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Combination of mural thrombus and age improves the identification of all-cause mortality following branched endovascular repair

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Abstract

Background: In-hospital and 30-day mortality rates of endovascular repair of thoracoabdominal aortic aneurysms shows a significant improvement over open surgery, although we are not seeing a significant difference at 1 year. We assess the hypothesis that a greater mural thrombus ratio within the aorta could function as an indicator of postoperative mortality.

Methods: The mural thrombus ratio and preoperative comorbidities of 100 consecutive patients from a single center undergoing endo-debranching between 2012 and 2019 were evaluated. Logistic regression, survival analysis, and decision tree methods were used to examine each variable's association with death at 1 year.

Results: At the time of analysis, 73 subjects had 1-year outcomes and adequate imaging to assess the parameters. At 1 year, the overall survival for all subjects was 71.2% (21 died, 52 survived). For patients with a favorable mural thrombus ratio (n = 36), the overall 1-year survival was 86.1% (5 died, 31 survived). The subjects with an unfavorable mural thrombus ratio (n = 37), had an

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overall 1 year survival of 56.8% (16 died, and 21 survived). The only preoperative mortality factor that was statistically significant between the subjects with an unfavorable mural thrombus ratio was age of the patient. The survival for subjects 75 years and older with an unfavorable mural thrombus ratio was 90% (one died, nine survived) vs only 44.4% survival for subjects less than 75 years with an unfavorable mural thrombus ratio (15 died, 12 survived).

Conclusions: This study examined whether a patient's mural thrombus ratio may be an indicator of 1-year survival. These findings suggest that the combination of a patient's aortic mural thrombus ratio and age can function as a preoperative indicator of their underlying cardiac reserve. Identifying patients with low cardiac reserve and fitness to handle the increased cardiac demands owing to the physiologic response to extensive aortic stent grafting before undergoing aortic repair may allow for modification of preoperative patient counseling and postoperative care guidelines to better treat this patient population.

Keywords

Aneurysm; Aorta; Mortality; Risk factors

Although open surgical repair has historically been the mainstay for the treatment of thoracoabdominal aortic aneurysms (TAAAs), endovascular techniques have evolved to allow a less-invasive treatment option for patients.[1] Owing to its minimally invasive nature, endovascular aneurysmal repair can be offered to patients who in the past would not have been considered candidates for open procedures owing to their underlying comorbidities. Since 2012, our team has investigated an endovascular aneurysm repair system geared towards the repair of TAAA that comprises a visceral manifold stent graft system (MVM) and a unitary stent graft system (UVM).[2,3] We have now treated more than 100 patients with either the MVM or UVM and have sufficient data to begin evaluating trends based on outcomes.

After review of the literature, Centers for Medicare and Medicaid Services data, and our data, the in-hospital and 30-day mortality rates of patients treated endovascularly for thoracoabdominal aneurysm show a statistically significant improvement over open surgery.[4-7] However, the 1-year all-cause mortality following endovascular repair of TAAAs shows no statistically significant difference as compared to open surgery.[8] Given this information, we believe that patients who historically have not been candidates for open surgical repair are now eligible for endovascular TAAA repair, thus exposing a population of patients to treatment that has not been studied previously. It is believed that these patients have a potentially limited cardiac reserve, which may take several months to manifest the full hemodynamic effects by shifting their Starling curve,[9] so although the shortterm survival of these patients is improved, the long-term survival is unchanged. Given the lack of aortic compliance after endovascular repair, we postulate the amount of aortic coverage owing to the endovascular system likely alters cardiac physiology.

There is significant interest from physicians, industry, and regulatory bodies to identify preoperative factors for patient selection in addition to guiding care protocols. This may influence preoperative counseling on risks and benefits, as well as having effects on postoperative management to optimize their care. We believe that a combination of preoperative factors might function as predictors of postoperative outcomes, and this combination may provide effective criteria to stratify patients before offering TAAA repair. Thus, identifying compensatory responses may be the key to estimating one's cardiac reserve and we hypothesize this paradigm may significantly contribute to the all-cause mortality following complex aneurysm repair.

Intraluminal mural thrombus is present in 70% to 80% of TAAAs,[10] suggesting compensatory narrowing of the aortic aneurysmal lumen is a common pathophysiologic response to reduce afterload and cardiac output demands to preserve perfusion. Thus, we hypothesized the degree of mural thrombus load and subsequent luminal narrowing within the aneurysm sac, compared to a wide open aneurysm, may correlate with a patient's cardiac reserve and serve as a valuable preoperative indicator of patients' postoperative viability.

METHODS

Patient selection.

This retrospective and prospective review included 100 consecutive patients treated between 2012 and 2019. Patients were treated before and following the initiation of our physician-sponsored investigational device exemption (PS-IDE), G140207. The PS-IDE was approved by the U.S. Food and Drug Administration and is listed on ClinicalTrials.gov (NCT02294435). The Sanford Health Institutional Review Board approved the use of the investigational devices as well as the collection and storage of retrospective and prospective patient data with informed consent required. The first 25 patients were treated before the initiation of the PS-IDE with their data collected retrospectively. Seventy-five patients were enrolled in the PS-IDE with their data were collected prospectively. Patients were excluded from the analysis if they had inadequate imaging to assess the parameters, had a dissection in the section being measured, or lacked 1-year outcomes (n = 27).

Patient and aneurysm characteristics.

Based on the preoperative workup, all patients were deemed unfit for open repair or commercially available devices. Crawford TAAA classifications 1 to 5[11,12] as well as juxtarenal, paravisceral, pararenal, and short neck infrarenal aneurysms (<10 mm) were treated. The most common comorbidities were smoking and hypertension (Table I).

Devices.

Patients were treated with either the physician-modified MVM (n = 27), Medtronic-manufactured MVM (n = 22; Medtronic, Dublin, Ireland), or physician-modified UVM (n = 51). The extent of the aneurysm informed the device used. The MVM was developed for the treatment of Crawford extent I to III, and V TAAAs while the UVM was developed for the treatment of pararenal, paravisceral, juxtarenal, short neck, and Crawford extent IV TAAAs.[2,3] The procedural technique has been described in detail elsewhere.[2]

Image analysis.

To investigate the hypothesis that the amount of mural thrombus within the aortic sac is an indicator of a patients' cardiac reserve the ratio of aortic diameter to flow lumen diameter was determined. Out of 100 patients, 92 had adequate imaging to assess these parameters. The outside aortic diameter (OD) and the inside aortic flow lumen diameter of the flow lumen (ID) were measured at the location representing the largest mural thrombus load (Fig 1). The imaging used to determine the level of mural thrombus was computed tomography angiography before any aortic interventions; however, in the case of noncontrast imaging, the differing of densities within the aorta were used to determine the mural thrombus load (4/73 [5.5%]).

Once the OD and ID measurements were obtained, the areas for the internal flow lumen (IDA) and the entire aortic sac (ODA) were extrapolated. It should be noted that these calculations assumed both lumens to be perfect circles. Following these calculations, the ID/OD, OD/ID, IDA/ODA, and ODA/IDA were plotted and patients with a mortality within their first year postoperatively were identified.

Statistical analysis.

The patients' baseline comorbidity data were analyzed to determine correlation between IDA/ODA with other preoperative variables to further elucidate potential indicators of poor postoperative outcomes. Intraoperative and postoperative variables were not examined because this investigation was aimed at establishing criteria for patient selection.

Logistic regression, survival analysis, and decision tree methods were used to examine each variable's association with death at 1 year. Unadjusted logistic regression was performed for each variable to calculate an odds ratio (OR) and *P* value. Multivariate logistic regression with stepwise variable selection techniques and analysis of variable interactions were also explored. Decision trees were used to determine optimal variable cutoff points and explore subpopulations with significant separation in 1-year mortality rates. Kaplan-Meier curves and log-rank tests were used to compare mortality rates between groups. A *P* value of .05 was considered statistically significant. R[13] was used for all statistical analyses including logistic regression, rpart[14] for decision trees, and survival[15,16] and survminer[17] for Kaplan-Meier curves.

RESULTS

Procedural results were previously reported.[2,3] After the treatment of 100 TAAA patients with the UVM and MVM devices, 92 patients had adequate imaging to assess the parameters. Kaplan-Meier curves were first used to compare survival rates between patients with a favorable mural thrombus ratio and an unfavorable mural thrombus ratio (Fig 2). A log-rank test concluded a significant difference between favorable and unfavorable thrombus ratio (P=.0016).

Logistic regression analyzed 73 patients who had either died before or reached the 1-year end point with a median follow-up time of 26.7 months for all patients. One-year survival is crucial for positive long-term outcomes; therefore, mortality at 1 year is used as a binary outcome. This surrogate end point allowed for a simple decision making algorithm. Exploratory analysis of patient characteristics was completed by unadjusted logistic regression. The logistic regression and decision tree methods were then used to expand on this difference and determine any decision making rules that could be applied and validated with future data.

Results of the unadjusted logistic regression (Table I) showed IDA/ODA and prior peripheral vascular bypass have a statistically significant association with mortality at 1 year. Several interaction effects were also explored using logistic regression and the interaction between age and favorable mural thrombus ratio was significant (OR, 0.846; $P = .045$), whereas all other interactions failed to show statistical significance. Potential confounders were checked for association with thrombus through unadjusted logistic regression. Prior aortic surgery was the only variable found to be associated with unfavorable thrombus classification (OR, 0.2963; $P = .0149$). Multivariate logistic regression demonstrated that a favorable mural thrombus ratio and indication of age less than 75 years was statistically significant (OR, 11.681; $P = .006$) while controlling for confounding variables (Table II).

A decision tree (Fig 3) was used to verify that a patient's age of less than 75 years was the optimal cutoff point for examining mortality at 1 year. Using this 73-patient cohort, the 1-year overall survival was 71.2% (21 died, 52 survived). For patients with a favorable mural thrombus ratio (n = 36), the overall 1-year survival was 86.1% (5 died, 31 survived), whereas those with an unfavorable mural thrombus ratio (n = 37) had an overall survival of 56.8% (16 died, 21 survived). The only preoperative mortality factor that was statistically significant between subjects of unfavorable mural thrombus ratio was age of the patient. Interestingly, the survival for subjects 75 years and older with an unfavorable mural thrombus ratio was 90% (one died, nine survived), whereas subjects less than 75 years with an unfavorable ratio had a survival of 44.4% (15 died, 12 survived). Analysis showed these two variables—mural thrombus ratio and age—predicted 1-year mortality with sensitivity of 71.43% and specificity of 76.92%. Given the statistical significance of the relationship between mural thrombus ratio, age, and 1-year mortality, this model suggests this combination of preoperative variables function to predict those patients who are at an increased risk of mortality within the first postoperative year following endovascular TAAA repair.

The mural thrombus ratio and age cutoffs separating patients with an unfavorable mural thrombus ratio and less than 75 years old from all other patients was applied. Fig 4 shows the Kaplan-Meier curves and the results of the log-rank test for the comparison between these two groups ($P = .006$).

DISCUSSION

After treating 100 TAAA patients with the MVM or UVM, a thorough data analysis was conducted to examine trends in patients' preoperative comorbidities/indices and postoperative outcomes. One such index considered patients' pathophysiologic aortic mural thrombus formation within thoracoabdominal aneurysmal sacs that decreased the functional aortic lumen within the TAAA. Preoperative computed tomography imaging was used to quantify the ratio of mural thrombus relative to the aneurysmal diameter and separate patients based on their ratios. Based on our knowledge of fluid mechanics (Supplementary Information, online only), we hypothesized a patient's aortic mural thrombus ratio functions as an indirect measure of cardiac reserve and that its measurement has the potential to serve as an indicator of a patient's tolerance of the increased afterload on the heart following extensive stent grafting of the aorta. We believe this increased afterload, when applied to patients with insufficient cardiac reserve, contributes to many cases of TAAA repair patients' 1-year mortality, effectively putting these patients into diastolic heart failure and resulting in the overall dwindling of health over time (Table III). This exploratory analysis (or proof-of-concept analysis) showed statistical significance when comparing 1-year mortalities of patients on either side of a determined mural thrombus ratio, with patients with a higher mural thrombus ratio faring worse. These data indicate that patients with poor cardiac reserve likely compensate by developing a higher mural thrombus load and these patients have difficulty tolerating the change in aortic compliance and subsequent increased afterload following endo-debranching. This change in aortic compliance results in a decrease in diastolic run-off postoperatively because the prosthetic graft does not mimic the natural aortic recoil during diastole. Thus, without the physiologic elasticity (recoil in diastole) of the aorta to aid in perfusion and decrease resistance, the cardiac afterload is increased postoperatively, slowly moving some patients on the back side of their Starling curve. This increase in afterload may overwhelm patients whose cardiac reserves cannot handle the increased workload placed on the heart. Currently, there is difficulty identifying patients with decreased cardiac reserve because the lackof reserve is likely masked by the body's compensatory responses.

When quantifying the effects an aneurysm may have on cardiac work, mathematical modeling shows that an abrupt dilation of a vessel can have an effect on after load and cardiac output as it relates to the diameter and length of an aneurysm. In fluid mechanics, engineers have developed correlations for relating fluid velocity, viscosity, density, flow rate, flow resistance, pressure, and power requirements for incompressible fluids, that is, liquids flowing through a piping system. Details of the mathematical derivations may be found in the Supplementary Information (online only) at the end of the article. Based on the combination of these relationships, aneurysms that are larger in diameter and length would have a reduction in system head, which decreases the pump head requirement. To maintain a constant pressure at the pump with decreased losses, the volumetric flow rate would have to increase. Therefore, applying these parameters to an aneurysmal model suggests the heart needs to pump more blood per minute to maintain systemic perfusion in a system with a dilated aortic inner lumen. If patients with TAAA cannot account for this increased flow demand by increasing their cardiac output (ie, their cardiac reserve is insufficient), there remains only one pathophysiologic, compensatory response to preserve cardiac output and systemic perfusion in the presence of such limited cardiac reserve—narrowing of the aortic inner flow lumen.

Ultimately, these patients with high mural thrombus ratios manifest increasing 1-year mortality rates compared with patients with lower mural thrombus ratios. Specifically, we determined a mural thrombus ratio of less than 0.4 in MVM-treated patients and less than 0.3 in UVM-treated patients demonstrates an increased incidence of 1-year mortality after endovascular repair of TAAA. Our analysis found patient age to further increase the specificity to predict the probability of 1-year all-cause mortality. It is believed that a high degree of mural thrombus at an earlier age is an indicator of more advanced underlying vascular disease and the development of mural thrombus is a physiologic response to preserve a patient's ejection fraction.

Although we currently do not have a viable test to predict cardiac reserve, we have identified a preoperative aggregate—age and extent of aortic intraluminal mural thrombus. Patients who are at or near their limit of cardiac reserve may find it difficult or impossible to compensate for the challenge of the increased afterload on their cardiovascular system. These findings have impacted the patient selection and treatment process. All patients who meet the criteria are counseled on their risk of 1-year mortality. After the procedure, patients are treated aggressively with angiotensin-converting enzyme inhibitors and their blood pressures are well-controlled. These patients follow up with their primary physician on a monthly basis and are closely monitored by cardiology with frequent brain natriuretic peptides to assess for impending heart failure. By identifying these patients early, we can preoperatively counsel them more accurately on the risk and benefits of the repair as well as start to institute measures to optimize their postoperative care.

Limitations.

Although using software would provide standardization of mural thrombus ratio measurements to ensure accuracy and consistency, it is our contention that the adoption of this model should be feasible for any physician. The ultimate goal is for a treating physician to be able to make an initial determination of mural thrombus load based on routine image review. Adding additional complex analysis tools may deter physicians from broadly adopting this method, which would negate the need for hospital systems to adopt new technology to examine a patient's predicted outcome. Another limitation was that there were not enough data to develop as well as validate a statistical method for predicting 1-year mortality in this patient population. The decision rules explored here will continue to be validated with new patients.

CONCLUSIONS

This study examined whether a patient's mural thrombus ratio may be an indicator of 1-year survival. These findings suggest that the combination of a patient's aortic mural thrombus ratio and age can function as a preoperative indicator of their underlying cardiac reserve. Identifying patients with low cardiac reserve and fitness to handle the increased cardiac demands owing to the physiologic response to extensive aortic stent grafting before undergoing aortic repair may allow for modification of preoperative patient counseling and postoperative care guidelines to better treat this patient population. Furthermore, by using routine imaging modalities to calculate mural thrombus ratios, this identification model has feasible application without the need for additional analysis software.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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ARTICLE HIGHLIGHTS

- **Type of Research:** Single-center, retrospective study
- **Key Findings:** In 73 patients who underwent endovascular repair of thoracoabdominal aortic aneurysms, the 1-year survival was 71.2%. One-year survival was 86.1% for patients with a favorable mural thrombus ratio (n = 36), but only 56.8% for those with unfavorable mural thrombus ratio (n = 37). The survival for patients more than 75 years of age with an unfavorable ratio (n = 10) was 90% whereas patients less than 75 years of age with an unfavorable ratio (n = 27) had a survival of 44.4% at 1 year.
- **Take Home Message:** The combination of a patient's aortic mural thrombus ratio and age can function as a preoperative indicator of 1-year survival.

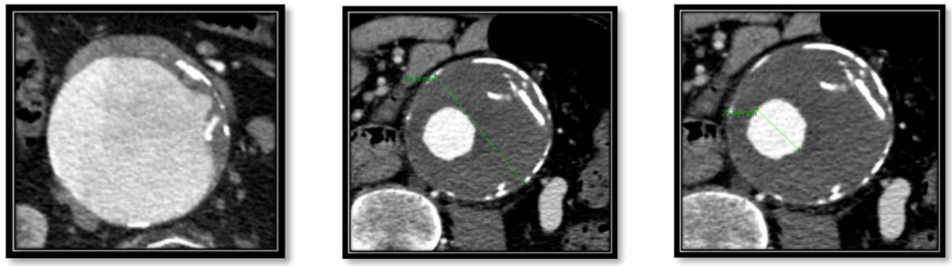

Fig 1.

Image analysis using computed tomography angiography. Computed tomography imaging was used to measure both the inner and outer diameter at the site of the largest thrombus burden in the aorta.

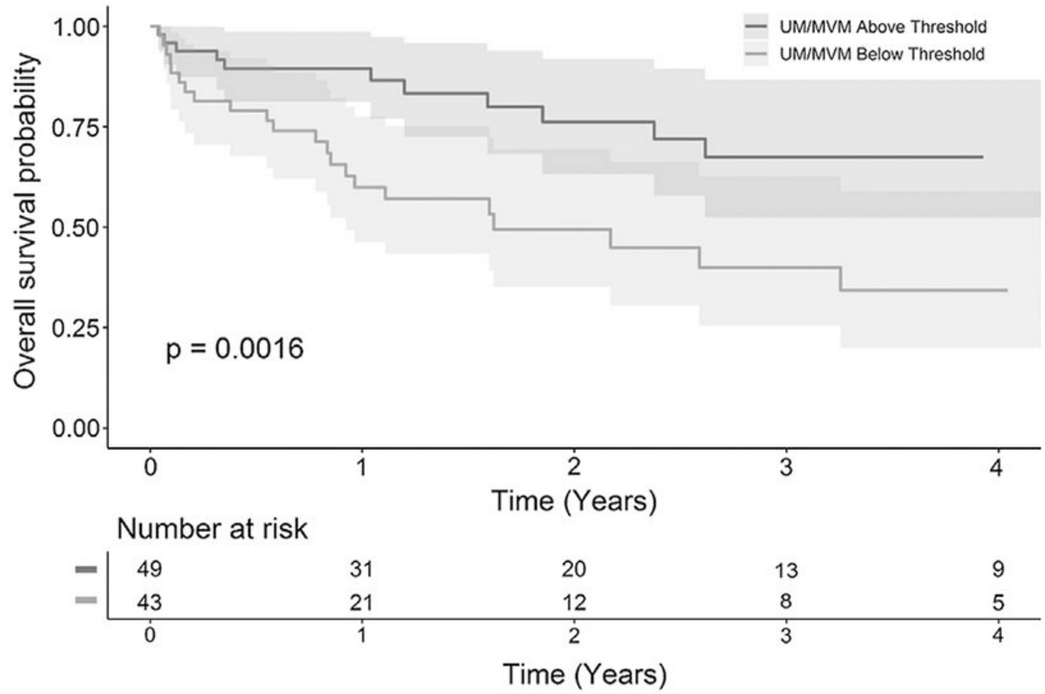

Fig 2.

Survival rates. Kaplan-Meier analysis of survival rates between patients with a favorable mural thrombus ratio and an unfavorable mural thrombus ratio. Survival of patients with a thrombus ratio above the threshold is represented in *black*, and patients with a thrombus ratio below the threshold is represented in *gray*.

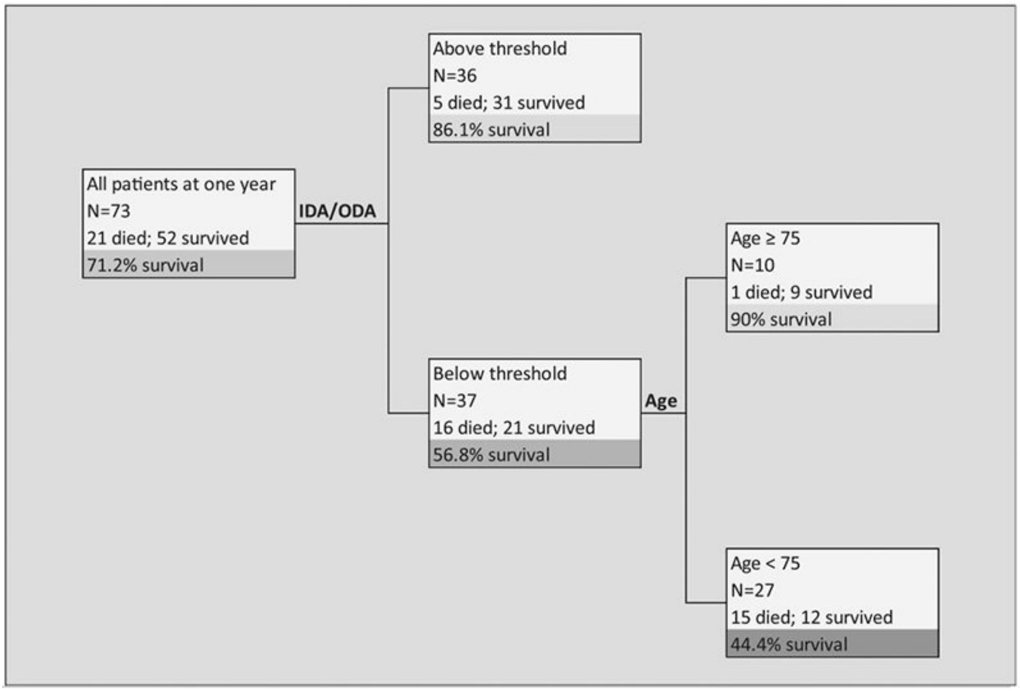

Fig 3.

Decision tree based on optimal IDA/ODA and patient age cutoffs. This decision tree was used to verify that a patient's age of less than 75 years was the optimal cutoff point for examining mortality at 1 year for patients with an unfavorable mural thrombus ratio.

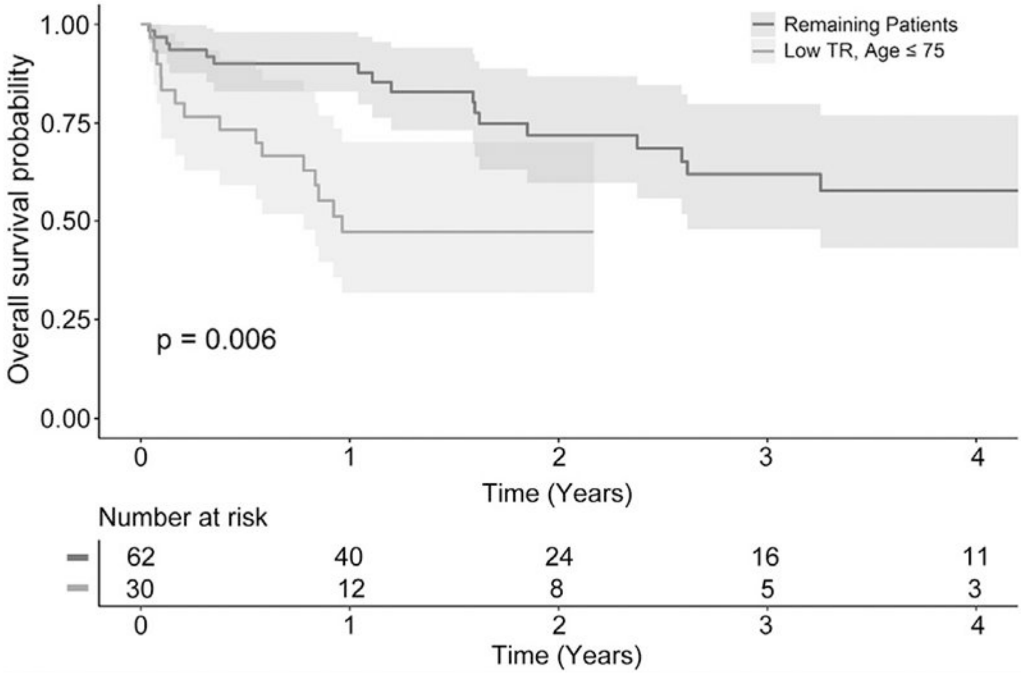

Fig 4.

Kaplan-Meier analysis of mural thrombus ratios and age cutoffs separating patients with an unfavorable mural thrombus ratio and less than 75 years old (*gray line*) from all other patients (*black line*).

Table I.

Patient characteristics with unadjusted odds ratios (*ORs*) for death at 1 year

Variable	Total patients (N = 73)	OR	*P* value
Age, years	71.49 ± 7.74	–	–
Age <75 years	51 (69.9)	2.2500	.1963
Male sex	44 (60.3)	0.5043	.2199
Coronary artery disease	29 (39.7)	0.9084	.8564
Congestive heart failure	17 (23.3)	0.7059	.5871
Chronic obstructive pulmonary disease	31 (42.5)	1.3420	.5719
Diabetes mellitus	13 (17.8)	1.1944	.7904
Renal insufficiency	16 (21.9)	0.3905	.1976
Hypertension	65 (89.0)	0.3542	.6876
Smoking	66 (90.4)	1.0106	.9904
Peripheral vascular disease	36 (49.3)	1.1440	.7955
Prior peripheral vascular bypass	12 (16.4)	4.700	.0190
Prior aneurysm repair	30 (41.1)	1.4545	.4726
Thrombus burden below threshold	37 (50.7)	4.7238	.0080
Thrombus burden below threshold plus age <75 years	27 (37.0)	8.3333	.0003
Presentation			
Symptomatic	32 (43.8)	2.8224	.0519
Asymptomatic	41 (56.2)		
Urgency			
Elective	64 (87.7)	0.4521	.2756
Urgent/emergent	9 (12.3)		
Type of TAAA			
Juxtarenal (reference)	2 (2.7)	NA	NA
Pararenal	3 (4.1)	0.5000	.7110
Paravisceral	4 (5.5)	3.0000	.5474
Crawford type I	7 (9.6)	0.4000	.5771
Crawford type II	16 (21.9)	0.4545	.6024
Crawford type III	11 (15.1)	0.5714	.7175

Variable	Total patients (N = 73)	OR	*P* value
Crawford type IV	29 (39.7)	0.2083	.2948
Crawford type V	1 (1.4)	0.0000	.9915

NA, Not applicable; *TAAA*, thoracoabdominal aortic aneurysm.

Continuous variables reported as mean ± standard deviation and categorical variables reported as count (%).

Table II.

Results of multivariate logistic regression

	Estimate	OR	SE	z Value	*P* value
(Intercept)	−8.188	–	2.715	−3.016	.003
Prior repair	−4.037	0.018	2.028	−1.991	.047
Noncontrast	4.182	65.505	1.920	2.178	.029
Peripheral vascular disease	−1.737	0.176	1.054	−1.647	.099
Bypass - peripheral vascular intervention	3.617	37.214	1.355	2.669	.008
Presentation (symptomatic)	2.174	8.792	0.897	2.425	.015
Aneurysm type (saccular)	3.947	51.776	1.510	2.614	.009
Maximum aortic diameter, mm	0.073	1.075	0.034	2.107	.035
Thrombus; age <75 years	2.458	11.681	0.901	2.729	.006

OR, Odds ratio; *SE*, standard error.

Table III.

Mortality

	0-30 days (n = 73), No. (%)	31-180 days (n = 68), No. (%)	181-365 days (n = 59), No. (%)
Cardiac	3 (4.1)	1 (1.5)	1 (1.7)
Stroke	1 (1.4)	4 (5.9)	1 (1.7)
Respiratory	1 (1.4)	2 (2.9)	2 (3.4)
Renal failure	0 (0)	1 (1.5)	1 (1.7)
Sepsis	0 (0)	0 (0)	1 (1.7)
Rupture	0 (0)	0 (0)	1 (1.7)
Gastrointestinal	0 (0)	1 (1.5)	0 (0)
Total	5 (6.8)	9 (13.2)	7 (11.9)

Respiratory includes pneumonia, respiratory failure, and acute respiratory distress syndrome; gastrointestinal includes perforated ulcer; cardiac includes cardiac arrest and pulseless electrical activity.