

Prospective cohort 20 years after endovascular treatment for abdominal aortic aneurysm



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ABSTRACT

Objective: To describe the factors associated with survival 20 years after endovascular treatment of an abdominal aortic aneurysm (AAA) in a single center.

Methods: Prospective cohort of asymptomatic patients with an infrarenal aortic aneurysm treated with a bifurcated endovascular graft (Talent) between June 1997 and August 2008. Cox proportional hazard multivariable regression was used for analysis of independent risk factors for survival. Kaplan-Meier curves were done with the long-rank test. $P < .05$ was considered significant.

Results: We followed 229 patients, 184 without an endoleak and 45 with an endoleak. Ages ranged between 52 and 89 years, and the mean diameter of the aneurysm was 59.51 ± 14.6 mm. Implantation of the endovascular graft was possible in 99% of the patients. The 30-day mortality rate was 3.4%. In the Cox regression, age <73 years (hazard ratio [HR], 0.42; 95% confidence interval [CI], 0.27-0.64), aneurysm size ≤ 55 mm (HR, 0.62; 95% CI, 0.40-0.95), male sex (HR, 0.17; 95% CI, 0.05-0.52), American Society of Anesthesiologists surgical risk category I and II vs III and IV (HR, 0.51; 95% CI, 0.34-0.75), and aneurysm size reduction ≤ 3 mm after treatment (HR, 2.23; 95% CI, 1.11-4.51) were significantly correlated with the survival of the patients followed in this long-term case series.

Conclusions: This 20-year prospective cohort included patients with an AAA treated with a bifurcated endovascular graft (Talent) at a university hospital in Brazil. This study supports that sex, age, aneurysm size, aneurysm size reduction, and American Society of Anesthesiologists surgical risk category are significantly correlated with patient survival after endovascular treatment of the AAA. (J Vasc Surg 2018;67:1102-9.)

Abdominal aortic aneurysms (AAAs) are considered a prevalent disease, mainly in elderly and is two to three times more common in males.¹ The main risk related to aneurysms is rupture, which is an event with high lethality. In the United States, an estimated 15,000 deaths occur per year as a result of ruptured aneurysms that reach the hospital, and this number doubles or triples if all cases of sudden death that occur outside the hospital setting are included.¹

Since Parodi et al² described the use of endovascular grafts for the treatment of AAAs, the use of this technique has grown rapidly worldwide, surpassing 50% of current elective surgeries.²⁻⁴ Endovascular aortic aneurysm repair (EVAR) is a less invasive alternative associated

with less perioperative morbidity than conventional open repair, including less blood loss and transfusion requirement, shorter procedure times, diminished stay in the intensive care unit, reduced duration of hospital stay, and quicker recovery. In the United States, more than 70% of interventions for AAA treatment are performed using the endovascular technique.⁵

Despite a large number of publications on this technique, there are very few reports on the long-term results. Long-term success depends on aneurysm exclusion. Endoleak could lead to aneurysm pressurization and rupture. The experience with endovascular treatment of AAAs in our service began in 1997.⁶ The results of the first 6 and 10 years were previously published.^{7,8} In this study, our goal is to present the long-term results (20 years) for the implantation of endovascular grafts in AAAs from a single center in Brazil.

METHODS

The experimental protocol and informed consent of this study were approved by the Research Ethics Committee of our institution (number 237/290). We used a prospective cohort of patients with AAA surgically treated with endovascular grafts selected from patients referred for surgical treatment in our institution. We considered all patients subjected to endovascular treatment for AAA between June 1997 and August 2008 for participation in this cohort. Data were collected

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concurrently on all consecutive patients using a propriety database with the clinical and technical variables.

The criteria for the indication of endovascular surgical repair at our institution were as follows: (1) diameter of the aneurysm sac >45 mm, (2) aortas with a diameter greater than or equal to two times the normal diameter of the infrarenal aorta, and (3) an increase in the diameter of the AAA of >5 mm within 6 months. All procedures were performed by the same surgical team using TALENT aortic endograft (Medtronic Vascular, Santa Rosa, Calif) exclusively. Patients with an aneurysm in one of the common iliac arteries were treated with an extension to the external iliac artery and intentional occlusion of the ipsilateral hypogastric artery.

The exclusion criteria for participation in this cohort were (1) patients residing outside the state of Rio de Janeiro or who could not be followed at our institution, (2) nonbifurcated endovascular graft implantation, (3) clinical signs of rupture or hemodynamic instability during the preoperative period, (4) inflammatory aneurysm, (5) surgical risk classified as American Society of Anesthesiologists (ASA) V, (6) bilateral iliac aneurysm with the need for occlusion of both hypogastric arteries, and (7) aneurysms <40 mm. The variables used and the definitions of the outcomes followed the recommendations of the American Society for Vascular Surgery.⁹

According to the protocol, patients underwent clinical assessments and serial imaging through computed tomography angiography within the first 30 days, at 6 months, and then annually. Treatment success was defined as endovascular graft implantation in the absence of (1) an endoleak, (2) twists, (3) kinks, (4) obstructions, dilation, migration, or loss of integrity of the endovascular graft, (5) rupture of an aneurysm associated with the procedure, (6) conversion to open surgery, and (7) death associated with the procedure.

The statistical analysis was conducted with R Statistical Software (Foundation for Statistical Computing, Vienna, Austria). Categorical variables are expressed as frequencies and percentages, and continuous variables are expressed as means and standard deviations. Variables were analyzed by Cox regression model, considering death as the dependent variable and the mean age (≤ 72 years vs >72 years), ASA surgical risk (ASA I and II vs ASA III and IV), sex (male or female), endoleak (yes or no), aneurysm size before treatment (≤ 55 mm vs >55 mm), and aneurysm size reduction (≤ 3 mm or >3 mm) as the independent variables. Kaplan-Meier curves were used to depict event frequencies over time. Comparisons of Kaplan-Meier curves were done with the long-rank test. $P < .05$ was considered significant.

RESULTS

We identified 521 patients with AAAs referred for surgical treatment during the study period. Of these patients, 379 (72.4%) underwent endovascular repair, with a total

ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective analysis of prospectively collected data
- **Take Home Message:** In 229 of 363 patients undergoing endovascular aortic aneurysm repair and followed for a maximum of ≤ 20 years, late survival was associated with age <73 years (hazard ratio [HR], 0.42), abdominal aortic aneurysm size < 55 mm (HR, 0.62), male sex (HR, 0.17), American Society of Anesthesiologists surgical risk I and II (HR, 0.51), and abdominal aortic aneurysm size reduction of <3 mm (HR, 2.23).
- **Recommendation:** This study suggests that age, small aneurysm size, male sex, American Society of Anesthesiologists surgical risk, and sac reduction are specific factors associated with improved late survival after endovascular aortic aneurysm repair.

of 363 bifurcated endovascular grafts, 14 aortouniiliac grafts, and 2 straight tube grafts. The Endovascular graft implantation was possible in 99% of the patients (376/379), and the 30-day mortality rate was 3.4% ($n = 13$).

Among the 363 patients who received a bifurcated graft, the following patients were excluded from the study: 73 patients who resided outside of the defined geographical area, 4 who underwent emergency surgery and presented with hemodynamic instability, 2 owing to the presence of an inflammatory aneurysm, and 1 owing to surgical risk category ASA V. Considering the perioperative deaths of 13 patients and the loss to follow-up of 41 patients, a total of 229 patients in this cohort were available for long-term follow-up, including 45 with an endoleak and 184 without an endoleak.

All patients were followed with computed tomography angiography during the postoperative period according to the described research protocol. Demographic and clinical characteristics of study participants are shown in [Table 1](#).

The mean age of the women was 73.43 ± 0.86 years, which was significantly greater than the mean age of the men (70.43 ± 0.49 years; $P < .05$). The survival time according to the Kaplan-Meier survival curve was significantly better for male patients (8.08 ± 0.49 years) than for female patients (7.77 ± 0.86 years; $P < .05$).

Outcomes in the group without endoleaks. A total of 184 patients (151 men and 33 women) were followed for a maximum of 20 years. Their ages ranged between 52 and 89 years (mean, 71.7 ± 7.85 ; median, 72 years), and the mean AAA diameter ranged between 40 and 115 mm (mean, 59.51 ± 14.6 ; median, 56 mm). Three patients (1.6%) required a second endovascular procedure owing to kinking of the iliac branch of the endovascular graft. Seven patients (3.8%) presented endotension with

Table I. Demographic data and primary characteristics of patients with abdominal aortic aneurysm (AAA) treated with endovascular grafts

Characteristic	
Gender	
Male	185 (80.8)
Female	44 (19.2)
Age, years	71.7 ± 7.85
Diameter of the aneurysm, mm	59.51 ± 14.6
Hypertension	146 (63.8)
Diabetes mellitus	30 (13.1)
Smoking	144 (62.9)
Dyslipidemia	99 (43.2)
History of myocardial infarction	45 (19.7)
Lung disease	59 (25.9)
Peripheral vascular disease	34 (15)
Renal failure	20 (8.7)
Heart failure	19 (8.3)
History of stroke	15 (6.6)
History of neoplasm	13 (5.7)
ASA grade	
I	27 (11.8)
II	111 (48.5)
III	85 (37.1)
IV	6 (2.6)
ASA grade, Surgical risk according to the American Society of Anesthesiologists criteria.	
Values are reported as number (%) or mean ± standard deviation.	

an increase in the diameter of the aneurysm sac of >10 mm, of which one patient (0.5%) required open surgical repair owing to a 24-mm increase in the diameter of the aneurysm sac at year 11 of follow-up. No patient died owing to aneurysm rupture.

At the end of the cohort, 128 patients (69.6%) had died. The causes in order of frequency were cardiovascular, 52 (40.6%); neoplasms, 21 (16.4%); respiratory complications, 15 (11.7%); stroke, 9 (7%); liver failure, 6 (4.7%); sudden death, 6 (4.7%); digestive bleeding, 5 (3.9%); traffic accident, 5 (3.9%); diabetes-related complications, 2 (1.5%); septicemia, 1 (0.8%); and other causes, 6 (4.7%). The most frequent causes of death related to the cardiovascular system were acute myocardial infarction in 26 patients (44.8%), congestive heart failure in 14 patients (24.1%), and arrhythmia in 12 patients (20.7%). Based on the Kaplan-Meier analysis, the estimated survival rate for year 1 was 95.1 ± 1.7%, for year 5 was 71.6 ± 3.5%, for year 10 was 36.2 ± 3.9%, and for year 15 was 22.7 ± 4.0%. For this group, the mean survival time was 8.24 ± 0.43 years.

Outcomes in the group with an endoleak. The 45 patients (31 men and 14 women) with an endoleak were followed for a maximum of 15 years. Their ages

ranged between 73 and 89 years (mean, 78.2 ± 4.1 years), and the mean AAA diameter ranged between 57 and 113 mm (mean, 68.3 ± 12.0 mm).

There were 11 type I, 29 type II, 3 type III, and 2 type IV endoleaks. Among these patients, 26 (57.8%) required a second endovascular procedure, 11 in type I, 14 in type II, and 1 in type III. Open repair was done in three patients with type II and in two patients with type III endoleak. Five patients (11.1%) underwent elective transabdominal open surgical repair with the removal of the graft (two patients died). Additionally, three patients (6.7%) died from aneurysm rupture (emergency surgery was performed in one of the patients, but the patient did not survive).

At the end of the follow-up period, 40 patients (88.9%) had died. The causes in order of frequency were cardiovascular, 14 (35%); multiorgan failure, 6 (15%); aneurysm rupture, 5 (12.5%); respiratory complications, 5 (12.5%); stroke, 3 (7.5%); liver failure, 2 (5.0%); digestive bleeding, 1 (2.5%); renal failure, 1 (2.5%); and other causes, 3 (7.5%). Based on Kaplan-Meier analysis, the estimated survival rate for year 1 was 75.0 ± 6.5%, for year 5 was 47.7 ± 7.5%, and for year 10 was 13.4 ± 6.9%. The mean survival time was 5.29 ± 0.62 years. The long-term results for patients with and without an endoleak are presented in Table II. There was no statistically significant difference ($P = .13$; Fig 1).

Outcomes related to age. For categorization by age, the cohort was divided based on the median age into patients aged ≤72 years and patients ≥73 years. In the Kaplan-Meier analysis, the estimated overall survival time was 9.73 ± 0.61 years for patients ≤72 years of age and 5.97 ± 0.48 years for patients ≥73 years of age ($P < .01$). The cumulative survival rate over time in the younger patients was 96.6 ± 1.9% at 1 year, 70.5 ± 4.9% at 5 years, 44.3 ± 5.6% at 10 years, and 38.6 ± 5.8% at 15 years. In the older patients group, the rate was 83.8 ± 4.3% at 1 year, 51.4 ± 5.8% at 5 years, 17.4 ± 4.8% at 10 years, and 0.0% at 15 years (Fig 2).

Outcomes related to aneurysm size. Regarding the aneurysm size, we considered two groups. The first group had AAAs ≤55 mm in diameter and the second group had larger aneurysms according to the American Guidelines for the indication of surgical treatment of AAAs based on the aneurysm diameter.¹⁰ In the Kaplan-Meier analysis, the estimated overall survival time was 9.38 ± 0.65 years for patients with AAAs ≤55 mm in diameter and 6.79 ± 0.53 years for patients with AAAs with diameters ≥56 mm. The cumulative survival rate over time in patients with AAAs ≤55 mm in diameter was 89.7 ± 3.4% at 1 year, 69.2 ± 5.2% at 5 years, 46.3 ± 5.9% at 10 years, and 30.4 ± 6.4% at 15 years. In the group of patients with AAAs with diameters ≥56 mm, the cumulative survival rate was 91.7 ± 3.0% at 1 year,

Table II. Cause of death in the long-term follow-up of patients with and without an endoleak

Subgroups	Alive	Cardiovascular death	Cancer death	Death owing to respiratory complications	Death owing to aneurysm rupture	Other causes of death
Without endoleak	52 (28.3)	52 (28.3)	21 (11.4)	15 (8.2)	0 (0)	25 (13.6)
With endoleak	5 (11.1)	14 (31.1)	0 (0)	5 (11.4)	5 (11.4)	16 (35.6)

Values are reported as number (%).

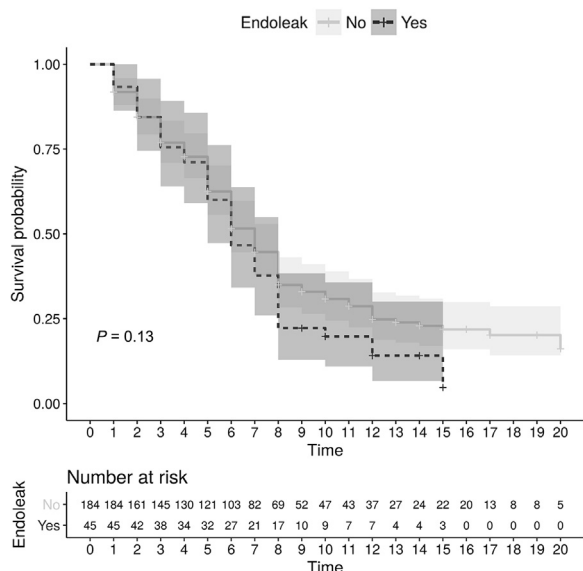


Fig 1. Survival function according to endoleak presence.

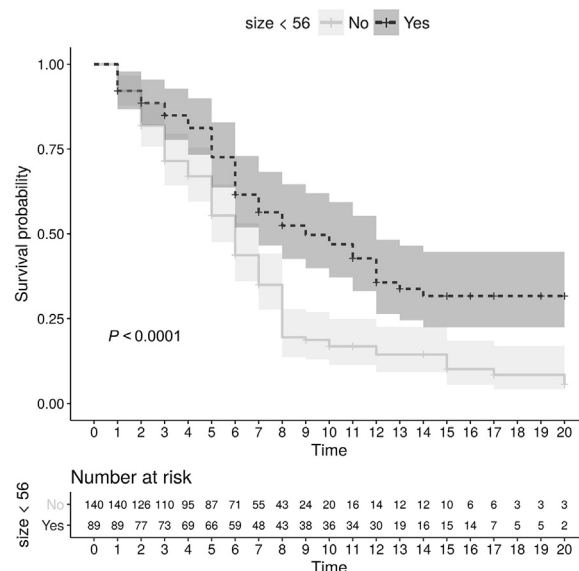


Fig 3. Survival function according to aneurysm size.

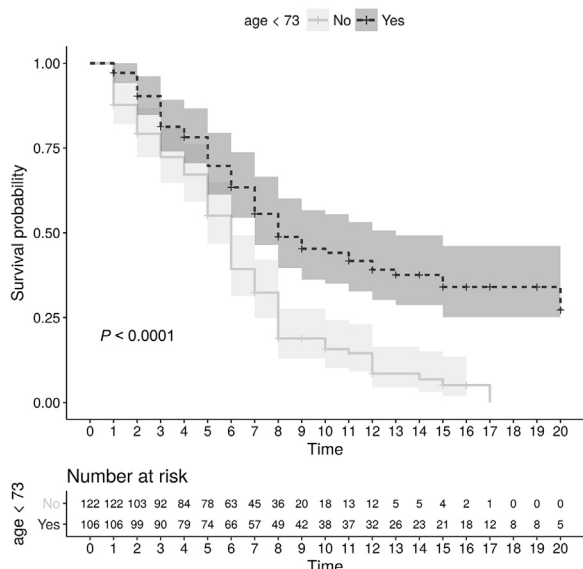


Fig 2. Survival function according to age.

54.8 ± 5.4% at 5 years, 18.1 ± 4.5% at 10 years, and 15.8 ± 4.5% at 15 years. There was a significant difference between aneurysm sizes (log-rank test, $P < .01$; Fig 3).

Outcomes combining age and aneurysm size. Age and aneurysm size were combined in four groups: age ≤72 with AAA ≤55 mm, age ≤72 with AAA >55 mm, age >72 with AAA ≤55 mm, and age >72 with AAA >55 mm. In the age stratum ≤72 years, the overall survival time estimated based on the Kaplan-Meier analysis (Fig 4) was 11.17 ± 0.79 years for patients with AAAs ≤55 mm in diameter and 7.94 ± 0.88 years for patients with AAAs with diameters ≥56 mm ($P < .01$). The cumulative survival rate over time in patients with smaller AAAs was 95.8 ± 2.9% at 1 year, 79.2 ± 5.9% at 5 years, 57.8 ± 7.5% at 10 years, and 47.6 ± 8.2% at 15 years. In the group with the larger AAAs, the rate was 85.0 ± 5.6% at 1 year, 60.0 ± 7.7% at 5 years, 27.2 ± 7.7% at 10 years, and 22.7 ± 7.6% at 15 years.

In the age stratum >72 years, the overall survival time estimated based on the Kaplan-Meier analysis (Fig 4) was 6.45 ± 0.87 years for patients with AAAs ≤55 mm in diameter and 5.59 ± 0.52 years for patients with AAAs with diameters ≥56 mm ($P < .01$). The cumulative survival rate over time in patients with smaller AAAs was 80.0 ± 7.3% at 1 year, 53.3 ± 9.1% at 5 years, 28.1 ± 8.6% at 10 years, and 0.0% at 15 years. In the group with the larger AAAs, the rate was 86.4 ± 5.2% at 1 year, 50.0 ± 7.5% at 5 years, 9.5 ± 5.3% at 10 years, and 0.0% at 15 years.

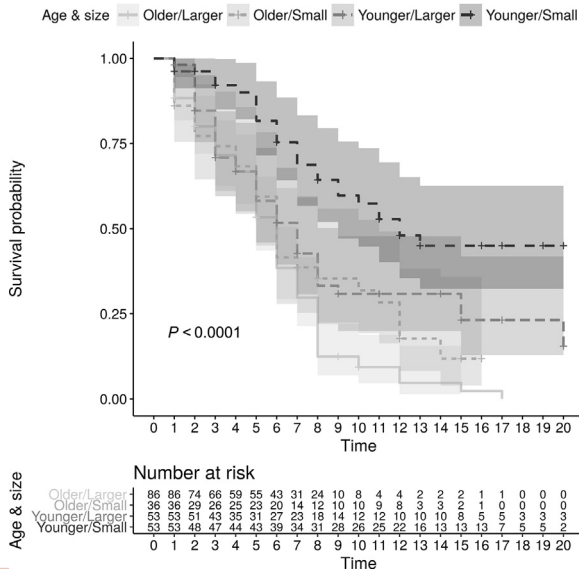


Fig 4. Survival function according to age and aneurysm size.

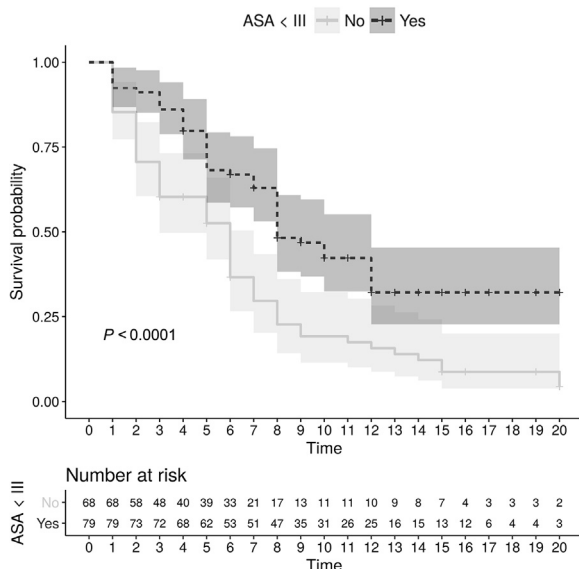


Fig 5. Survival function according to American Society of Anesthesiologists (ASA) risk.

Outcomes according to ASA surgical risk. The ASA classification is used worldwide by anesthesia providers as an assessment of the preoperative physical health of patients. Considering that there were only five patients in ASA IV category, we decided to analyze two groups, ASA I and II vs ASA III and IV. There was a significant difference between ASA risk groups I and II vs III and IV (log-rank test, $P < .01$). The ASA risk survival curve is presented in Fig 5.

Cox regression analysis. We tested in Cox regression model the variables death as the dependent variable

and the mean age, ASA surgical risk, sex, endoleak, aneurysm size, and aneurysm size reduction as the independent variables. The analysis demonstrated as significant five independent variables (Supplementary Table): (1) aneurysm size (hazard ratio [HR], 0.62; 95% confidence interval [CI], 0.40-0.95), (2) age (HR, 0.42; 95% CI, 0.27-0.64), (3) ASA risk (HR, 0.51; 95% CI, 0.34-0.75), (4) sex (HR, 0.17; 95% CI, 0.05-0.52), and (5) aneurysm size reduction <3 mm in the first 30 days after endovascular treatment (HR, 2.23; 95% CI, 1.11-4.51). Endoleak (HR, 0.72; 95% CI, 0.43-1.18) was not significant.

DISCUSSION

Few publications have reported long-term results after endovascular treatment of AAAs. In the vast majority of cases, the studies compared the immediate and late results of endovascular treatment vs conventional open surgical repair.¹¹⁻¹⁸ Brewster et al³ found a survival rate of 52% at 5 years after treatment, and Gloviczki et al¹⁹ reported a survival rate of 66% for the same follow-up period. The EVAR study found a survival rate of 68.9% at 6 years after treatment.¹⁶ Wibmer et al²⁰ observed a survival rate of 70.8% at 5 years and 37.7% at 10 years. These results are similar to those found in our study, with survival rates of 71.6% at 5 years and 36.2% at 10 years.

Cardiovascular diseases were the most frequent among the preoperative comorbidities and the main causes of mortality in the long-term follow-up, followed by neoplasms. Several publications confirmed cardiovascular diseases as the main preoperative comorbidities.^{3,16,21,22}

In all studies, most patients who underwent endovascular treatment for AAAs were male. Female patients corresponded with only 14.7% of the study population of the EVAR study and 19.2% of the population in our study.¹⁴ Several publications claimed that the mortality rate in patients subjected to endovascular treatment for AAAs was higher in females, and this difference was confirmed in our study.^{19,23}

Aneurysm diameter is correlated with thrombosis of the aneurysm sac and an increased risk of endoleak development.²⁴ In our study, the presence of an endoleak was correlated with a larger aneurysm sac diameter. Age was also reported to be correlated with an increased size of the aneurysm sac, which was reflected in our group of patients with an endoleak. The need for reintervention and the presence of an endoleak are factors known to significantly reduce survival as well as risk factors associated with rupture.^{24,25} In our study, patients with an endoleak presented higher mortality and reintervention rates, albeit without statistical significance.

AAA is a disease related with age.²⁶ When we analyzed the influence of age using the Kaplan-Meier survival curve, we observed that the life expectancy of 20 years for patients aged ≤ 72 years was 38.6%, whereas all patients >72 years of age died. Age as a predictor of survival has been well-described in various studies.^{18,19,25-29}

A quick recovery and an improved quality of life are observed in patients undergoing endovascular treatment, which is particularly important in elderly patients.²⁸ The improvement in postoperative care, anesthesia, and the introduction of the endovascular technique has led to better results and fewer complications; thus, the indication of the endovascular technique for these patients has increased in recent years.²⁸ Therefore, elderly patients (especially those with favorable anatomy) can benefit from the endovascular technique as long as they do not have severe life-limiting comorbidities. Considering (1) the 30-day mortality after treatment with EVAR, (2) the risk of death from aneurysm rupture, and (3) the life expectancy of the patients considered inoperable, we observed significant heterogeneity between the clinical study results. Therefore, in patients considered at high surgical risk, we suggest that endovascular treatment should be used only after an individual risk analysis. The reduction in the risk of death from rupture associated with the endovascular treatment based on the life expectancy and patient preference must offset the risk of the procedure (30-day mortality).

The AAA size has several implications in the decision to apply endovascular treatment. Large aneurysms are associated with greater technical difficulty than small aneurysms.³⁰ Furthermore, clinical follow-up of small diameter AAAs (41–54 mm) requires thorough observation using imaging methods for safety.³¹ Although several studies have demonstrated the lack of superiority of endovascular treatment over clinical observation in small diameter AAAs, recent studies have shown that most of these patients will require interventional treatment over time.^{32–34} In the CAESAR study (Comparison of surveillance vs aortic endografting for small aneurysm repair), the need for treatment at 36 months was 59.7% for small AAAs under observation, and this value increased to 84.5% at 54 months.³¹ After 3 years of follow-up, Chang et al²⁵ found a mortality rate of 2.0% for AAAs ≥ 55 mm and 0.1% for AAAs < 55 mm among patients undergoing endovascular treatment. Ouriel et al³⁴ claimed that endovascular treatment was a safe option for small aneurysms. The EUROSTAR analysis revealed excellent long-term results for the endovascular treatment of small aneurysms and suggested that these findings justified a modification in the currently accepted treatment indications.³⁰ Peppelenbosch et al³⁰ concluded that the endovascular treatment of AAAs was less effective in aneurysms with larger diameters and suggested that this treatment was more long lasting in small aneurysms. In our study, we observed a significant difference in survival after 20 years of follow-up.

In our case series, age and AAA size were moderately correlated. Thus, we decided to study the influence of both variables on survival. Young patients with small

AAAs presented a survival rate of 47.6% at 15 years of follow-up, whereas the survival rate of patients in the same age group with aneurysms > 55 mm was 27.2%. The survival rate in elderly patients (> 72 years of age) with large aneurysms (> 55 mm) was 0%. The patients with advanced age and large aneurysms had a greater incidence of comorbidities and consequently a greater surgical risk.³⁰ The high surgical risk has been a concern since the publication of the EVAR-2 study, which found an immediate mortality rate of 9% in high-risk patients for open surgery.³⁴ We studied the effect of this variable over 20 years and observed a mean life expectancy of 12.17 years for ASA class I patients and 3.3 years for ASA class IV patients.

Another important finding in this series was that the 30-day aneurysm sac diameter reduction was an independent factor related to better survival. It seems to reflect a treatment success, and future studies should consider this variable in their outcomes.

Our study has some limitations. First, this study is not a randomized study; therefore, the direct comparisons between subgroups must be evaluated with caution. Another limitation is the attrition bias owing to the loss to follow-up of 14.5% of the patients, although this percentage cannot be considered high for a 20-year follow-up. The results were generated by a single surgical team and with a single type of graft; therefore, the external validity of these results must also be evaluated. The learning curve (ie, the lower initial experience of the team with the selection or the procedure) can influence the surgical results; for example, no intraoperative deaths occurred for the last 78 patients in our series. Finally, the number of patients at the end of the follow-up was small, which potentially reduces the validity of the results.

CONCLUSIONS

This is a 20-year prospective cohort of patients with AAA treated with a bifurcated endovascular graft (Talent) in a university hospital in Brazil. This study supports that sex, age, aneurysm size, aneurysm size reduction, and ASA surgical risk class are variables significantly correlated with the survival of the patients after endovascular treatment of an AAA.

AUTHOR CONTRIBUTIONS

Conception and design: GE, LD, CM

Analysis and interpretation: GE, BG, RR, PS, LD, CM

Data collection: GE, GL, MA

Writing the article: GE, PS, LD, CM

Critical revision of the article: GE, GL, MA, BG, RR, PS, LD, CM

Final approval of the article: GE, GL, MA, BG, RR, PS, LD, CM

Statistical analysis: RR, CM

Obtained funding: Not applicable

Overall responsibility: GE

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Supplementary Table. Hazard ratio and confidence interval (CI) based on Cox model for patients undergoing endovascular treatment of abdominal aortic aneurysm (AAA)

Variable	Hazard ratio	95% CI
Endoleak	0.72	0.43-1.18
Male sex	0.17	0.05-0.52
Aneurysm size < 55 mm	0.62	0.40-0.95
ASA class < III	0.51	0.34-0.75
Age < 73 years	0.42	0.27-0.64
Aneurysm size reduction $\leq$ 3 mm	2.23	1.11-4.51
ASA, American Society of Anesthesiologists.		

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