

Ninety Days Mortality after Thoracic Endovascular Aortic Repair

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Background: The thoracic endovascular aortic repair (TEVAR) has become popular due to its favorable immediate outcome. However, the outcome in longer duration is still questionable. The aim of the present study was to analyze the incidence and risk factors associated with 90 days mortality after TEVAR.

Material and Method: After the Siriraj Institutional Review Board, Thailand approved and waived the need for the informed consent, the database that included 160 consecutive patients having TEVAR procedures between December 2006 and December 2010 was examined. Patients' characteristics, including operative procedures and anesthesia techniques were studied. The mortality and complications were extracted and analyzed. Major adverse events and the others factors were analyzed to determine the risk factors. Other complications such as bleeding, endoleak, infection, and reintervention were examined and analyzed.

Results: One hundred sixty patients underwent TEVAR. They included 118 male (74%) and 42 female (26%) with mean age of 65. Perioperative mortality (within 24 hours postoperatively) was 1 (0.6%), 30 days mortality was 7 (4.4%) and the overall 90 days mortality was 10 (6.25%). Causes of death included sepsis [4 patients (2.5%)], multi-organ failure [3 patients (1.9%)], ischemic heart disease [1 patient (0.6%)], uncontrolled bleeding [1 patient (0.6%)], and graft ruptured [1 patient (0.6%)]. The risk factor related to mortality was postoperative neurological morbidity (OR 6.77, 95% CI = 1.08-42.36, $p = 0.4$). General anesthesia with endotracheal tube was used in the majority of the patients (92.5%), with no statistical significance in anesthesia-related mortality. Major adverse events including pneumonia 11.9%, cardiac arrhythmia 11.3%, graft infection 7.5%, neurological complication 7.0% (ischemic stroke 9 and paraplegia 1), renal failure 3.8%, and myocardial ischemia 0.6%.

Conclusion: The incidence of 90 days mortality after TEVAR was 6.25% (10 from 160). The risk factor associated with mortality was the development of neurologic complication postoperatively.

Keywords: Mortality, Endovascular, Aorta, Stent

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Thoracic endovascular aortic repair (TEVAR) is a part of changing trends to less invasive medical procedures. The use of aortic stent graft in thoracic aortic diseases has been accepted and expanded in the recent years after the promising early outcome was established^(1,2). The morbidity and mortality have been constantly declining since the introduction of the device in 2005. However, the mid-term and long-term outcomes in patients after this procedure are somehow varied⁽³⁾.

The initial experiences of TEVAR in Siriraj hospital had high success rate with low early morbidity and mortality, compared to opened surgical repair⁽⁴⁾.

Therefore, the aim of the present study was to evaluate the mid-term outcome, including 90 days mortality, and major adverse events, as well as risk factors associated with mortality after TEVAR.

Material and Method

The Siriraj Institutional Review Board, Bangkok, Thailand had approved the study protocol, and waived the need for the informed consent because of retrospective review. The database that included all patients that had thoracic aortic stent-graft procedures between September 2005 and December 2010 was analyzed.

Patients' characteristics, including operative procedures were studied. The mortality and complications were extracted and analyzed. Major adverse events were defined as death, stroke, myocardial infarction, renal failure, spinal cord ischemia and the others factors

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that related to death. These major adverse events were analyzed to find the perioperative risk factors. Anesthetic technique was recorded to identify anesthesia related death including fluid replacement, blood transfusion, hemodynamic changes, and spinal drainage. Other complications such as bleeding, endoleak, infection, and reintervention were examined.

Sample size was calculated, based on the literature that the average mortality rate is 9%, to detect an accepted variation of 0.045 with a type I error of 0.05.

Statistical analyses were performed using SPSS 15.0 for windows. Continuous data were presented as mean and SD. The risk factors related to mortality and categorical data were analyzed by Chi-square test. Multivariate stepwise logistic regression analysis was used to determine predictors of death, while $p < 0.05$ was considered statistically significant.

Results

One hundred sixty consecutive patients, 118 male, 42 female, with a mean age of 65.4 (range 19-89 years) underwent 167 TEVAR procedures. Baseline characteristics were given in Table 1. The majority of the cases were elective ($n = 112$, 70%), whilst 30% ($n = 48$) were emergency cases. The underlying pathology was aortic aneurysm ($n = 95$, 59.4%), acute aortic dissection ($n = 23$, 14.4%), chronic aortic dissection ($n = 16$, 10%), traumatic aortic disruption ($n = 14$, 8.8%), penetrating atherosclerotic ulcer of the aorta ($n = 10$, 6.2%), and others such as endoleak ($n = 2$, 1.2%) as shown in Fig. 1. Adjuvant extra-anatomic bypass was employed in 65 patients (40.6%). Two patients were converted to open procedures, one immediate in the operating theater and the other on postoperative day 11 due to aorto esophageal fistula.

One patient (0.6%) had intraoperative mortality from uncontrolled bleeding; hence we excluded this case from the risk factor analysis. There was no mortality within 24 hours postoperatively. One patient (0.6%) died at 48 hours postoperatively from multi-organ failure. She was diagnosed with intramural hematoma of the descending aorta and stent insertion failed due to severe tortuous aorta. She had conversion to open graft interposition procedure with unstable hemodynamics and developed severe hypoxic brain injury and multi-organ failure in 48 hours. The 30 days mortality was 4.4% ($n = 7$) and the overall 90 days mortality was 6.25% ($n = 10$). Causes of

death were sepsis [4 patients (2.5%)], multi-organ failure [3 patients (1.9%)], ischemic heart disease [1 patient (0.6%)], uncontrolled bleeding [1 patient (0.6%)], and graft ruptured [1 patient (0.6%)].

When divided the patients into the group of TEVAR alone and TEVAR with adjuvant extra-anatomic bypass or hybrid TEVAR, the overall mortality rate was 1.9% and 5% respectively.

Major adverse events including pneumonia 11.9%, cardiac arrhythmia 11.3%, graft infection 7.5%, neurological injury 7.0% (ischemic stroke 9 and paraplegia 1), renal failure 3.8%, and myocardial ischemia 0.6%.

Of the 137 patients (84.6%) with descending aortic lesion, CSF pressure monitor and drain were inserted in 27 patients. None of these developed paraplegia. However, one patient had paraplegia without CSF drain, he had traumatic aortic disruption with thoracolumbar spine fracture and cord compression prior to TEVAR. Nine patients developed stroke, six had permanent neurologic injury and three died. Amongst nine patients who developed stroke, one had

Table 1. Baseline characteristics

Variables	Values
Age	65.4±14.2 (19-89)
Body weight (Kg)	61.9±13.0 (35.0-100.0)
Height (cm)	162.3±8.3 (140.0-187.0)
ASA physical status	
Class 3	134 (83.8%)
Class 4	26 (16.2%)
Euroscore	4.7±1.3 (2-8)
Co-morbidities	
Hypertension	119 (74.4%)
Chronic kidney diseases	70 (43.8%)
Coronary artery diseases	49 (30.6%)
Pulmonary diseases	23 (14.4%)
Cerebrovascular diseases	19 (11.9%)
Diabetes mellitus	17 (10.6%)
Preoperative Hb (g/dL)	11.5±2.0 (6.7-16.3)
Preoperative serum Cr	1.4±1.3 (0.4-11.5)
Anesthetic time (minute)	268.1±134.6 (90.0-780.0)
Operative time (minute)	200.6±131.2 (40.0-695.0)
Length of ICU stay (days)	3.4±5.7 (0-41)
Hospital stay (days)	16.9±14.4 (2-102)
Aneurysm diameter (cm)	6.0±1.6 (2-10.7)

ASA = American Society of Anesthesiologist; Hb = hemoglobin; Cr = creatinine; ICU = intensive care unit
Data presented in mean ± SD (min-max) or n (%)

pathology at 1/3 proximal descending aorta, one had aortic arch lesion, and six received extra-anatomic bypass operation.

General anesthesia was the technique used in the majority of the patients (n = 150, 93.75%) with both endotracheal tube and laryngeal mask airway.

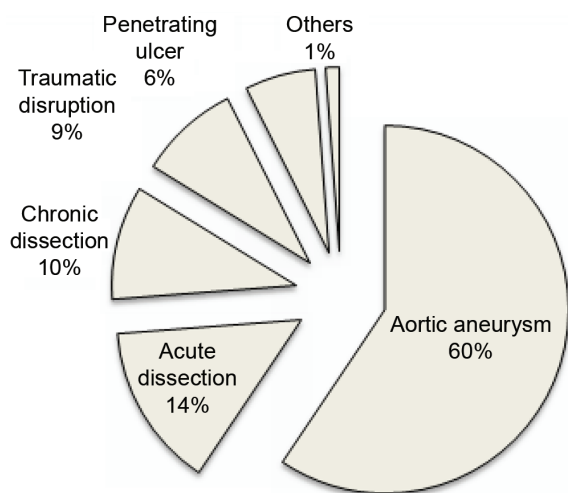


Fig. 1 Diagnosis.

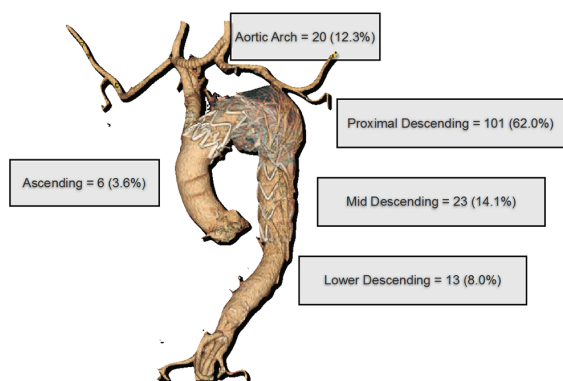


Fig. 2 TEVAR landing zone.

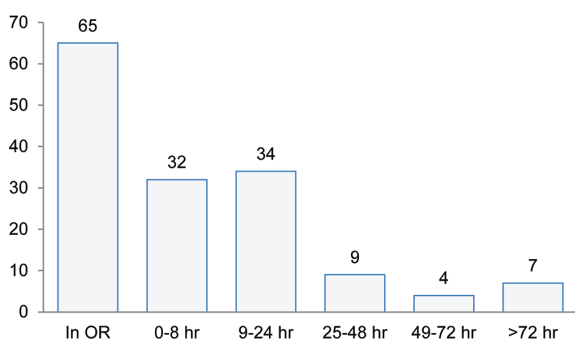


Fig. 3 Time to extubation.

Table 2. Factors associated with 90-day mortality

Factors	OR	95% CI	p-value
Preoperative hemodynamic instability	7.19	0.68-76.07	0.1
Euroscore	1.70	0.99-2.92	0.5
Neurological morbidity	6.77	1.08-42.36	0.4

Other techniques were intravenous anesthesia and sedation (n = 8, 5%) and combined general and epidural anesthesia (n = 2, 1.25%). Fifty-six patients (36.3% of general anesthesia group) were immediately extubated in the operating theaters and the others required mechanical ventilation in intensive care unit. Seventy-nine patients (91.9% from the remaining 86 patients) can be extubated within 72 hours postoperatively. There was no statistical significant in anesthesia-related mortality.

Logistic regression analysis was used to determine predictors for risk factor in the patients with mortality. The only strong predictor was neurological morbidity (OR 6.77, 95% CI = 1.08-42.36, p = 0.4) as shown in Table 2.

Discussion

The present study demonstrated the early result of our center's initial experience in TEVAR, incorporated 160 patients between 2005 and 2010. The perioperative mortality within 30 days was 4.4% and the ninety day mortality was 6.25%. This result is encouraging and comparable to the recent experiences reports by others.

Several studies have demonstrated perioperative mortality of TEVAR varied between 2% to 26% depending on urgency of the procedures, the extent of co-morbidities and operators' experiences⁽⁵⁾. However, they have consistently demonstrated lower early perioperative morbidity and mortality than conventional open surgical procedures^(6,7). In our study, we found the 30-day mortality of 4.4% and 90-day mortality of 6.25%, which was reasonably low compared to other institutes. Cheng et al found 30-day mortality rate of 5.8% and 1-year mortality rate of 16% in TEVAR patients. In the open surgical reconstruction group, their 30-day and 1-year mortality rate were 13.9% and 21.9% respectively⁽⁸⁾.

When divided the patients into the group of TEVAR only and TEVAR with adjuvant extra-anatomic bypass or hybrid TEVAR, the overall mortality rate was 1.9% and 5% respectively. While the hybrid TEVAR are complicated surgical procedures that

combined endovascular stent and vascular bypass graft at the same time^(9,10). Our result shown that the hybrid procedures lead to longer duration of surgery, more blood loss and more blood transfusions, as well as increased morbidity and mortality. The hybrid procedure may be an important risk factor of death, but could not confirm with the statistical analysis in the present study. This may be due to the number of hybrid cases in our series was limited. Further study regarding this concern would be very valuable.

The regression analysis from the present study shown postoperative complication especially neurological morbidity was the risk factor of mortality. Our results were different from Dillavou's study, which revealed predictors of death for endovascular and open aortic aneurysm repair were symptomatic aneurysms and male gender⁽¹¹⁾. This may be due to different institutions and different population.

Anesthetic technique in the majority of the patients was general anesthesia with endotracheal intubation (92.5%). There was 59% required postoperative mechanical ventilation, which the hybrid procedure was the important factor. Anesthetic technique, hemodynamic variation, fluid resuscitation and blood transfusion were not the significant risk factor of death.

However, the issue of stroke following TEVAR raises several considerations relating to operative and anesthetic factors such as hypotension, management of the left subclavian artery, athero-embolism secondary to tracking, and manipulating wires, catheters, and large delivery systems across the aortic arch, as well as inadvertent coverage of the great vessels^(12,13). In Patel's study, strokes were clustered in patients with proximal aneurysmal diseases, which was not different from our result⁽¹³⁾.

The hybrid procedure was a predisposing factor of stroke from our study. Feezor et al found that endograft implantation in zones 1 and 2 of the arch, covering the left subclavian artery had strong relation with stroke particularly in the setting of a dominant left vertebral artery, and/or a stenotic, occluded or diminutive right vertebral artery⁽¹⁴⁾. Moreover, Preventza et al found Paraplegia following thoracic endografting appears to be associated with female sex, long segment coverage of the thoracic aorta, and aneurysmal disease⁽¹⁵⁾. In our result, CSF drainage may have benefit in neurological outcome because the number of stroke and paraplegia patient decrease in CSF drainage group. We believe the efficacy of lumbar CSF drainage during TEVAR warrants further study.

From the present study, we expected to reduce mortality by early resuscitation and stabilized hemodynamic of the patient, well controlled comorbid disease, considered CSF drainage intervention in high risk group, and early detected complication especially in neurological complication and pulmonary infection will be decrease postoperative mortality.

Conclusion

Despite the many advances in the field of TEVAR, stent-grafting of the thoracic aorta remains in a developmental phase. The early outcomes determines long-term outcomes, hence require further studies.

What is already known on this topic?

Thoracic endovascular aortic repair has a promising early outcome in Thailand. This technique has been widely implemented for less invasive option than open repair. However, it has been adopted recently with small numbers of patients. The mid-term and long-term outcome has never been studied.

What this study adds?

This study described the 90-day mortality for thoracic endovascular aortic repair at Siriraj Hospital of 6.25%, which is comparable to the previous studies from other countries. The risk factor for mortality is development of neurologic complication postoperatively.

Potential of conflicts of interest

None.

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อัตราการเสียชีวิตที่ระยะ 90 วันหลังจาก *thoracic endovascular aortic repair*

กษณา รักษาภรณ์, พรสิริ วรรณดิถ, วรวงศ์ ศลิษฐ์อรอดกร

ภูมิหลัง: การทำ *thoracic endovascular aortic repair* (TEVAR) นั้นได้รับความนิยมมากขึ้นเรื่อยๆ เนื่องจากผลลัพธ์ในระยะเริ่มต้นได้ผลดี อย่างไรก็ตามผลในระยะยาวยังมีความหลากหลาย ยังต้องมีการศึกษาเพิ่มเติมต่อไป การศึกษานี้จัดทำเพื่อศึกษาอัตราการเสียชีวิตที่ระยะ 90 วัน รวมถึงปัจจัยเสี่ยงต่อการเสียชีวิต

วัสดุและวิธีการ: หลังจากได้รับการรับรองจากคณะกรรมการจริยธรรมการวิจัยในคนของสถาบัน เพื่อได้รับการยกเว้นการขอความยินยอมจากผู้ป่วยแล้ว ข้อมูลของผู้ป่วย 160 ราย ที่ได้รับการทำ TEVAR ตั้งแต่เดือนธันวาคม พ.ศ. 2549 ถึง ธันวาคม พ.ศ. 2553 ได้ถูกนำมาศึกษาและวิเคราะห์ โดยข้อมูลที่ศึกษาได้แก่ ลักษณะพื้นฐานของผู้ป่วย การผ่าตัด และการระบุความรู้สึก รวมถึงอัตราการเสียชีวิตและภาวะแทรกซ้อนต่างๆ เช่น การเสียชีวิตมาก ภาวะ *endoleak* การติดเชื้อ และการต้องกลับไปทำหัตถการซ้ำ

ผลการศึกษา: จากการศึกษาข้อมูลของผู้ป่วย 160 ราย ที่ได้รับการทำ TEVAR เป็นเพศชาย 118 ราย (ร้อยละ 74) เพศหญิง 42 ราย (ร้อยละ 26) โดยมีอายุเฉลี่ย 65 ปี มีผู้ป่วยเสียชีวิตภายใน 24 ชั่วโมงแรก 1 ราย (ร้อยละ 0.6) เสียชีวิตภายใน 30 วัน 7 ราย (ร้อยละ 4.4) และภายใน 90 วัน 10 ราย (ร้อยละ 6.25) สาเหตุของการเสียชีวิตได้แก่ภาวะ *sepsis* [4 ราย (ร้อยละ 2.5)] *multi-organ failure* [3 ราย (ร้อยละ 1.9)] หัวใจขาดเลือด [1 ราย (ร้อยละ 0.6)] เสียเลือดมากควบคุมไม่ได้ [1 ราย (ร้อยละ 0.6)] และกราฟที่ทะลุ [1 ราย (ร้อยละ 0.6)] ปัจจัยเสี่ยงต่อการเสียชีวิตคือ การเกิดภาวะแทรกซ้อนทางระบบสมองหลังผ่าตัด (OR 6.77, 95% CI = 1.08-42.36, $p = 0.4$) การระบุความรู้สึกส่วนมากเป็นการระบุความรู้สึกแบบทั้งตัว (ร้อยละ 92.5) โดยไม่พบภาวะแทรกซ้อนจากการระบุความรู้สึกเป็นปัจจัยที่มีนัยสำคัญต่อการเสียชีวิต ภาวะแทรกซ้อนหลักที่พบได้แก่ ปอดติดเชื้อ ร้อยละ 11.9 หัวใจเต้นผิดจังหวะ ร้อยละ 11.3 การติดเชื้อของกราฟต์ ร้อยละ 7.5 ภาวะแทรกซ้อนทางระบบสมอง ร้อยละ 7.0 ไตวาย ร้อยละ 3.8 และกล้ามเนื้อหัวใจขาดเลือด ร้อยละ 0.6

สรุป: อัตราการเสียชีวิตที่ระยะ 90 วัน หลังจาก TEVAR นั้นคือ ร้อยละ 6.25 ภาวะที่เป็นปัจจัยเสี่ยงต่อการเสียชีวิตคือ การที่ผู้ป่วยเกิดภาวะแทรกซ้อนทางระบบสมองหลังผ่าตัด
