

Early Result of TEVAR for Thoracic Aortic Aneurysm: An Experience in Ramathibodi Hospital

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Background: Traditional treatment of patients with thoracic aortic aneurysms is open surgical graft replacement. At present, thoracic endovascular aortic repair (TEVAR) is an alternative option for treat patients who have high surgical risk. The authors retrospectively reviewed result of TEVAR in patients diagnosed with thoracic aortic aneurysm in Ramathibodi Hospital in 5 years, especially mortality, postoperative morbidity.

Objective: To evaluate a results of TEVAR for thoracic aortic aneurysm and to identify post-operative complication.

Material and Methods: The authors reviewed data from patients who were diagnosed with thoracic aortic aneurysm and underwent TEVAR procedure at Ramathibodi Hospital from 1 January 2014 to 31 December 2018. Baseline characteristics and post procedural imaging were collected and analyzed. Univariate analysis was used to identify risks associated with endoleak. Survival and reintervention rate were estimated using Kaplan-Meier methodology and between groups comparison was analyzed using the log rank test.

Results: Total 33 patients were included in the analysis, with a mean age of 68.57 years. There were 7 patients with endo leak (21.21%). Endo leak was more common in male (6 out of 7, 85.70%). Renal failure occurred in only 1 patient from all (3.00%). Stroke and/or paraplegia was found in 1 patient (3%) and respiratory complication in 5 patients (15.10%). Two patients in non endoleak group died (6.1% of all). No incidence of graft migration and distal sine (stent induced new entry tear). Operative time was found to be associated with risk for developing endo leak (p-value=0.015, 95% CI 1.00 to 1.03).

Conclusion: TEVAR procedure for thoracic aortic aneurysm in Ramathibodi Hospital has low in mortality and postoperative complications. However, longer operative time is associated with an increased risk in endoleak in TEVAR procedure.

Keywords: Thoracic aneurysm; Thoracic endovascular aortic repair; TEVAR

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The natural history of degenerative thoracic aortic disease is progressive and may lead to dilation, dissection, and rupture of the aorta. Aggressive medical treatment and appropriate follow-up imaging help to improve survival of these patients. However, medical therapy alone can only slow the progression of disease, but cannot prevent aneurysm expansion and/or rupture. Reported 5-year mortality is 16% for aneurysms smaller than 6 centimeters in diameter and 31% for aneurysms larger than 6 centimeters⁽¹⁾. An incidence of thoracic aortic aneurysms (TAAs) is estimated to be at

least 5 to 10 per 100,000 person-years⁽²⁾. Traditional treatment for TAA is open surgical graft replacement, but despite of many evolving surgical advances, conventional surgical repair is still associated with substantial morbidity and mortality, especially in elderly patients with other major medical comorbidities^(3,4). In the present, thoracic endovascular aortic repair (TEVAR) is an alternative procedure to treat TAAs patient who have suitable anatomy and high surgical risk. The authors retrospectively reviewed result of TEVAR in patients who were diagnosed with thoracic aortic aneurysm in Ramathibodi Hospital in 5 years.

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Materials and Methods

Patient selection

We collected data from patients who were diagnosed with thoracic aortic aneurysm and underwent TEVAR procedure, both with and without supra-aortic bypass, at Ramathibodi hospital from 1 January 2014 to 31 December 2018. Patients who underwent TEVAR with other combined open heart surgery, using extracorporeal circuit were excluded. The study protocol was approved by ethics committee of Faculty of Medicine, Ramathibodi Hospital, Mahidol University, Thailand (COA. MURA2020/17).

Patient characteristics

Pre-operative demographic data including age, gender, weight and height, underlying diseases (e.g.: diabetes, hypertension, dyslipidemia, chronic obstructive pulmonary disease, coronary artery disease, atrial fibrillation, chronic kidney disease and old cerebrovascular accident) and smoking status were collected. All types of thoracic aortic aneurysm (fusiform, saccular and pseudoaneurysm) were included. Computerized tomography (CT) scan was performed for preoperative evaluation and planning in all cases. Size of the aneurysm was measured from CT scan, defined as the maximal diameter of aneurysm from outer-to-outer layer of the aneurysm. Additional procedures for cases that vascular stent was placed involving zone I or zone II were done in the same setting such as carotid to carotid with carotid to left subclavian bypass and carotid to left or right subclavian bypass, and were included in the study. The stent grafts used in this study were from Medtronic Public Limited Company and Cook medical Company, which were selected according to proper sizing and availability in the operating room.

Interventional endovascular procedure

All patients were operated under general anesthesia. Stented graft placements were achieved by transfemoral approach whenever feasible. An alternative vascular access site was necessary in some cases. Using fluoroscopic guidance and surgical exposure of the accessed artery, sheath and dilator system was advanced over a guide wire and positioned across the target lesion. Stented grafts were then deployed after optimal positioning of the device. When an endoleak was detected after graft deployment, additional procedures, such as additional graft placement, vascular plugging or coil embolization, were performed as necessary.

Postoperative data

We collected data for postoperative intensive care unit stay, and complications including acute kidney injury, stroke, respiratory failure, re-intervention and death. After discharged, every patients were to undergo follow-up imaging evaluation using CT scan, which data were collected and reviewed along with medical records at out-patient department (OPD).

Definition: endo leak group in this study

In this current study, endoleak was defined and classification as a presence of contrast filling into an aneurysm sac after stent placement that was detected from follow-up CT scans after hospital discharge⁽¹⁸⁾.

Statistical analysis

Baseline characteristics, procedural details, post-procedural clinical data and imaging were collected and analyzed. Categorical variables were described as frequency and percentage. Continuous variables were expressed as mean±standard deviation and/or median (interquartile range), where appropriate. Univariate analysis was used to identify risks associated with endoleak. Survival and reintervention

rates were estimated using Kaplan-Meier methodology and between group comparison analysis was done using the log rank test.

Results

Total 33 patients were included in the analysis, with a mean age of 68.57±9.82 years. Baseline patient characteristics were shown in Table 1. There were 7 patients with endoleak (21.21%), and 26 patients without endoleak (78.79%). All endoleak were type II, and was more common in male (6 out of 7 patients; 85.70%). Age was not associated with risk for developing endoleak (67.77±10.32 vs. 71.57±7.52, p-value=0.371). Preoperative underlying diseases were also not significantly different between both groups, as well as pre-operative aneurysm size, with a mean diameter of 5.57±2.08 cm in non-endoleak group and 5.47±2.02 cm in endoleak group, p-value=0.914.

Intraoperative data were collected and shown in Table 2. Additional procedures within the same setting of TEVAR such as carotid to carotid and carotid to left subclavian bypasses were performed in 4 patients (12.10%) due to the proximal landing zone was in zone 1. Post-operative follow-up imaging showed that 1 patient had endoleak, while 3 patients did not. For TEVAR with proximal landing zone in zone 2, carotid to left subclavian bypasses were performed in 5 patients. One patient had right sided aortic arch and underwent right carotid to right subclavian bypass, while other 4 patients underwent left carotid to left subclavian bypasses. Endoleak was encountered in a patient underwent right carotid to subclavian bypass, and none was found in left carotid to subclavian bypass group. The most common proximal landing zone in this study was at zone III (18 out of 33 patients; 54.5%). Zone II proximal landing zone was identified in 11 patients (33.3%) and zone I landing only 4 patients (12.2%). Fluoroscopic time was collected and showed that, in endoleak group, the time was longer than in non-endoleak group but without statistical significance (median and interquartile range of 36 minutes (14.4, 50) vs. 12.7 minutes (8, 19.4), p-value=0.197). Operative time was longer in endoleak group compared to non-endoleak group (228.75±106.92 vs. 148.85±94.07, p-value=0.064). There was no significant difference in periprocedural blood loss among both groups, with estimated blood loss 220 ml (200, 1,000) and 250 ml (100, 600) in endoleak group and non-endoleak group, respectively.

During the index hospital admission, renal failure occurred in 1 patient (3.00%), stroke and/or paraplegia in 1 patient (3.00%) and respiratory complication was identified in 5 patients (15.10%), as shown in Table 3. Two patients in non-endoleak group died (6.1% of all), one from hospital acquired pneumonia (HAP) in the same admission, while another patient was dead from gastric ulcer perforation, after discharge from the indexed TEVAR procedure (as in Figure 1 and Figure 2). No graft migration and distal SINE were documented in this study, as well as no incidence of aortic rupture until the end of follow-up period.

In patients with endoleak identified on follow-up

Table 1. Demographic data between non endoleak group and endoleak group

Variable	Total (n=33)	Non-endo leak (n=26)	Endo leak (n=7)	p-value
Age (years), mean±SD	68.57±9.82	67.77±10.32	71.57±7.52	0.371
Gender, n (%)				
Male	21 (63.6)	15 (57.7)	6 (85.7)	0.223
Female	12 (36.4)	11 (42.3)	1 (14.3)	
Weight (kg), mean±SD	64.36±11.85	64.22±10.80	64.88±16.20	0.898
Height (cm), mean±SD	161.57±9.09	161.31±9.03	162.57±9.96	0.749
Body surface area, mean±SD	1.69±0.18	1.69±0.16	1.70±0.25	0.916
Diabetes mellitus, n (%)	4 (12.1)	3 (11.5)	1 (14.3)	0.999
Hypertension, n (%)	25 (75.7)	20 (76.9)	5 (71.4)	0.763
Dyslipidemia, n (%)	15 (45.5)	13 (50.0)	2 (28.6)	0.413
Chronic obstructive pulmonary disease, n (%)	3 (9.1)	2 (7.7)	1 (14.3)	0.523
Coronary artery disease, n (%)	7 (21.1)	5 (19.2)	2 (28.6)	0.623
Atrial fibrillation, n (%)	2 (6.1)	1 (3.8)	1 (14.3)	0.384
Chronic kidney disease, n (%)	8 (24.4)	7 (26.9)	1 (14.3)	0.652
Stage, n (%)				
III	6 (18.2)	5 (19.2)	1 (14.3)	-
IV	1 (3.0)	1 (3.8)	0	
V	1 (3.0)	1 (3.8)	0	
Cerebrovascular accident, n (%)	1 (3.0)	1 (3.9)	0	0.999
Congestive heart failure, n (%)	1 (3.0)	1 (3.8)	0	0.999
Smoke, n (%)	15 (45.5)	11 (42.3)	4 (57.1)	0.674
Left ventricular ejection fraction (pre), mean±SD, n=29	63.06±9.36	62.42±9.73	65.50±8.09	0.484
Maximal aneurysm size (cm), mean±SD	5.55±2.08	5.57±2.08	5.47±2.20	0.914

BSA = body surface area; DM = diabetes mellitus; HT = hypertension; DLP = dyslipidemia; COPD = chronic obstructive pulmonary disease; CAD = coronary artery disease; AF = atrial fibrillation; CKD = chronic kidney disease; CVA = cerebrovascular accident; CHF = congestive heart failure; LVEF = left ventricular ejection fraction

CT scans, median time to occurrences after the TEVAR procedure was 1.9 months (range from 1.4 to 11.7 months). For risk factors of developing post-operative endoleak, we found that operative time was significantly associated with the presence of endoleak, univariate HR=1.009 (p-value=0.015, 95% CI 1.00 to 1.02). No other pre-operative characteristics nor procedural details were associated with endoleak, as shown in Table 4.

Discussion

Thoracic aortic aneurysm is a life-threatening condition with an estimated incidence of 6 to 10 cases per 100,000 person-years⁽⁵⁾. The prevalence of thoracic aortic aneurysms appears to be increasing⁽⁶⁾, whether this is a real phenomenon as the population ages or predominately just a reflection of advances in noninvasive diagnostic imaging is not known. The natural history of untreated patients with thoracic aortic aneurysms is characterized by progressive

expansion and eventual rupture of the aorta⁽⁵⁻⁸⁾, with an estimated 5-year survival in patients with unoperated thoracic aortic aneurysms to be from 15% to 55%^(5,6,8). Currently, Thoracic endovascular aortic repair (TEVAR) is an alternative treatment option for patients who have suitable anatomy and high surgical risk, aside from open surgical repair. Endovascular stented-graft repair of thoracic aortic aneurysms started at Stanford in 1992 as a less invasive alternative to conventional open surgical graft replacement^(9,10). In early reports, the treatment was usually reserved for poor candidates for open operation⁽⁹⁻¹²⁾. After the safety of this procedure was established and evidence of acceptable short-term results were demonstrated, use of stent grafts progressively expanded to other patients and other thoracic aortic pathologies⁽¹³⁻¹⁶⁾. In 2002, Richard P et al, reported a result of TEVAR in 28 patient, which they found only 1 patient died in the study (3.5%) and 6 patients (21%) had endoleak⁽¹⁴⁾. In 2001, Dake et al suggested that stented graft

Table 2. Operation data between non endoleak group and endoleak group

Variable	Total (n=33)	Non-endo leak (n=26)	Endo leak (n=7)	p-value
Add on procedure, n (%)				
Carotid to carotid and carotid to left subclavian bypass	4 (12.1)	3 (11.5)	1 (14.3)	-
Carotid to left subclavian bypass	4 (12.1)	4 (15.4)	0	
Carotid to left subclavian bypass and coil embolization at proximal left subclavian artery	1 (3.0)	0	1 (14.3)	
Carotid to right subclavian bypass (right sided aortic arch)	1 (3.0)	0	1	
Zone, n (%)				
I	4 (12.1)	2 (7.7)	2 (28.6)	0.131
II	11 (33.3)	8 (30.8)	3 (42.9)	
III	18 (54.5)	16 (61.5)	2 (28.6)	
Fluoroscopic time(min), median (IQR), n=28	14.1 (8.3, 21.2)	12.7 (8.0, 19.4)	36.2 (14.4, 50.0)	0.197
Device, n (%), n=32				
Cook	16 (50.0)	12 (48.0)	4 (57.1)	0.669
Medtronic	16(50.0)	13(52.0)	3(42.9)	
Operative time(min), mean±SD	165.60±100.66	148.85±94.07	227.85±106.92	0.064
Blood loss (ml), median (IQR)	250 (100, 600)	250 (100, 600)	220 (200, 1,000)	0.580
Lumbar drain, n (%)	12 (36.4)	9 (34.6)	3 (42.9)	0.686

Table 3. Post-operation data between non endoleak group and endoleak group

Variable	Total (n=33)	Non-endo leak (n=26)	Endo leak (n=7)	p-value
ICU stay (day), median (IQR)	2 (1, 3)	2 (1, 3)	1 (1, 1)	0.086
Length of stay (day), median (IQR)	7 (5, 15)	6 (5, 15)	7 (7, 21)	0.170
Post-op complication, n (%)				
AKI	3 (9.1)	3 (11.5)	0	-
Hemodialysis	1 (3.0)	1 (3.8)	0	-
Respiratory	5 (15.1)	4 (15.4)	1 (14.3)	-
Stroke	1 (3.0)	1 (3.9)	0	-
Re-intubation	2 (6.1)	2 (7.7)	0	-
Re-intervention	2 (6.1)	2 (7.7)	0	-
Death	2 (6.1)	2 (7.7)	0	-
Time to endoleak (month), median (IQR)	-	-	1.9 (1.4, 11.7)	-

therapy may potentially reduce operative risk, hospital stay and procedural expenses of TAA repair. These potential benefits were especially attractive for patients at high risk for open TAA repair. Current results of endovascular TAA therapy documented an operative mortality of between 0 to 4%, aneurysm thrombosis in 90 to 100% of cases, and paraplegia as a complication in 0 to 1.6% of patients⁽¹⁶⁾. In Jun 2020, Zehang Chen et al, report mortality rate of aortic related after TEVAR procedure is 8.8%⁽¹⁹⁾, this report

was collected data from 2000 to 2014. In the present study, from 33 patients, we found 2 mortality (6.1%), consistent with many previous studies that reported early mortality rate of about 6 to 7% after TEVAR (1.17). Both of our patients who died were not directly related to TEVAR procedure, one from pneumonia and another one from gastric ulcer perforation. There were 7 cases with endoleak documented on postoperative imaging, all were type II endoleak. Our data showed that endoleak were predominant

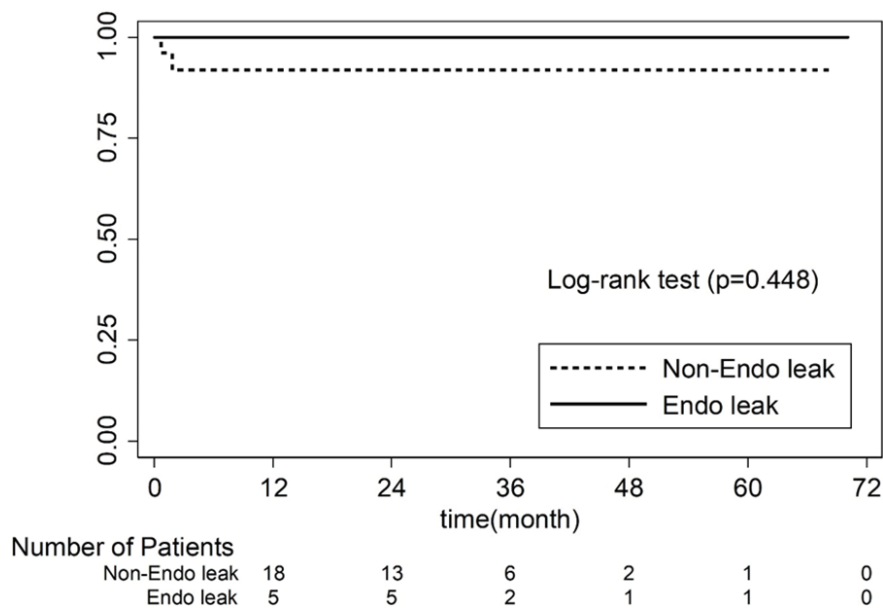


Figure 1. Dead by Endoleak.

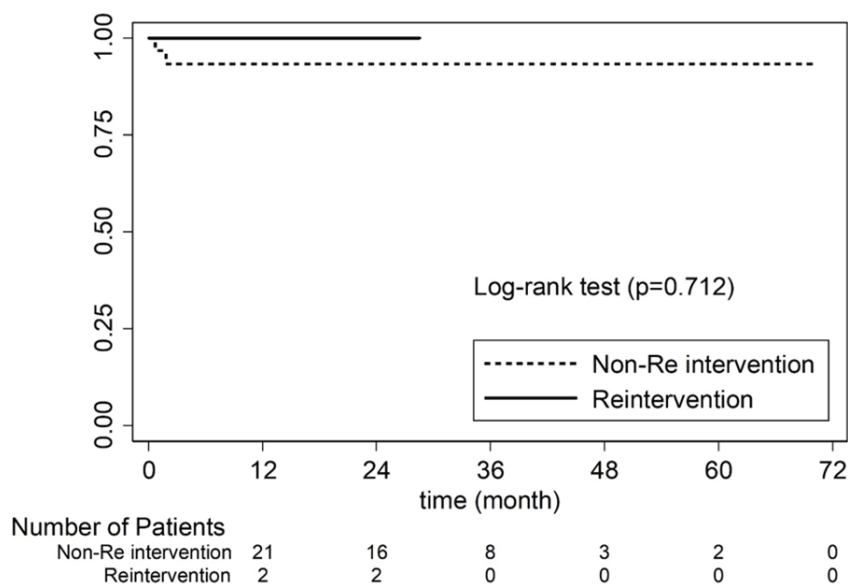


Figure 2. Dead by Reintervention.

in male; 6 out of 7 patients (85.70%) but without statistically significant (p-value=0.223), however this might be due to the small number of patients included in the present study. The early cases of TEVAR procedure in Ramathibodi Hospital, we did not routinely use vascular plug to occlude

left subclavian artery in cases with endovascular stent landing in zone II, and there were some cases with difficult anatomy. These might explain why there were cases with endoleak type II on follow-up imaging. CTA of the whole aorta was used to follow-up for endoleak progression every 3 to 6

Table 4. Risk factors for endoleak group

Data	Univariate	
	HR (95% CI)	p-value
Age (years)	1.022 (0.95 to 1.10)	0.550
Gender		
Male	1	
Female	0.342 (0.04 to 2.84)	0.321
Weight (kg)	1.005 (0.94 to 1.08)	0.890
Height (cm)	1.007 (0.93 to 1.10)	0.861
Body surface area	1.267 (0.01 to 143.27)	0.922
Diabetes mellitus	0.963 (0.12 to 8.01)	0.972
Hypertension	0.877 (0.17 to 4.54)	0.876
Dyslipidemia	0.579 (0.11 to 3.02)	0.517
Chronic obstructive pulmonary disease	0.869 (0.10 to 7.26)	0.898
Coronary artery disease	1.085 (0.21 to 5.62)	0.922
Atrial fibrillation	-	-
Chronic kidney disease	0.544 (0.06 to 4.58)	0.576
Smoke	1.776 (0.39 to 8.00)	0.454
Left ventricular ejection fraction (pre)	1.018 (0.92 to 1.13)	0.720
Valvular	2.298 (0.26 to 20.01)	0.451
Maximal aneurysm size (cm)	1.019 (0.70 to 1.48)	0.920
Distance (cm)	1.093 (0.80 to 1.49)	0.568
Zone		
I	1	
II	0.604 (0.10 to 3.74)	0.588
III	0.165 (0.02 to 1.20)	
Fluoroscopic time (min)	1.144 (1.04 to 1.26)	0.077
Device		
Cook	1	
Medtronic	1.084 (0.24 to 4.87)	0.915
Operative time (min)	1.009 (1.00 to 1.02)	0.015
Blood loss (ml)	1.410 (0.24 to 8.12)	0.700
Lumbar drain	1.507 (0.33 to 6.81)	0.594

months and showed no sac progression in all cases, and in some cases the endoleak resolved spontaneously. Operative time was found to be a significant factor associated with postoperative endoleak (p-value=0.015, Univariate HR 95% CI: 1.00 to 1.02). Longer operative time might signify a more complex anatomy of disease and a more difficult procedure, which could explain why it is associated with the presence of endoleak after the operation. It is also important to note that this study have some limitations, mainly because of small number of patients and there is not yet adequate data for longer period follow-up.

Conclusion

TEVAR procedure for thoracic aortic aneurysm

in Ramathibodi Hospital is substantially safe, with low mortality and associated postoperative complications. However, longer follow-up period is needed for evaluation of durability and late complications.

What is already known on this topic?

Endovascular intervention for Thoracic aortic aneurysm is prefer in patient with high risk and suitable anatomy.

What this study adds?

Short term result of endovascular for treatment of thoracic aortic aneurysm in a tertiary hospital in Thailand.

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Potential conflicts of interest

The authors declare no conflict of interest.

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