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ORIGINAL SCIENTIFIC REPORT

Outcomes Following Non-operative Management of Thoracic and Thoracoabdominal Aneurysms

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Abstract

Background Surgical decision making remains difficult in several patients with aneurysmal disease of the descending thoracic (DT) or thoracoabdominal (TA) aorta. Despite previous studies that have investigated aneurysms treated non-operatively using a prospective growth analysis, completeness and accuracy of follow-up were inconsistent. We aim to describe the survival and freedom from adverse aortic events in patients with DT and TA who did not undergo operative repair.

Methods This is a single-center retrospective analysis of all patients with either a descending degenerative atherosclerotic or dissection-related DT or TA aortic lesion who were treated non-operatively from April 2002 to December 2016. We studied patients who did not undergo operative repair of descending degenerative atherosclerotic or dissection-related DT or TA aortic lesion. Primary end points were overall survival and freedom from aortic-related mortality (ARM).

Results Of the 315 patients diagnosed with DT or TA disease, 56 (18%) did not undergo surgical repair. Mean aneurysm diameter was 65 mm ± 15 (range 50–120; IQR 5.4–7.15). Extent of the aortic aneurysms was DT in 36 (11%) patients and TA in 20 (6%). Median duration of follow-up was 12 months (range 1–108; IQR 3–36). Over the course of the study, 41 (73%) patients died for an overall survival rate of 53% ± 7 at 1 year (95% CI 40–65) and 23% ± 7 at 3 year (95% CI 17–42.5). Aortic-related mortality was 27% (n = 15), significantly higher in patients with aneurysms ≥ 60 mm [n = 13, (39%) vs. n = 2, (9%); P = 0.025; OR = 5.04]. Overall, estimated freedom from ARM was 81% ± 5.5 at 1 year (95% CI 68–89) and 66.5% ± 9 at 3 year (95% CI 48–81). Only TA extent was independently associated with freedom from ARM during the follow-up (P = 0.005; HR: 5.74; 95% CI 1.711–19.729).

Conclusions Thoracoabdominal extent of the aneurysmal aortic disease is the most important predictor of ARM in unrepaired DT or TA aortic diseases. Mortality from aortic-related events was significantly more premature than mortality from non-aortic-related mortality.

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Introduction

Repairing an aneurysm of the descending thoracic (DT) and thoracoabdominal (TA) aorta is often a dilemma. The aim of a surgery is to operate; clinical decision making is challenging as the surgeon recommends intervention only when necessary, but also does not wish to delay a possible life-saving procedure. Most of the recent analyses coming from "real-world" experience showed that thoracic endovascular aortic repair (TEVAR) is associated with better early outcomes when compared to open repair (OR). In order to take advantage of the minimally invasive nature of TEVAR, it has been suggested to lower the size threshold for operative repair [1–5]. Nevertheless, even in this endovascular era, surgical decision making remains challenging in patients who are considered unfit for any surgical repair due to comorbidities and risk factors [6–9]. Following this recommendation may deprive these patients of a potentially life-saving intervention due to an overestimation of the operative risk, also because dedicated predictive risk scores for a potential minimally invasive treatment such as TEVAR are still not available [10–14].

Few previous studies have investigated the natural history of DT or TA aortic aneurysms. They often included small aortic lesions, posed most of the attention on a prospective analysis of the aortic growth, and completeness as well as accuracy of follow-up was not always thoroughly completed [15–24].

The aim of this study was to analyze the survival and freedom from aortic-related mortality (ARM), in patients with DT and TA aneurysms who were potential surgical candidates due to the aortic lesion diameter but were not treated with operative repair because of their adverse operative risk profile.

Materials and methods

Study design and cohort of patients

This is a single-center, observational, descriptive cohort study. Starting from April 2002, all continuous patients diagnosed with a thoracic or thoracoabdominal aortic disease were collected into a dedicated database. Variables collected include demographic characteristics, either clinical or morphological data, operative details of aortic interventions, and follow-up outcomes. This database has been implemented with additional information during these years. For this specific analysis, a post hoc research identified patients:

- Who did not undergo operative repair of DT or TA aortic aneurysms with an aortic diameter of 50 mm at least;
- Who had computed tomography (CT) or magnetic resonance imaging (MRI) of the whole aorta performed at baseline.

Exclusion criteria for the final analysis were as follows:

- Operative repair (either conventional graft replacement, hybrid treatment, total endovascular exclusion) of the aortic disease;
- Known connective tissue disorders (Marfan, Loeys–Dietz, and Ehlers–Danlos syndromes), aortic cancer, isolated ascending aortic aneurysm, history of prior thoracic aortic surgery, or anomalies of the aorta (e.g., free-floating thrombus, coarctation of aorta and Kommerell diverticulum);
- Rupture as first diagnosis of the DT or TA aortic aneurysms.

Informed consent for baseline CT or MRI was acquired for each patient. Retrospective analysis of the anonymized data did not require approval of the Institutional Review Board, according to the National Policy in the matter of Privacy Act on retrospective analysis. A local coordinator (GP) was responsible for follow-up examinations review and data collection. For the final analysis, the end of study was December 31st, 2016.

Aortic assessment, treatment protocol and follow-up

Aortic diameters were measured systematically at the levels of ascending, arch, descending thoracic, and thoracoabdominal segments, all measurements were adventitia-to-adventitia. After the first diagnosis of DT or TA aortic aneurysm, every patient received recommendations for optimal medical treatment, generally comprising an association of β-blocker, aspirin and statins [7, 8]. Every patient entered a program of clinical and radiological surveillance which included contrast-enhanced CT performed on a yearly basis.

Definition

Aortic disease extent was classified according to Estrera et al. [25] for isolated DT lesions, to the modified [26] Crawford classification for TA lesions, and to DeBakey et al. [27] for dissection-related lesions. In order to assess the validity of the clinical decision making, operative risk was defined prohibitive after a multidisciplinary evaluation which considered the clinical visit, a full panel of laboratory blood tests, and evaluation of the respiratory, cardiac and renal function. Comorbidities were defined according

to the Society of Thoracic Surgeons adult database [28]. Morphologic characteristics and outcomes were defined according to the European Association for Cardio-Thoracic Surgery/European Society for Cardio-Vascular Surgery (EACTS/ESCVS) best practice guidelines for reporting treatment results in the thoracic aorta, and/or the Society for Vascular Surgery (SVS) ad hoc committee on TEVAR reporting standards [29, 30]. Primary end points were overall survival and freedom from ARM. Accordingly, to establish unbiased definitions of the aortic events, we estimated ARM as definite and possible event [24, 31]. Definite event was an aortic rupture confirmed by adequate imaging studies or autopsy finding. Possible event included sudden death not explained by causes other than aortic disease. Through December 2016, information on major end points, vital status and date of death of individual patient were validated by death certificate, electronic charts managed by the regional health care system, or certified data from Emergency Department admission.

Statistical analysis

Clinical data were prospectively recorded and tabulated in Microsoft Excel (Microsoft Corp, Redmond, Wash) database. Statistical analysis was performed with SPSS, release 23.0 for Windows (IBM SPSS Inc.; Chicago–ILL; USA). Categorical variables were presented using frequencies and percentages, and continuous variables were presented with mean ± standard deviation (SD) and interquartile (IQR) range; otherwise, medians with range were applied. For categorical variables, we used the Pearson's chi-squared test. Independent samples Student's *t*-test was used for continuous variables. For multivariable analyses, Cox proportional hazards models were used to determine independent risk factors for mortality and of ARM during the follow-up. The significance within the models was evaluated with the Wald test, whereas the strength of the association of variables with postoperative mortality or adverse aortic events was estimated by calculating the odds

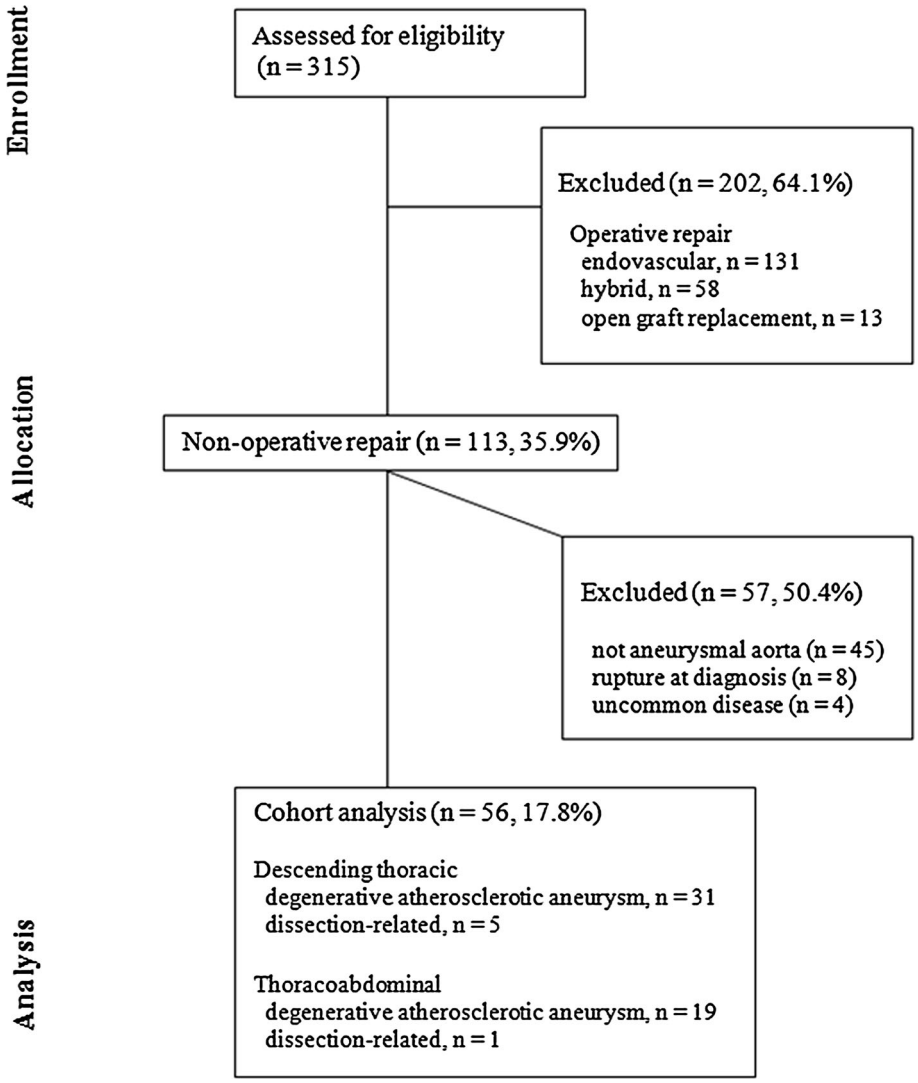


Fig. 1 Consort diagram of all patients evaluated for descending thoracic or thoracoabdominal aortic diseases

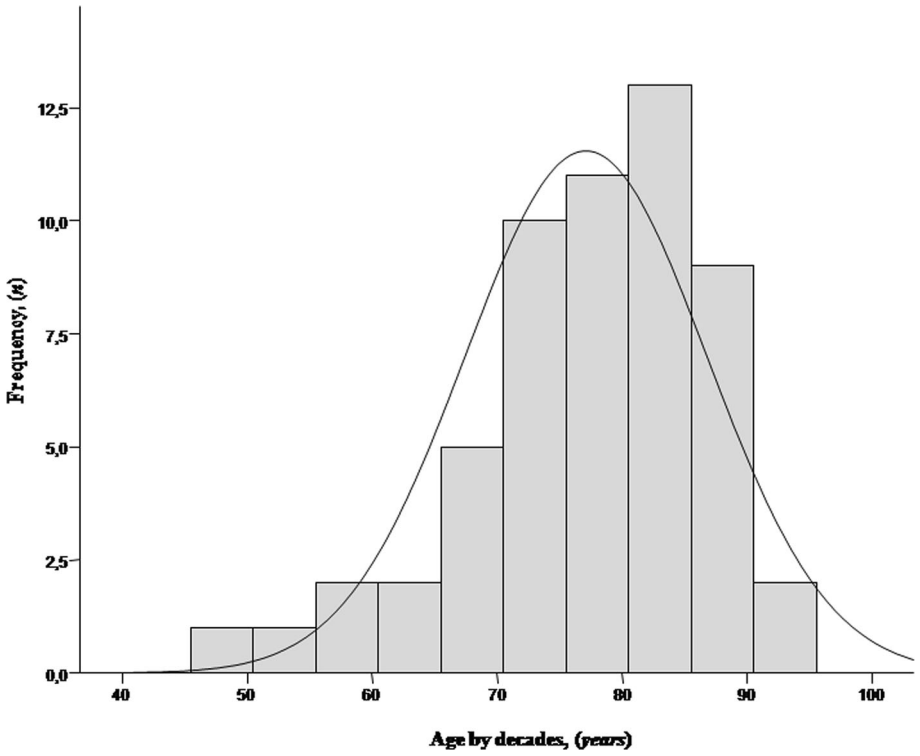


Fig. 2 Baseline distribution of the age by decade

ratio (OR) and 95% confidence intervals (CIs). The model was built using variables that demonstrated a P value < 0.20 in univariable mode. Kaplan–Meier curves, ± standard error (SE) and 95% confidence interval (CI), estimated the probability of mortality or adverse aortic events. Log-rank tests were used to compare between-group differences in rates. All reported P values were two-sided; P value < 0.50 was considered significant.

Results

General population and cohort data

Overall, 315 patients were referred to our unit being diagnosed with DT or TA aortic disease. We identified and included into the final analysis 56 (18%) patients. Figure 1 shows the consort diagram indicating all patients with thoracic aortic diseases during the period of study, including the patient population from which this series was derived. The cohort was predominantly male (n = 37, 66%). Overall, mean age was 77 ± 10 (range 48–91; IQR 73–83), with age distribution is represented in Fig. 2. A significant difference of age was observed between patients who underwent operative repair versus those who did not undergo operative treatment (69 ± 14 vs. 77 ± 10, $P < 0.001$). Comorbidities and risk factors of the entire cohort are summarized in Table 1. We observed 50 (89%) degenerative atherosclerotic aneurysms and 6 (11%) dissection-related aneurysms: mean aneurysm diameter was 65 mm ± 15 (range 50–120; IQR 5.4–7.15). Extent of the aortic aneurysms is summarized in Table 2.

Follow-up outcomes

Some of these (n = 7, 12.5%)refused operative intervention regardless of indication; whereas, others were considered unfit for any type of surgical repair as reported in Table 3. Median duration of follow-up was 12 months (range 1–108; IQR 3–36), and 39 (70%) patients had a follow-up evaluation ≥ 12 months. During the follow-up, 41 (73%) patients died; 26 (46%) patients died of non-aortic events (Table 4). The estimated overall survival was 53% ± 7 at 1 year (95% CI 40–65) and 23% ± 7 at 3 years (95%CI 17–42.5). No demographic variable, clinical or morphological parameter was independently associated with all-cause mortality during the follow-up (Fig. 3). Mortality due to aortic events accounted for 15 (27%) patients: it was definite in 10, and considered possible in 5. Most (n = 10, 67%) of the ARM occurred ≤ 12 months from the first diagnosis of the aneurysmal disease. All had a diameter ≥ 60 mm, and none of ARM was determined by dissection-related aneurysm. Estimated mean survival (months, 43 ± 7 vs. 16 ± 5) was significantly lower when mortality was aortic-related if compared to non-aortic-related events (Fig. 4), The ARM rate was significantly

Table 1 Comorbidities and risk factors for the entire cohort

Variable	*N* (%)
Comorbidities	
Hypertension	52 (93)
COPD	25 (45)
CAD	17 (30)
Obesity (BMI > 30)	15 (27)
CKD (eGFR < 30 mL/min)	14 (25)
CVA	9 (16)
Arrythmia	10 (18)
Cancer	9 (16)
Diabetes	6 (11)
LHF	5 (9)
AVS	2 (4)
Risk factors	
≥ 3 risk factors	31 (55)
Prox Asc/Arch surgery	6 (5.3)
Previous Asc surgery	2 (4)
Previous AA surgery	7 (12.5)
Associated Asc/Arch lesion	2 (4)
Associated AA lesion	17 (30)
$EuroSCORE_{st}$ (mean ± SD)	13 ± 4 (IQR 10–14.75)
$EuroSCORE_{log}$ (mean ± SD)	41 ± 26 (IQR 19.8–55.4)

Sources Cockcroft and Gault (1976), Roques et al. (1999)

N number, *SD* standard deviation, *IQR* interquartile range, *COPD* chronic obstructive pulmonary disease, *CAD* coronary artery disease, *CKD* chronic kidney disease, *CVA* previous cerebrovascular accidents, *LHF* chronic left heart failure, *AVS* aortic valve stenosis, *Prox* proximal, *Asc* ascending, *AA* abdominal aortic, *BMI* body mass index, *eGFR* estimated glomerular filtration rate

higher in patients with aneurysms ≥ 60 mm [$n = 13$, (39%) vs. $n = 2$, (9%); $P = 0.025$; OR = 5.04] and remained significantly different when stratified for aneurysm diameter [< 56 mm, (10%) vs. 56–60 mm, (18%), vs. > 60 mm, (44%); $P = 0.029$; OR = 7.06]. Overall, estimated freedom from ARM was 81% ± 5.5 at 1 year (95% CI 68–89), and 66.5% ± 9 at 3 year (95% CI 48–81). No preoperative comorbidities were significantly associated with ARM. In contrast, associated ascending/arch disease, aortic disease extent, and an aortic aneurysm diameter ≥ 60 mm entered the multivariable analysis: only aortic disease extent (thoracoabdominal vs. descending) was independently associated with freedom from ARM during the follow-up ($P = 0.005$; HR: 5.74; 95% CI 1.711–19.729).

Table 2 Type and extent of the aneurysmal disease of the thoracic aortic disease

Variable	*N* (%)
Degenerative atherosclerotic aneurysms[a]	
Type A	5 (9)
Type B	15 (27)
Type C	11 (20)
Degenerative atherosclerotic aneurysms[b]	
Extent 1	3 (5)
Extent 2	7 (12.5)
Extent 3	5 (9)
Extent 4	1 (2)
Extent 5	3 (5)
Dissection-related aneurysms[c]	
Type 3 (thoracic)	1 (2)
Type 3 (thoracoabdominal)	5 (9)

N number

[a]Isolated descending thoracic, according to the Estrera classification

[b]Thoracoabdominal extent, according to the modified Crawford classification

[c]According to the Debakey classification

Table 3 Indication for non-operative treatment of thoracic aortic disease

Non-operative treatment	*N* (%)
Not indicated	
Prohibitive risk	37 (66)
Aortic size	9 (16)
Advanced cancer	3 (5)
Refused	7 (12.5)

N number

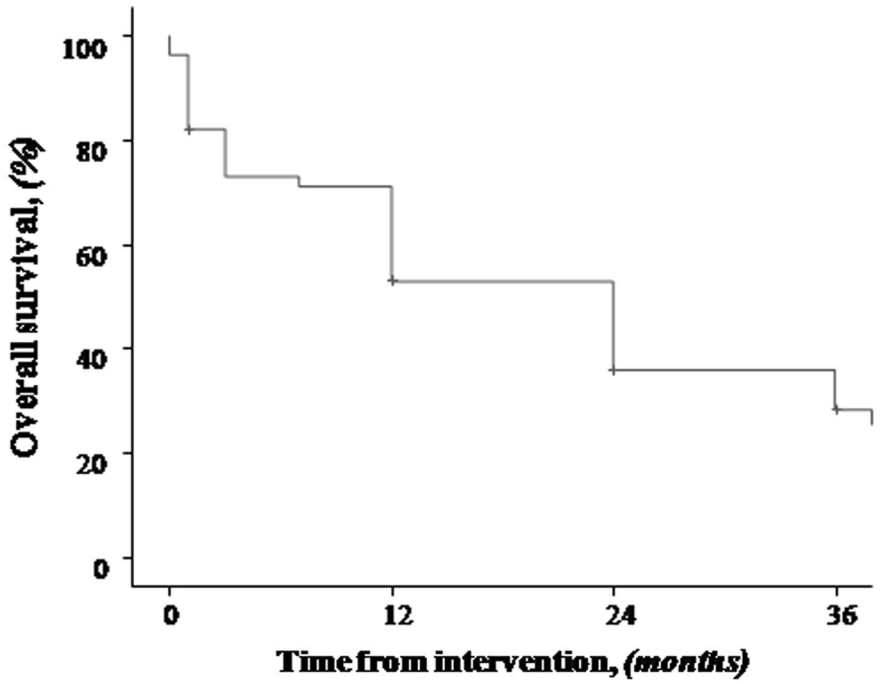
Discussion

Most of the studies reporting on thoracic aortic diseases have been focused on outcomes after operative repair of DT or TA lesions, either using conventional graft replacement or endovascular techniques. There are few studies reporting specifically on the natural history of DT or TA. Furthermore, these studies included different types of aortic lesions and took into the analyses also small aortic lesions [19, 21]. In this analysis, we took into account only those patients with DT or TA whose aortic met the threshold recommended for operative treatment according to consensus documents and guidelines [7, 8]. In this setting, specific outcome prediction rests on a favorable risk/benefit ratio which is still very demanding in surgical decision-making evaluation [10–13]. Thus, a group of

Table 4 Non-aortic mortality for the entire cohort

Cause of death	*N*	%
Advanced cancer	7	17.1
Sepsis	3	7.3
Chronic left heart failure	3	7.3
Old age	3	7.3
Respiratory insufficiency	2	4.8
Multiple organ failure	2	4.8
Bowel ischemia	2	4.8
Acute myocardial infarction	1	2.4
Major stroke	1	2.4
Acute kidney injury	1	2.4
Trauma	1	2.4

patients may still not be considered a good candidate for operative repair, even with the advent of the minimally invasive nature of TEVAR [32]. Prior to the widespread availability of TEVAR, Masuda et al. [16]. opted for non-operative treatment in 45% of their thoracic aortic aneurysms, because of small diameter, high risk for surgery, or because of patient's refusal. This percentage is not significantly different from the 40% reported by Kim et al. [24] in a more recent era when TEVAR was an available less traumatic alternative operative treatment. Considering the diameter threshold suggested for operative repair in currently accepted guidelines, the number of patients excluded was 20% in our experience. This was the result of a multidisciplinary team evaluation, which is a suggestion reported in these guidelines [30, 32]. If we take into



No. at risk	54	29	17	11
Survival, (%)	96	53	36	28
S.E.	2.5	7	7	7
95%CI	88-99	40-65	24-50	17-42.5

Fig. 3 Kaplan–Meier estimate of overall survival

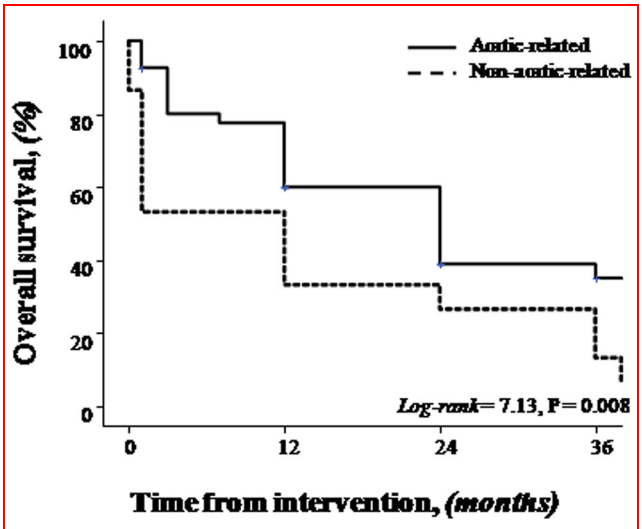


Fig. 4 Kaplan–Meier estimate of freedom from aortic-related mortality and non-aortic-related mortality

account that aortic-related mortality was significantly early if compared to non-aortic-related mortality, with our results we can suggest a more aggressive approach to operative repair which includes patients currently considered at too prohibitive risk even for TEVAR. The creation of a risk score specifically designed for TEVAR could further refine the operative risk evaluation even in these latter patients; this would not deprive our patients of a potentially life-saving intervention due to an overestimation of operative risk, for example simply based on age evaluation.

Aortic lesion diameter is the most commonly used and probably most significant predictor of adverse events during the follow-up [21, 24]. The latest guidelines reported that 60 mm is the diameter threshold over which the rate of adverse events increases exponentially [8, 32–34]. The findings in our experience confirm this observation since most of the ARM occurred in lesion $\geq$ 60 mm. Most alarmingly, ARM most often occurred within the first year from detection of the aortic lesion. This novel finding may support operative intervention with TEVAR in patients who have, to date, been considered to be at a very high risk [35–37]. Finally, the fact that 13% of the aortas with a diameter $<$ 60 mm ruptured, occurring in 50% of the case within the first year from the detection, could support a reduction in the diameter threshold for potential intervention, particularly if less invasive endovascular approaches are anatomically feasible [23, 37]. Our recommendation is consistent with a recent report of Kim et al. [24] who showed that discriminating aortic events were higher for indexed aortic sizes referenced by body size rather than absolute aortic diameter.

Despite the influence of the aortic diameter on ARM, in our experience the only independent parameter of ARM was the TA extent of the aortic lesion. These data may find a potential explanation in the fact that TA aneurysms were more frequently associated with a diameter $\geq$ 60 mm. An observation which finds support in previous studies which already recognized the TA extent as the most limiting factor in achieving acceptable rate of perioperative mortality while treating thoracic aortic pathologies [38].

Limitation

The present study has several limitations. The cohort is small, and data represent the experience of a single tertiary academic referral center. Therefore, the results may not be "generalizable." Also, despite our decision-making process for non-operative management of such lesions followed with the suggestions of recognized guidelines (e.g., multidisciplinary team evaluation), no consensus exists on the definition of a truly "untreatable" patient. Nevertheless, this cohort represents an estimation of the prognosis of unrepaired aortic diseases. Further, all DT and TA aortic diseases were managed by members of our service only, and not by different divisions or departments. Studies on larger cohorts are needed to further verify the main findings of the present study.

In conclusion, TA extent of the aneurysmal aortic disease is an important predictor of ARM in unrepaired lesions. These data incorporate the impact of the aortic diameter as a prognostic factor of mortality. Considering the lack of adequate risk prediction scoring methods to define a patient truly "unfit" for surgery and the wide variation in mortality from aortic-related events, we recommend a re-evaluation of the indications for operative repair and considering including patients who have been previously deemed at prohibitive risk.

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