factors associated with lower ASR, such as type II endoleaks, could be raised. The main limitation of our study is its retrospective design. However, it raises some questions that could be answered with a prospective study.

5. CONCLUSIONS

The aneurysmal sac reduction rate after EVAR was high in our series and was associated with increased survival rate. The overall survival at medium term was good despite the high surgical risk of our series.

CONSENT

It is not applicable.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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