LONG-TERM RESULTS OF THORACIC AORTIC ANEURYSM INVOLVING THE AORTIC ARCH TREATED BY HYBRID PROCEDURE AT VIET DUC UNIVERSITY HOSPITAL

Duong Ngoc Thang[1,2,✉], Nguyen Huu Uoc[1,3], Nguyen Tung Son[2]

[1]Hanoi Medical University

[2]Viet Duc University Hospital

[3]Tam Anh General Hospital

Treatment of thoracic aortic diseases remains a major challenge for cardiovascular surgeons, especially in the ascending aorta and aortic arch. This study aims to evaluate long-term outcomes, exploring risk factors of mortality and complications in thoracic aortic aneurysm treated by hybrid procedure. This is a retrospective and prospective descriptive study from the hospital database at Viet Duc hospital University, which includes patients diagnosed with thoracic aortic aneurysm and treated with hybrid procedure from January 2014 to December 2023. 50 patients, composed of 44 males (88.0%) and 6 females (12%) were included in the analysis The mean age of the patients was 64.6 ± 10.96 years old (30 - 81). 36 patients had left thoracic pain (62.0%), 18 cases (36.0%) underwent aorto-bicarotid bypass with median sternotomy, 27 patients (54.0%) had carotid–carotid bypass with or without left subclavian artery revascularization, 5 patients (10.0%) had left subclavian artery transposition into left carotid artery. The survival estimation was 78.0% at 1 year, 73.8 at 3 years, 69.7% at 5 years and 53.4% at 7 years. Zone 0 intervention had increased risk of procedure-related mortality. At present, hybrid procedure can provide successful treatment suitable younger and older patients in Vietnamese condition.

Keywords: Hybrid procedure, thoracic aortic aneurysm, thoracic aortic diseases.

I. INTRODUCTION

Thoracic aortic diseases represent a broad spectrum that includes thoracic aortic aneurysm, aortic dissection, penetrating aortic ulcer, intramural hematoma, traumatic aortic injury.[1] Treatment of thoracic aortic diseases remains a major challenge for cardiovascular surgeons, especially in the ascending aorta and aortic arch due to the complex anatomical structure in this area with the presence of large arteries supplying the brain. Thoracic Endovascular Aortic Repair (TEVAR) has become increasingly favored for treating all thoracic aortic diseases due to its procedural simplicity and greater adaptability compared to open surgical repair.[2] However, isolated endovascular intervention has many difficulties treating lesions of aortic arch. To solve this problem, many solutions have been proposed such as the “chimney” technique, fenestrated endovascular grafts, and hybrid procedure. Among them, the supra-aortic debranching combined with endovascular intervention in one stage (Hybrid procedure) allows to expand the treatment indications, limit the complications of classic surgery and endovascular intervention, and give good outcomes results, especially in high-risk patients. Despite several advantages, there are still concerns about

Corresponding author: Duong Ngoc Thang
Hanoi Medical University
Email: ngocthang244@gmail.com
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hybrid procedure's durability, and surveillance is necessary to assess operational success in different aortic pathologies and the relationship with comorbidities. Endoleaks, such as type I, II, and III, require close monitoring due to the corresponding increased rupture risk. Graft breakage, graft defects, and stent migration are other concerns. Likewise, post-implantation syndrome, or graft thrombosis and intraluminal mural thrombosis cause for concern. Complication management and reintervention following TEVAR depend on clinical experience and perspective. This study will share clinical hybrid procedure experiences, focus on thoracic aortic aneurysm, and long-term follow-up results, while exploring risk factors in ten years.

II. MATERIALS AND METHODS

The data were retrospectively and prospectively obtained with descriptive methods, from the hospital database at Viet Duc Hospital University, which includes patients who were diagnosed with thoracic aortic aneurysm and treated with hybrid procedure (supra-aortic debranching combined with endovascular aortic repair) from January 2014 to December 2023.

Surgical Procedures

Supra-aortic debranching was performed prior to TEVAR to ensure an adequate PLZ.

For zone 0 repairs, the stent graft needed to cover all the supra aortic arteries, an aorto-bicarotid bypass was applied via median sternotomy. Ascending aorta, brachiocephalic trunk (BCA), left carotid artery (LCA) and left subclavian artery (LSA) were exposed. Aorta was clamped partially, a bifurcated Dacron graft was used to realized bypass from ascending aorta to BCA, LCA and LSA. All their origins were ligated after the anastomosis were completed.

In zone 1 procedures, the stent graft needed to cover LCA and LSA, carotid–carotid bypass was performed via cervical incisions. A graft of annuled PTFE or Dacron was placed between two carotid arteries to creat a new pathway. The prothesis was placed in the pretracheal region. LSA was revascularized or not.

In zone 2 procedures, the stent graft needed to cover only LSA, LCA-LSA bypass or transposition was performed via cervical incisions. These arteries were exposed at the level above the left subclavian. With bypass technique, a PTFE or Dacron prothesis was placed between LCA and LSA, then the LSA origin was occluded by endovascular technique or remaining patent. With transposition technique, once LSA was divided, its proximal stump would be carefully ligated, and an end to side anastomosis was created between the LSA distal stump and LCA.

Endovascular thoracic stent grafts of Medtronic valiant, Bolton relay or Jotec Evita were deployed via femoral or iliac access under general or local anesthesia, depending on patient condition and procedural complexity. Selective cerebrospinal fluid drainage (CFD) was employed in patients at high risk for spinal cord ischemia. In patients presenting with aneurysm rupture and associated hemothorax, intraoperative chest drainage was applied.

We obtained demographic data, comorbid diseases, laboratory results, radiological images, and clinical and operational details from archive files or telephone clinical assessments. All enrolled patients were documented according to their indications. Complications and adjunctive procedures were determined. Primary endoleaks detected in the operation room were addressed as needed. In the postoperative period, endoleaks detection was performed using a contrast-enhanced

CT scan. Aortic arch variants, anomalies, endoleaks classification, measurements, graft landing zones, and graft landing lengths were investigated. Graft brand, diameter, length, and used number of grafts, and proximal landing zones based on Ishimaru's classification were explored. Complications were documented; long-term outcomes were investigated according to the PLZ. Hypertension, hyperlipidemia, chronic obstructive pulmonary disease, diabetes mellitus, anticoagulant usage, and chronic renal failure were considered comorbid diseases. Long-term survival based on etiology and landing zone was also investigated.

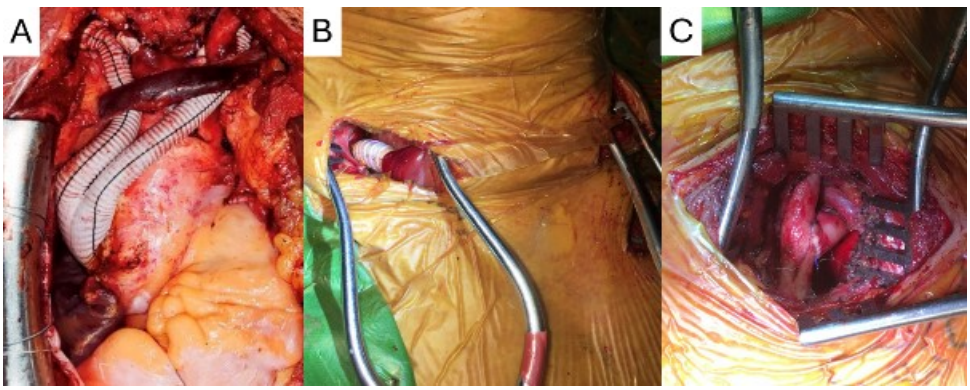

Figure 1. Supra aortic debranching surgery in hybrid procedure

1A. Aorto bicarotid and left subclavian bypass; 1B. Carotid carotid bypass with pretracheal pathway; 1C. Left subclavian transposition into carotid

All statistical analyses were performed using SPSS 20.0 for Windows. Significance was accepted below $p < 0.05$ in all groups. Confidence intervals (CIs) were set at 95%. Potential risk factors on 10-year survival and endoleaks occurrence were investigated with Cox regression analysis. Kaplan-Meier analyses were performed according to characteristics of aneurysm.

3. Research ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by Hanoi Medical University Institutional Ethical Review Board, approval number 632, study code T2404.

III. RESULTS

From January 2014 to December 2023, 50 patients were included in our analysis. There were 44 males (88.0%) and 6 feamles (12.0%). The mean age of the patients was 64.6 ± 10.96 years old (ranging from 30 to 81). There was no difference of mean age between male and female groups ($p = 0.919$). Seven were overweight with BMI more than 25. There were 10% patients who were admitted without any symptoms. Most of the patients have left thoracic pain (62.0%) and the other (20.0%) presented a hoarse voice as the first symptom. Thirteen were admitted with ruptured aneurysm into left pleural cavity or mediastinum, among them, three presented respiratory insufficiency at the time of hospitalization. One had a bronchial fistula with hemoptysis. Forty-four (88.0%) have a history of hypertension but only

12 patients were treated with antihypertension. More than half of patients (27/50) smoked more than 20 packs per year, 7 patients had alcohol use disorder. A history of intervention for abdominal aortic aneurysm was noted in 3 patients (2 with open surgery and 1 with endograft). One had surgery for type A aortic dissection. Four presented a history of renal insufficiency but no one needed dialysis.

All patients were diagnosed by aortic CT scanner but there were 44 (88.0%) had carotid, peripheral vessel ultrasound as complementary exam. Three patients with aortic arch variation were observed with two right subclavian artery lusoria and one vertebral aberrant. Ten (20.0%) had carotid stenosis and nine (18.0%) had lower limbs arterial stenosis. Twenty-six (52.0%) had associated coronary artery disease but no one needed coronary stenting. Aortic lesions identified by multislices CT scan included fusiform aneurysm (n = 21, 42.0%) and sacciform aneurysm (n = 29, 58.0%). Mean diameter of fusiform type was 59.9 ± 12.37cm, sacciform type was 52.3 ± 16.08cm and there was no significant difference (p = 0.076). There was no difference of mean aneurysmal diameter between male/female group, hypertension/non hypertension group, tabagism/non tabagism group (p > 0.05). Mean thickness of mural thrombus within aneurysm was 19.39 ± 8.65cm and had significant difference between ruptured and non-ruptured aneurysm group (p < 0.05).

All patients were treated by arterial supraortic debranching and TEVAR; eighteen (36.0%) underwent aorto-bicarotid bypass with median sternotomy, 27 patients (54.0%) had carotid–carotid bypass with or without left subclavian artery (LSA) revascularization, 5 patients (10%) had LSA transposition into left carotid artery (LCA). There were 2 patients who underwent associated left vertebral artery transposition into LCA. Thirty-six (72.0%) had a LSA revascularization. In the early phase of our series, LSA was neither revascularized nor occluded. We occluded the LSA by plug to avoid type II endoleak due to the difficulties in surgical techniques to expose and ligate the proximal segment of LSA. Totally, in 43 patients (86.0%), LSA was ligated before aortic stenting or occluded by plug after aortic stenting. Two perioperative surgical complications were noted with one left carotid artery clamp slippage with urgent blood loss and one thrombosed left branch of bifurcated graft. According to Ishimaru classification, 21 cases (42.0%) from zone 0, 24 cases (48.0%) from zone 1, and 5 cases (10.0%) from zone 2 were treated. Three from zone 0 underwent a carotid-carotid bypass with chimney technique for right brachial cephalic trunk. Medtronic variant was the most used stent graft (28 cases, 56.0%). One stent graft was used in 32 patients (64.0%), two stent graft in 12 patients (24.0%) and three stent graft in 6 patients (12.0%). Mean surgical time was 186.9 ± 36.88 minutes, mean endovascular time was 49.3 ± 29.73 minutes. All patients were heparinized with a bolus intravenous dose during arch debranching and repeated with a half dose during stent graft deploying.

Table 1. Postoperative complications. Cerebral stroke was the most popular complication during hybrid procedure

Complication	n = 50	%
Paraplegia	1	2.0%
Wound infection	3	6.0%

Complication	n = 50	%
Bleeding	2	4.0%
Stroke	6	12.0%
Pneumonia	5	10.0%
Renal insufficiency	5	10.0%
Multiple organ failure	1	2.0%
Lymphatic leakage	1	2.0%
Aorto bronchial fistula	1	2.0%
Early endoleak	2	4.0%
Cardiac arrest	3	6.0%

Table 2. Risk factors affecting post-operative stroke and mortality during hybrid procedure in logistic univariate regression analysis

Variable	30 days mortality			Cerebral stroke		
	OR	95% CI	p	OR	95% CI	p
Age	0.65	0.06 - 6.84	0.719	0.53	0.05 - 5.69	0.597
Male sex	0.79	0.08 - 7.98	0.841	0.64	0.06 - 6.66	0.710
HTA	-	-	-	-	-	-
Diabete	1.63	0.15 - 17.10	0.686	2.00	0.19 - 21.61	0.568
Coronary disease	0.65	0.13 - 3.27	0.603	2.00	0.33 - 12.07	0.450
Carotid disease	1.27	0.25 - 6.38	0.769	0.42	0.07 - 2.52	0.340
Anticoagulation	0.19	0.02 - 1.41	0.104	-	-	-
Antihypertension	0.17	0.01 - 2.37	0.186	0.42	0.03 - 5.71	0.512
Landing zone						
0	1			1		
1	0.11	0.01 - 1.00	0.050	0.14	0.01 - 1.31	0.084
2	-	-	-	-	-	-
LSA revas	0.97	0.16 - 5.68	0.971	2.10	0.22 - 19.75	0.518
Bypass type	0.42	0.08 - 2.15	0.298	0.27	0.04 - 1.66	0.157
Number of stent graft						
1	1			1		
2	0.49	0.05 - 4.70	0.537	0.64	0.06 - 6.34	0.700
3	1.08	0.10 - 11.32	0.949	1.40	0.12 - 15.26	0.783

Table 3. Cox regression analysis outcomes for 10 years hybrid procedure related mortality

Demographic Characteristics	B	SE	HR	95% CI	p
The number of stent graft	-0.65	0.44	0.52	0.22 - 1.23	0.137
Zone	-2.10	0.90	0.12	0.02 - 0.72	*0.020*
Bypass procedure	1.19	0.92	3.29	0.54 - 19.93	0.195
Anti-hypertension	-0.57	0.27	0.56	0.33 - 0.96	*0.036*
Anti-coagulation	-1.71	0.67	0.18	0.05 - 0.68	*0.011*

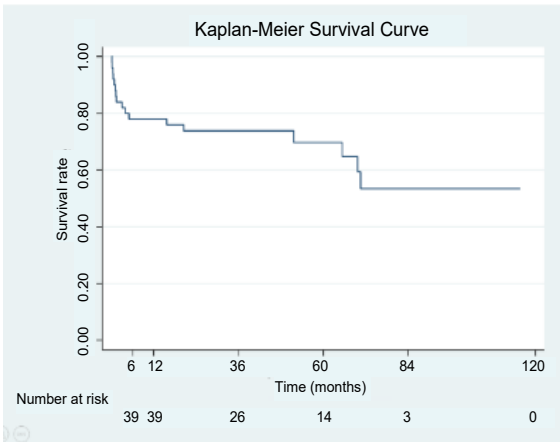

Chart 1. Kaplan – Meier long-term survival curve

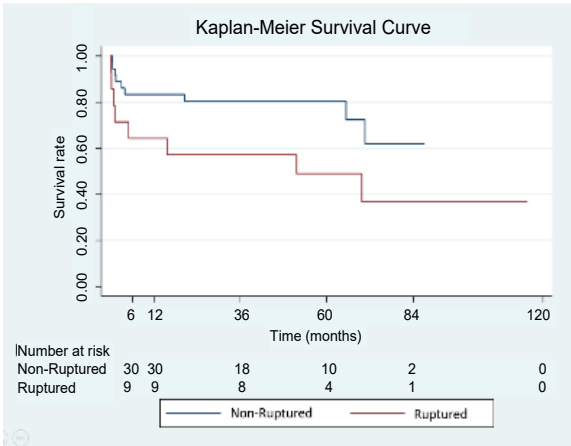

Chart 2. Kaplan-Meier long-term survival curve comparing non – ruptured aneurysm and ruptured aneurysm (p = 0.055)

IV. DISCUSSION

An aortic aneurysm is a condition in which the aortic segment increases in size by at least 150% compared to the normal aortic segment.[3] In the United States, approximately 13,000 patients die each year from aortic diseases, of which thoracic aortic aneurysms are the 18th leading cause.[4] The incidence of thoracic aortic aneurysms is approximately 10:100,000 people year, the disease can lead to death if untreated by ruptured complication.[5] The 5-year survival rate is only 15-55% in patients with thoracic aortic aneurysms. Isolated lesions in the aortic arch account for only 10%, while this rate is 60% in the ascending aorta and 30% in the descending aorta, however, the survival rate if the lesion involves the aortic arch is relatively low.[6]

In our study, 88% of the patients who underwent hybrid procedure were male, and 12% were female, with a ratio of men to women of 7.3:1. With Cox regression analysis for 10 years mortality, we found that gender did not affect the outcomes as noted in the literature.[7]23 females; mean age: 61.2 ± 16.0 years; range, 42 to 86 years This finding suggested that TEVAR in female gender was safe and effective with successful early morbidity and mortality results and the difference in gender did not affect the early and mid-term outcomes of hybrid procedure.

There was a wide range of age disturbances. In our research, age was not associated with higher mortality. A 30-year-old female and two 81-year-old patients the youngest and the oldest patients in this series, had a successful mid-term result. Previous research has shown that endovascular repairs yield similar outcomes in young and elderly patients.[8] However, we still prefer to apply hybrid procedure in the elderly patient group who were in high risk to ensure good early outcomes. Although study of Benedetto demonstrated that even an extra-anatomic bypass such as carotid – carotid bypass was durable at midterm follow-up, we tried to limit it in young patient.[9]

LSA is often necessary to be covered to achieve acceptable proximal "landing zone" in at least 40% patients treated with TEVAR.[10] According to the guidelines of Society for Vascular Surgery (SVS), LSA revascularization should be realized in circumstances include[11]: (1) presence of a patent left internal mammary to coronary artery bypass graft, (2) termination of the left vertebral artery into the posterior inferior cerebellar artery, (3) absent, atretic, or occluded right vertebral artery, (4) patent left arm arteriovenous shunt for dialysis, (5) prior infrarenal aortic operation with previously ligated lumbar and middle sacral arteries, (6) planned extensive (> 20cm) coverage of the descending thoracic aorta, (7) hypogastric artery occlusion, (8) presence of early aneurysmal disease where future therapy involving the distal thoracic aorta may be necessary.

In the early phase of our series, LSA was neither revascularized nor occluded. Then we revascularized LSA by LCA – LSA bypass. Because of the difficulties in the surgical technique of exposure and ligation of the proximal segment of LSA, we selected the occlusion by amplatzer plug to avoid type II endoleak. Role of LSA revascularization in reducing the stroke after TEVAR is still controversial. Some researchers considered that there were no significant associationbetween LSA coverage and stroke.[12]EMBASE, CINAHL, the Cochrane Central Register of Controlled Trials, the World Health Organization International Clinical Trials Registry, ClinicalTrials.gov, ISRCTN Register, and bibliographic reference lists. The primary outcome parameters were perioperative stroke, spinal cord ischemia (SCI Other recent meta-analyses demonstrated that LSA revascularization did lower the stroke incidence after TEVAR, with pooled stroke rates of 3.2% for LSA remaining uncovered, 5.3% for coverage with revascularization, and 8% for coverage without revascularization.[13] LSA coverage leads to reduced or obstructed blood flow to the left vertebral artery, which theoretically can provoke cerebrovascular ischemia and stroke.[14] Additionally, coverage of the more proximal aortic arch requires delivery of bulky stent-grafts across the orifice of arch vessels, potentially leading to embolization into the cerebral circulation. In our study, covered LSA was not a risk factor of neither mortality nor stroke. Although this study did not show the same result as the other analyses, we tended to reconstruct the blood flow of LSA bypass or fenestration in almost cases except in emergency situations. In our study, 36 patients (72%) had LSA revascularization with 25 LSA transposition into LCA.

The incidence of paraplegia after TEVAR can range from 0 to 12.5%, but it is commonly between 3% and 6%.[15] Even though it is rare, it is one of the deadliest complications associated with high mortality in the short and long-term following. Cerebrospinal fluid drainage proven ability to lower spinal cord ischemia's (SCI) rates in open thoracic aortic surgery by

increasing spinal cord perfusion pressure, has made it a preferred method for SCI prevention during TEVAR.[16] The debate over CFD usage in TEVAR continues due to insufficient evidence of whether it reduces the incidence of SCI sufficiently to justify the additional risks involved. Some surgeons perform prophylactic CFD in all patients undergoing TEVAR, while others perform selective CFD using salvage CFD only when necessary. It has been reported in a historical paper that 8% of paraplegia is seen in TEVARs performed without CFD. A systematic review showed that the pooled SCI rate without routine prophylactic drainage was around 1.98 – 5.37%, even though the SCI rate with regular prophylactic drainage being 1.7 – 5.1%.[17] In addition, CFD can cause some complications such as infection, epidural hematoma, subdural hematoma, intracranial bleeding especially in patients under intravenous heparinized. In our study, preoperative selective CFD was performed in three patients (6.0%) with high SCI risk such as prolongation of endograft to proximal abdominal aorta which covered Adamkiewich artery combined with ligation or occluded LSA without revascularization; however, paraplegia still occurred in 1 patient (2%).

Despite advances in endovascular technology, stroke continues to be an important complication of TEVAR and is associated with significant in-hospital mortality. In the literature, the stroke rate is between 2% and 8%.[18] Indeed, we noted 6 patients who had postoperative stroke, and 4 of them died in 30-days. The underlying mechanisms contributing to acute ischemic stroke after TEVAR are not completely understood. However, the constellation of preoperative risk factors, temporal relationship of stroke to the procedure, neurological findings, and patterns of brain infarction observed in patients with stroke associated with TEVAR have led most investigators to believe that cerebral embolization and vascular insufficiency are two separate mechanisms that may contribute, either independently or in combination, to the development of perioperative strokes after TEVAR.[19] Embolic events are caused by instrumentation of the aortic arch in patients with atheromatous disease, whereas vascular insufficiency is the consequence of planned or inadvertent endovascular coverage of supra-aortic vessels. The clinical severity of the stroke depends on the size and quantity of cerebral emboli, the vascular territory affected, and the age and rehabilitation potential of the patient.

We noted that 3/6 patients who had postoperative cerebral stroke in our study had the “shaggy aorta”. Shaggy aorta commonly refers to an aorta with irregular mural thrombus as demonstrated on CT, and results when atherosclerosis contributes to cholesterol crystals that accumulate in the aortic wall with an irregular appearance. Because these plaques and mural thrombus are often scattered to the periphery and occlude arteries including cervical, visceral, and extremities, they may induce various pathological conditions referred to as “shaggy aorta syndrome”.[20] To investigate the correlation between shaggy aorta and embolic complications during thoracic endovascular aneurysm repair, Maeda et al proposed a shaggy aorta scoring system.[21] Shaggy aorta was evaluated based on axial images obtained at 5mm interval using a 64 row multidetector CTA and every 5mm axial image of the entire aorta between the sinotubular junction and aortic bifurcation excluding the aneurysm was evaluated. One shaggy point was given when the following three conditions were met for each axial slice: 1) ulcer like thrombus, 2) maximum thrombus thickness ≥

5mm, and 3) mural thrombus occupying more than two thirds of the circumference of the aortic diameter in the axial statue. To measure the score easily, the thrombus site of the aorta was divided into three regions where A1 is from the ascending aorta (sinotubular junction) to the orifice of the left subclavian artery, A2 is the descending thoracic aorta from the distal edge of the orifice of the LSA to the orifice of the coeliac artery, and A3 is the abdominal aorta from the coeliac artery to the aortic bifurcation. The score was evaluated in each of the three regions of axial image and the total points calculated. This study demonstrated that that patients with shaggy scores ≥ 3 points are likely to suffer embolic events and suggested that the indications for TEVAR in patients with a high shaggy score should be considered carefully, weighing the risks and benefits.

There were 3 patients who suffered sudden cardiac arrest. We found retrograde dissection type A in 2 patients and thoracic aortic aneurysm ruptured in 1 patient. All these patients received cardiopulmonary resuscitation without success. These were life threatening complications with high mortality rate. One patient with aortobronchial fistula fully recovered after the TEVAR procedures and medical treatment without hemoptysis.

We observed that the mortality increased at zone 0 intervention. Our results are similar to published litterature.[22] But our results did not find zone 0 intervention as a risk factor of early mortality by univariate and multivariate linear regression analysis. However, in Cox's regression analysis, zone 0 intervention (HR = 0.12, p = 0.02, 95% CI: 0.02 - 0.72) with anticoagulation usage (HR = 0.56, p = 0.036, 95% CI: 0.33 - 0.96) and antihypertension usage (HR = 0.18, p = 0.011, 95% CI: 0.05 - 0.68) are the independent risk factors which affect the long-term mortality. Currently, we don't apply this procedure much anymore. With patients in high risk, we prefer use carotid – carotid bypass with innominate chimney technique and with young patients, low risk, we suggest a FET (frozen elephant trunk) technique.

The survival estimation was 78% in 6 months, 78% in 1 year, 73.8 at 3 years, 69.7% at 5 years and 53.4% at 7 years. The Kaplan-Meier survival curves showed no significant difference according to morphology and ruptured complication before intervention. Our results showed that hybrid procedure could be applicated even in ruptured aneurysm with acceptable outcomes.

Single center study with small sample size, analysis only one of thoracic aortic disease which can be treated by hybrid procedure are limitations of our study.

V. CONCLUSION

Hybrid procedure in zone 1 and 2 can be used safely to treat thoracic aortic aneurysm, it can provide successful treatment suitable for younger and older patients. However, some complications still limit the outcomes. Zone 0 intervention had increased risk of procedure-related mortality. Close monitoring and adherence to the surveillance protocols for these patients is recommended.

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The authors declare no conflict of interest.

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