Original Article

Predictive Factors for Endoleaks and Aneurysm Enlargement after Thoracic Endovascular Aortic Repair of Thoracic Aortic Aneurysm

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Objective: To analyze the incidence and predictive factors of endoleaks and associated increased aneurysm size after thoracic endovascular aortic repair (TEVAR).

Materials and Methods: The medical records and computed tomography (CT) angiography imaging of 69 patients with thoracic aortic aneurysm that underwent thoracic endovascular aortic repair at a single institute between June 2012 and May 2019 were reviewed. The incidences of endoleak were calculated. The patients' demographic data, operative details, and imaging data were collected. The risk factors of endoleak occurrence were analyzed between endoleak and non-endoleak groups. The association between endoleak and aneurysm enlargement was also evaluated.

Results: Endoleaks were noted in twenty-nine cases (42.0%) including four type Ia (5.8%), six type Ib (8.7%), seventeen type II (24.6%), and two type III (2.9%). Fifty-nine percent of the patients with endoleak were found with aneurysm enlargement. The predictive factors of endoleak were bird beak configuration and distal neck length of less than 20 mm (p=0.014 and 0.019, respectively). For type Ia, endoleak presented with short proximal neck length (p=0.031). Short distal neck and angulation of distal stent less than 160 degrees were the predictive factors of type Ib endoleak (p=0.045 and <0.001, respectively). Increased number of intercostal arteries is the only significant risk factor of type II endoleak (p=0.005). The other complications were endograft migration in about 5.8%, endograft infection in 2.9%, cerebrovascular complications in 5.8%, and ruptured aortic aneurysm in 2.9%.

Conclusion: Interval follow up CT angiography is recommended to detect endoleak and other late complications after TEVAR. Special considerations are noted in the underlying renal insufficiency and the young patient for radiation dose in long term follow up.

Keywords: Endoleak, Thoracic endovascular aortic repair, Thoracic aortic aneurysm, CT angiography, Aneurysm enlargement

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The overall incidence proportion of thoracic aortic aneurysms (TAAs) was 7.6 per 100,000 in a previous study(1). The incidence of TAA also increased over time. Aortic aneurysm is the nineteenth leading cause of overall death in the United States from reports of the Centers for Disease Control and Prevention in 2017(2). There is high mortality rate in cases of ruptured TAA at about 97% to 100%(3). Early diagnosis and treatment of TAA can decrease the mortality rate. Thoracic endovascular aortic repair (TEVAR) is an alternative treatment to the open aortic surgery. The advantage of the TEVAR is less invasive procedure, and decreased morbidity and mortality as compared to the open repair(4). However, some complications can occur after TEVAR that include endoleak, endograft migration, endograft fracture, and aortic neck dilatation(5). Endoleak is defined as a persistent blood flow outside the lumen of an endoluminal graft but within the aneurysmal sac or adjacent vascular segment. The blood flow into the sac causes continued pressurization of the aneurysm, increasesd aneurysm size, and increased risk for ruptured aneurysm(6).

The aim of the present study was to assess the incidence and predictive factors for endoleak and associated increased size of aneurysm after TEVAR at the Central Chest Institute of Thailand (CCIT). The secondary interventions in patients with endoleaks and other complications were also evaluated.

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Materials and Methods

The present study was approved by the Ethical Committee of CCIT (No.021/2563). A retrospective review of all consecutive patients with TAA treated by TEVAR over a seven-year period, between June 2012 and May 2019, was performed. The patients aged under 18 years old were not included. The dissecting aneurysms were excluded from the present study. Patients' demographic data, comorbidities, intraoperative data, postoperative clinical events, and secondary intervention were collected from the medical records.

Three different devices were used, the Valiant (Medtronic Vascular, Santa Rossa, CA), the Relay NBS plus (Bolton medical; US), and the Zenith Alpha (Cook Medical; Bloomington, IN).

After the procedure, computed tomographic angiography (CTA) examination was performed with multidetector scanner, Somatom Definition Flash (Siemens medical Solution, Erlangen, Germany). The CTA protocol consisted of non-contrast scan through the chest, followed by arterial phase contrast-enhanced scans of a chest and abdomen using 80 to 100 mL of non-ionic contrast material. A delayed computed tomographic (CT) scan was then performed again cover the stent graft area.

The endoleak was diagnosed on workstation with multiplanar reformatting and classified by two radiologists.

Radiological data including TAAs diameter, length, location of aneurysm, thrombus thickness, density of thrombus, number of intercostal arteries, aneurysmal sac expansion, the presence of endoleak, and its type were obtained from CTA images. Operative and radiological variables were evaluated between endoleak and non-endoleak groups to find the predictive factor.

The cut-off point of neck length was 20 mm and oversizing of stent by 20% were used to grouping variables according to the recommendation for proper position of stent graft.

Definition

The landing zone of proximal end of the stent was defined as zone 0 to zone 4 according to the classification proposed by Criado et al[7].

The endoleaks classification was evaluated as class I-V according to the Society for Vascular Surgery[4,8]. Type I endoleaks were indicated when blood flow contiguity with proximal (type Ia) or distal (type Ib) endograft attachment sites and early filling of the aneurysmal sac. Type II endoleaks were seen as retrograde blood flow from aortic branch vessels or in case of delayed enhancement of the sac. Type III endoleaks resulted from a defect or misalignment between the components of endografts. Type IV endoleaks occurred soon after the procedure due to porosity of the graft material. Type V endoleaks or "endotension" referred to aneurysm sac expansion without definite evidence of endoleak.

Increased aneurysm size was defined as an increase of aneurysm diameter more than 5 mm. Shrinkage of aneurysm was recorded by reduction of diameter more than 5 mm.

Bird beak configuration was defined as the lack of apposition of the proximal end of stent graft to the aortic wall, with a triangular shaped gap between the stent graft and the aortic wall[9].

Statistical analysis

Data were expressed as mean and standard deviation for continuous variables and as frequencies and percentages for categorical variables. Categorical variables were compared by using the chi-square or Fisher's exact test as appropriate. Comparison of continuous variables were performed using the independent sample t-test.

The univariate logistic regression analyses were performed to determined patient, procedural, aneurysm, and stent graft related variables associated with endoleak formation. The differences were considered as statistical significance at p-value less than 0.05.

Results

Between June 2012 and May 2019, 119 patients underwent TEVAR in the CCIT. Fifty patients were excluded from the present study due to aortic dissection (30 patients), and no follow up imaging (20 patients) due to death or lost follow up. Sixty-nine patients were included in the present study. Fifty patients (72.5%) were male.

Endoleaks were found in 29 patients (42.0%). Type II endoleaks were the most common type in the present study (58.6%). Type I endoleaks were detected in ten patients (34.5%), classified to type Ia in four patients (13.8%) and type Ib in six patients (20.7%). Type III endoleaks were found in two patients (6.9%). Type IV and V endoleaks were not seen in the present study. In 29 cases (42.0%) of endoleaks composed of early endoleaks in 21 cases and late endoleaks in eight cases, which occurred within one year for five cases and more than one year in three cases, with mean follow up time about 22.5 months. In the group

Table1. Demographic data of patients

Variable	Endoleak (n=29); n (%)	No endoleak (n=40); n (%)	p-value
Age (year); mean±SD	69.4± 9.1	66.2±10.9	0.197
Sex: male	19 (65.5)	31 (77.5)	0.271
Smoking	7 (24.1)	7 (17.5)	0.492
Diabetes	5 (17.2)	8 (20.0)	0.772
Hypertension	22 (75.9)	31 (77.5)	0.874
Dyslipidemia	22 (75.9)	26 (65.0)	0.333
CAD	16 (55.2)	10 (25.0)	0.011
CVD	6 (20.7)	7 (17.5)	0.738
Stroke	3 (10.3)	6 (15.0)	0.724
COPD	3 (10.3)	2 (5.0)	0.643
Antiplatelet	9 (31.0)	7 (17.5)	0.189
Anticoagulant	0 (0.0)	1 (2.5)	1.000

CAD=coronary artery disease; CVD=cardiovascular disease; COPD=chronic obstructive pulmonary disease; SD=standard deviation

of late endoleaks, there were type Ia (n=2), type Ib (n=5), and type II (n=1).

The mean age of the patients was 67.5±10.2 years (37 to 90 years). The mean ages were similar in the endoleak group and the non-endoleak group (69.4±9.1 years versus 66.2±10.9 years; p=0.218). There was significantly more underlying coronary artery disease in the endoleak group (55.2% versus 25.0%; OR 3.69, 95% CI 1.33 to 10.28, p=0.011). The other patient characteristic and co-morbidity variables were not associated with endoleak formation (Table 1).

The procedure related variables are presented in Table 2. There were no significant endoleak rates in different endovascular devices, increased number of stents, using of taper stent, left subclavian artery (LSA) coverage, total length of stent, and the landing zone.

The aneurysm and stent graft related factors were analyzed by univariate analysis (Table 2) and associations were found between endoleak and bird beak configuration (OR 4.00, 95% CI 1.28 to 12.51, p=0.017) and distal neck length of less than 20 mm (OR 10.17, 95% CI 1.15 to 89.90, p=0.019)

Subgroup analysis is presented in Table 3. Proximal neck length with less than 20 mm was the risk factor of type Ia endoleak (OR 12.33, 95% CI 1.25 to 121.33, p=0.031).

In type Ib endoleak, the factors associated with endoleak were distal neck length of less than 20 mm (OR 195.0, 95% CI 10.46 to 3630.00, p<0.001) and angulation of distal stent of less than 160 degree (OR 6.89, 95% CI 1.08 to 43.92, p=0.045).

The number of intercostal artery coverage was the only predictive factor for type II endoleak (OR 6.38, 95% CI 1.76 to 23.12, p=0.005).

Endoleaks were the significant risk for aneurysm enlargement. In the 29 cases of endoleak, 59% developed aneurysm enlargement. All of type Ia and III were associated with aneurysm enlargement, while 50% of type Ib and 47.1% of type II revealed increased size of aneurysm.

Secondary interventions were performed in eight patients composed of re-TEVAR with extended stent grafts (n=5), coil embolization (n=1), stent graft removal (n=1), and hemiarch replacement (n=1). The successful rate of the secondary intervention was about 87.5%.

The other device-related complications were endograft migration in about 5.8% (n=4) with all associated with type Ib endoleak, and endograft infection in 2.9% (n=2). One case of endograft infection occurred after re-TEVAR and developed aortoesophageal fistula within two months after the second intervention. Removal of stent was performed to control the infection. The patient died ten days later. Another case of endograft infection developed septicemia as the cause of death.

A ruptured aortic aneurysm was found in two cases (2.9%). One patient presented with mediastinitis and endograft infection after TEVAR with total arch and coronary artery bypass surgery (CABG) for one month. The aortic stent graft was removed with successful extraanatomic aortic bypass. The other patient with ruptured aortic aneurysm developed massive hemoptysis and emergency CTA revealed ruptured aortic aneurysm eight months after TEVAR.

The cerebrovascular complications were found in 5.8% (n=4) and one case fully recovered.

The survival rate in the mean follow-up time of 28.5 months (range 1.2 to 82.5 months) was 79.0% (n=49). The death rate was about twenty one percent (n=13). Ten percent of patients (n=7) were lost to follow up.

Discussion

Endoleak is the most common device-related complication following endovascular repair[10]. Earlier literature reported an endoleak rate after TEVAR in the range of 5% to 38.2%[11-15]. The present study detected endoleaks in 42.0% of the TEVAR cases, composed of type I, type II, and type III endoleaks in 34.5%, 58.6%, and 6.9%, respectively. This is similar to the data of Tanasoontornrerk et al[15] that found type I, type II, and type III endoleaks in 11.5%,

Table 2. Risk factors for Endoleaks after TEVAR

Variable	Endoleak (n=29)	No endoleak (n=40)	Odds ratio	95% CI	p-value
Device*					
Valiant	9 (45.0)	13 (44.8)			
Zenith Alpha	7 (35.0)	7 (24.1)	1.444	0.375 to 5.566	0.593
Bolton	4 (20.0)	9 (31.0)	0.642	0.150 to 2.743	0.721
Number of stent					
1	12 (41.4)	19 (47.5)			
2	16 (55.2)	19 (47.5)	1.333	0.499 to 3.560	0.566
3	1 (3.4)	2 (5.0)	0.792	0.065 to 9.711	1.000
Taper of stent	21 (72.4)	30 (75.0)	0.875	0.296 to 2.587	0.809
Total length of stent ≥ 300 mm	14 (48.3)	17 (42.5)	1.263	0.483 to 3.301	0.634
Landing zone					
4	4 (13.8)	5 (12.5)			
3	3 (10.3)	4 (10.0)	0.938	0.128 to 6.875	0.907
2	4 (13.8)	13 (32.5)	0.385	0.068 to 2.164	0.382
1	10 (34.5)	7 (17.5)	1.786	0.349 to 9.127	0.683
0	8 (27.6)	11 (27.5)	0.909	0.184 to 4.500	1.000
LSA coverage	24 (82.8)	30 (75.0)	1.600	0.482 to 5.313	0.443
Type of aneurysm					
Fusiform	17 (58.6)	18 (45.0)			
Saccular	12 (41.4)	22 (55.0)	0.578	0.220 to 1.518	0.264
Position of aneurysm					
Thoracoabdominal aorta	2 (6.9)	1 (2.5)			
Descending aorta	5 (17.2)	14 (35.0)	0.179	0.013 to 2.425	0.227
Aortic arch	22 (75.9)	25 (62.5)	0.440	0.037 to 5.191	0.602
Aortic diameter ≥ 60mm	17 (58.6)	24 (60.0)	0.944	0.357 to 2.498	0.908
Thrombus thickness ≥ 20 mm	13 (44.80)	14 (35.0)	1.509	0.567 to 4.015	0.409
Density of thrombus ≥ 35 HU	18 (62.1)	24 (60.0)	1.091	0.409 to 2.910	0.862
Proximal neck diameter ≥ 30 mm	18 (62.1)	25 (62.5)	0.982	0.366 to 2.632	0.971
Proximal neck length ≥ 20 mm	25 (86.2)	37 (92.5)	0.507	0.104 to 2.462	0.443
Distal neck length <20 mm	6 (20.7)	1 (2.5)	10.174	1.151 to 89.895	0.019
Bird beak configuration	12 (41.4)	6 (15.0)	4.000	1.279 to 12.506	0.014
Angulation of proximal stent <160 degree	24 (82.8)	36 (90.0)	0.533	0.130 to 2.190	0.477
Angulation of distal stent <160 degree	9 (31.0)	9 (22.5)	1.550	0.526 to 4.571	0.427
Oversizing ≥ 20%	10 (34.5)	19 (47.5)	0.643	0.240 to 1.726	0.380

CI=confidence interval

* Losing some data of stent graft device (n=49)

$p<0.05$ is significant

84.6%, 3.9%, respectively. Most of type Ib endoleaks occurred at one year follow up. The suspected cause of late type Ib endoleaks was cranial migration of distal landing zone, which represented displacement of endograft by more than 5 to 10 mm from the original position[10]. The endograft migration was detected in 5.8%, comparable to the prior literature that reported 0.7% to 23.0%[16-18]. All of them occurred in distal location of the stent with the length of migration range from 7 mm to 17 mm. Geisbüsch et al, reported that migration of the stent graft was observed in 7.3% and occurred at distal landing zone in about 55.6%[17]. The progressive dilatation of the aneurysm neck associated with shorter distal landing zone in the present study.

Table 3. Risk factors for endoleaks after TEVAR in subgroup analysis

Type	Variable	Endoleak; n (%)	No endoleak (n=40); n (%)	Odds ratio	95% CI	P-value
Type I	Bird beak configuration	n=10, 6 (60.0)	6 (15.0)	8.500	1.833 to 39.421	0.006
Type Ia	Proximal neck length <20 mm	n=4, 2 (50.0)	3 (7.5)	12.333	1.254 to 121.304	0.031
Type Ib	Distal neck length <20 mm	n=6, 5 (83.3)	1 (2.5)	195.000	10.475 to 3630.000	<0.001
	Angulation of distal stent <160 degree	n=6, 4 (66.7)	9 (22.5)	6.889	1.080 to 43.923	0.045
Type II	Number of intercostal artery ≥ 5	n=17, 9 (52.9)	6 (15.0)	6.375	1.757 to 23.124	0.005

CI=confidence interval

p<0.05 is significant

There was significant angulation of distal stent to the native aorta from aortic tortuosity. Successful treatment of all type Ib endoleaks with re-TEVAR was done with extended balloon expandable stents in 83.3%. Only one patient developed graft infection and aortoesophageal fistula after re-TEVAR. Surgical correction was performed three months later.

The predictive factor of type Ia endoleak was bird beak configuration. The longer distal neck of more than 20 mm in length was the predictive factor of endoleak. In subgroup analysis, type Ia endoleak occurred more when proximal neck length was less than 20 mm, while type II endoleak associated with an increased number of intercostal artery coverage of more than five in the endograft length. However, the size of intercostal artery had no effect on endoleak formation. The bird-beak configuration is significantly correlated with the risk of type Ia and IIs (type II endoleak from subclavian artery) endoleak formation with a sensitivity of 85% (17 of 20 cases) and a specificity of 75% from the study of Ueda et al[9]. The risk factors of endoleaks in the previous study of Kanaoka et al[19] were landing zone 0 to 2, LSA coverage, excessive oversizing, large proximal neck, and stent-graft diameters. The difference from the present study was that there was no significant correlation. In contrast to the data of Piffaretti et al[20], larger aortic diameter at the time of repair and coverage of LSA were not predictive factors of endoleaks in the present study patient population. Factors predictive of endoleak in the study of Parmer et al[11] included male gender, larger aneurysm size, the length of aorta treated by stent grafts, and an increasing number of stents used, which were not associated with endoleak in the present study. The authors found that thrombus thickness and density of thrombus in aneurysm were not associated risk of endoleak formation.

Endograft infection is a rare complication that more commonly occurred after TEVAR than EVAR.

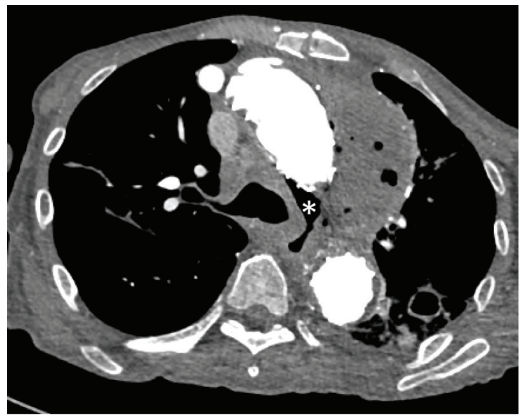

Figure 1. Aortoesophageal fistula (*) seen as tract of air density between aorta and esophagus as well as air in fluid collection surrounding stent graft.

The prevalence of EVAR and TEVAR infection in the prior study was 0.26% and 4.77%, respectively[21]. Patients with infected TEVAR were more likely to have fistula than those with infected EVAR, with the most common being aortoesophageal[22]. Endograft infection in the present study was identified in 2.9% (n=2), which occurred in late follow up and developed aortoesophageal fistula in 50% of endograft graft infection (n=1), as shown in Figure 1. Pulmonary infection was also seen as patchy consolidation and cavitary lesions (Figure 2). The predisposing factor of the patient who had both endograft infection and aortoesophageal fistula was malnutrition, which may cause low immune system susceptibility to infection.

Another serious complication was ruptured aortic aneurysm in 2.9% (n=2). One patient was the case earlier mentioned in endograft infection. Progressive enlargement of aneurysm was seen. This is similar to the study of Dake et al[23] that found fatal aneurysm rupture occurred in two patients (2%).

Embolic strokes have been reported to occur in 4% to 8% of the cases following TEVAR in the prior

Figure 2. Lung window of the same patient reveals nodular and cavitary lesions in left lung representing associated pulmonary infection.

study[10]. The incident rate was also comparable to the open surgery. Cerebrovascular events were found in 5.8% in the present study.

In the authors' experience, the rate of re-intervention was 12%, similar to 11.7% re-intervention in the study of Szeto et al[24]. Nine from twelve percent of re-intervention was endovascular repair with a success rate of about 83.3%.

The result of the present study represents the complications after TEVAR for aortic aneurysm in a referring center of cardiothoracic surgery.

Limitation

The limitation of the present study was due to being retrospectively reviewed. Some data were missed due to incomplete medical recordings such as the type of selected endovascular devices. Some patients were lost to follow up, so the survival rate was not well calculated. The length of follow up period of each patient varied due to the different timing of procedure.

Conclusion

The risk factors of endoleak were bird beak configuration and distal neck length less than 20 mm, for type Ia, proximal neck length less than 20 mm, for type Ib, distal angulation less than 160 degree and short distal neck length, for type II, and number of intercostal artery coverage of more than 5 in endograft length.

Follow up CT angiography is recommended in patients following TEVAR to detect endoleaks and other late complications including endograft infection and fatal ruptured aortic aneurysm. Special consideration is noted in underlying renal insufficiency and young patient for radiation dosage in long term follow up. Benefit and risk should be justified.

What is already known on this topic?

The predictive factors of endoleak were bird beak configuration, landing zone 0 to 2, LSA coverage, large proximal neck and stent-graft diameters, excessive oversizing, aneurysm enlargement, and length of aneurysm. In Thai population, the factors that had statistically significant differences between endoleak and non-endoleak patients were landing zone and aortic arch for the location of aneurysm.

What this study adds?

The present study found that angulation of distal stent with aorta less than 160 degrees was associated with type Ib endoleak. The number of intercostal arteries in stent graft length that were more than five was the predictive factor of type II endoleak. The density of thrombus was not associated with endoleak formation. The rate of re-intervention and some complications after TEVAR in Thai population were reported in the present study.

Conflicts of interest

The authors declare no conflict of interest.

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