

Cover Page



University of Cape Town

Outcomes after thoracic endovascular aortic repair (TEVAR) in patients with traumatic thoracic aortic injuries (TTAI) - a single center retrospective review

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Masters of Medicine (MMed) *in* General Surgery

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Title Page

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Outcomes after thoracic endovascular aortic repair (TEVAR) in patients with traumatic thoracic aortic injuries (TTAI) - a single center retrospective review

Submitted in partial fulfillment of the requirements for the degree

Masters of Medicine (MMed)

in

General Surgery

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Degree: Masters of Medicine- General Surgery

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Certification

The undersigned certify that he has read and hereby recommend for examination for a dissertation entitled: **The outcomes of Thoracic Endovascular Aortic Repair (TEVAR) after Traumatic Thoracic Aortic Injury (TTAI)-a single centre retrospective review** in fulfillment of the requirements for the degree of master of medicine (General Surgery) of the University of Cape Town.

Signed by candidate

Nadraj G. Naidoo

Main supervisor

Declaration

I, Nkhabe Chinyepi (Student Number-CHNNKH002), hereby declare that the work on which this dissertation is based is my original work (except where acknowledgments indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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Abstract

Background: Blunt and penetrating traumatic thoracic aortic injuries constitute surgical emergencies that are attended with high mortality rates. Most patients do not survive long enough, post injury, to reach a hospital. On-site mortality rates may approach approximately 85%. Two main treatment options for blunt thoracic aortic injuries (BTAI) are open surgery and thoracic endovascular repair (TEVAR). Penetrating thoracic aortic injuries (PTAI) have a higher mortality than blunt trauma, with patients often only reaching the hospital in extremis. Most will require early intervention. Currently TEVAR is rapidly evolving as the standard of care for thoracic aortic injuries (TAI) at many centres, primarily due to the emerging evidence of lower mortality and morbidity trends in comparison to open surgery (1–4).

Methods: From December 2006 to December 2016, 34 patients (30 blunt trauma, 4 penetrating trauma) with traumatic aortic injuries (grades I-IV) were treated with thoracic aortic stent-grafts in the Groote Schuur Hospital Vascular Unit, Cape Town. We assessed the technical and clinical outcomes following TEVAR in these patients.

Results: The 30- day mortality rate was 5.8%, corresponding to 2 deaths both associated with the index trauma-related fatal strokes. The overall mortality rate was 11.8% (4/34): three deaths were due to major strokes and one death was related to pulmonary complications.

Conclusion: TEVAR after TAI is associated with significantly lower procedural and post-operative mortality. The 30 day and overall mortality after TEVAR in our unit is comparable to international standards. Even though there is a paucity of literature on PTAI, TEVAR has low peri-procedural adverse events and is safe in selected patients.

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List of abbreviations and acronyms

AAST	-	American Association for the Surgery of Trauma
ASA	-	American Society of Anesthesiologist
BTAI	-	Blunt Thoracic Aortic Injury
CCA	-	Common Carotid Artery
CTA	-	Computed Tomography(Angiography)
CXR	-	Chest X-Ray
GCS	-	Glasgow Coma Scale
HAART	-	Highly Active Antiretroviral Therapy
Hb	-	Hemoglobin
HIV	-	Human Immunodeficiency Virus
i-SITE	-	Diagnostic tool for radiologists and doctors that provides diagnostic images and patients clinical information
ISS	-	Injury Severity Score
LSCA	-	Left Subclavian Artery
MVA	-	Motor Vehicle Accident
PTAI	-	Penetrating Thoracic Aortic Injury

PVA	-	Pedestrian Vehicle Accident
SVS	-	Society for Vascular Surgery
TEE	-	Trans-Esophageal Echocardiogram
TEVAR	-	Thoracic Endovascular Aortic Repair
TTAI	-	Traumatic Thoracic Aortic Injury
WHO	-	World Health Organization

Chapter 1

1.0 Introduction

Blunt traumatic thoracic aortic injury (BTAI) caused by motor vehicle accidents and less commonly by other blunt thoracic trauma, constitutes a surgical emergency that is often attended with high mortality rates. Most patients die at the scene of the trauma. Two main treatment options for BTAI are open surgical repair (OSR) and thoracic endovascular repair (TEVAR). Penetrating thoracic aortic injuries (PTAI) generally have a higher mortality than blunt trauma, with patients reaching the hospital often in extremis. On-site mortality in both these cases approach 85%. Currently TEVAR is rapidly evolving as the standard of care for thoracic aortic injuries (TAI) at many centers, primarily due to the publication of consistent evidence of lower mortality and morbidity rates when compared to open surgery (1–4). We only started performing TEVAR at Groote Schuur Hospital (GSH) since 2006.

1.1 Background and Literature Review

1.1.1 Trauma in South Africa

The burden of civilian trauma in South Africa is absolutely devastating (5). In 2007 the National Injury Mortality Surveillance System recorded 33 484 civilian trauma-related deaths, more than one-third of which were related to inter-personal violence, followed by traffic injuries (6). Thoracic aortic injury statistics are lacking in this part of the world mainly due to high pre-hospital mortality rates associated with this condition. Only a relatively few patients survive to an adequately equipped hospital, and even less will make it to the operating theatre.

1.1.2 Blunt thoracic aortic injuries (BTAI)

The first-reported case of BTAI was by the Italian anatomist Andreas Vesalius in 1557 (7), who identified aortic rupture as the cause of death in a patient thrown from a horse. Now with the availability of modern imaging technologies, BTAI, a life-threatening surgical emergency is more easily diagnosed and, untreated, is generally associated with a high mortality. The mechanism of injury is related to sudden horizontal or vertical acceleration-deceleration injury, and most cases are a result of motor vehicle accidents (MVA), pedestrians struck by vehicles (PVA), or falls (1–3).

1.1.3 Penetrating aortic injuries (PTAI)

Penetrating aortic injuries have an exceptionally high mortality rate with no improvement in survival despite improved trauma services. Regarding PTAI, gunshot wounds, un-recordable blood pressure on admission, and the need for emergency room thoracotomy, are important predictors of high mortality (8).

1.1.4 Open Surgical Repair

Thoracic endovascular aortic repair (TEVAR) has evolved since the introduction of open surgical repair in 1959 (7), with the first description of TEVAR by Volodos in 1991. (9) Open repair has been shown to be associated with a high peri-operative mortality and morbidity rate (3,4). The AAST-1 trial evaluated outcomes after open repair. The study reported that the mean time from trauma centre admission to thoracotomy was 15 hours. Most repairs in this study were performed using cardiac bypass support. Paraplegia occurred in 9% of patients. The peri-operative and overall mortality rates were 15 and 31 %, respectively (10)

1.1.5 Thoracic endovascular aortic repair (TEVAR)

Thoracic endovascular aortic repair (TEVAR) was a transformative advance in the treatment of BTAI and was first described for management of aortic injury in conventional practice by Michael Dake and colleagues in 1997 (11). We now appreciate that TEVAR offers several advantages, including minimally invasive peripheral access obviating a thoracotomy and single-lung ventilation, avoidance of aortic cross-clamping, avoidance of procedural anti-coagulation in critical cases (the vast majority), and avoidance of opening into the mediastinal hematoma (2). In 2008 the AAST-2 study was published. TEVAR was associated with significantly lower procedural and post-operative morbidity and mortality rates compared to open surgical repair (12). The RESCUE trial was a prospective, non-randomized, multi-centre device trial that enrolled 50 patients with BTAI and reported one year follow-up data. Major procedural and long-term device-related complications were infrequent, and no patients required aortic re-intervention or had neurologic complications. Of the 20 patients who had coverage of the left subclavian artery, only three (15 %) required revascularization. Overall mortality at 30 days and at 1 year was 8 and 12 %, respectively; two deaths (4 %) were adjudicated as aortic-related (13). TEVAR allows rapid and effective therapy in trauma patients with blunt aortic injury. The outcome is dependent on the severity of the concomitant injuries. The treatment is durable during the first decade after the procedure, but even longer follow up is needed to determine the impact of TEVAR in young patients on the degenerative changes that take place in the aging aorta.(14)

1.1.6 The paradigm shift

Comparison between the two AAST studies in 1997 and 2007 showed a major shift in the diagnosis of the aortic injury, with the widespread use of CT scan and the almost complete elimination of

aortography and TEE. The concept of delayed definitive repair has gained wide acceptance. This provides a window of opportunity to attend to critical issues and interventions, and more importantly to prognosticate before aortic repair. Endovascular repair has virtually replaced open repair. These paradigm shift has not only resulted in a major reduction in mortality

and procedure-related paraplegia, but is also associated with a significant decrease of early stentgraft-related complications (15). A Metaanalysis of publications with open and stent-graft repair cohorts was performed by Hoffer et al. to evaluate whether there was a difference in treatment effect with regard to mortality and paraplegia. Nineteen publications that compared the outcomes of 262 endograft repairs and 376 open surgical repairs were identified. The data support stent-graft repair as a highly successful technique that may reduce mortality and paraplegia rates by half compared with open surgery and supports endograft repair as first-line therapy for blunt thoracic aortic trauma.(16) The evolution of stentgraft design over time has resulted in more conformable devices that are better equipped to accommodate severely angulated aortic arches, especially in young patients. Consequently, stentgraft compression seen with earlier devices are less frequently reported nowadays.

1.1.6 Indications for TEVAR

A classification scheme for grading the severity of aortic injury has been proposed: type I (intimal tear), type II (intramural hematoma or intimal flap), type III (pseudo aneurysm), and type IV (rupture) (17). The Society for Vascular Surgery (SVS) 2011 guidelines recommends expectant management with serial imaging for type I injuries, while types II to IV should be repaired. With the advent of high-resolution helical CT scanning for the diagnosis of suspected BTAI, identification of minimal aortic lesions has become increasingly prevalent. Approximately 10% of patients with BTAI experience minimal aortic injuries that result in focal intimal tears with no or little involvement of the media (18). However, 21% of BTAI patients with minimal aortic injuries undergo TEVAR despite the clinical practice guidelines of the Society of Vascular Surgery to the contrary (19).

1.2 Purpose and study justification

Several studies have shown favourable results after TEVAR for blunt thoracic aortic injury (BTAI). Here we report our 10-year experience with TEVAR for traumatic thoracic aortic injuries (TTAIs). There has been paucity of literature on TEVAR after penetrating thoracic aortic injury (PTAI). We believe that this study could produce data and stimulate further research that may be of real benefit

to patients including long term outcomes, durability of stent grafts, and the use of stent grafts in the younger population, CT angiography surveillance and exposure to radiation.

1.3 Hypothesis

Our hypothesis is that TEVAR after TAI is associated with significantly lower procedural and post-operative morbidity and mortality. We postulated that the 30-day mortality after TEVAR, despite resource limitations in an African setting, will be comparable to international standards

1.4 Research aim and objectives

The study specific objectives are to assess the technical and clinical outcomes following TEVAR in patients with civilian trauma-related TAIs (TTAI)

Outcome measures

➤ **Primary outcomes**

- 30 day and overall mortality

➤ **Secondary outcomes**

- Procedure-related morbidity (paraplegia, cerebrovascular accident, conversion to open repair)
- Systemic complications (acute renal failure; pulmonary complications; etc.)
- Device-related complications (stent configuration and wall apposition-arch, stent fracture, stent migration, endo-leak; stent-graft sepsis and retrograde dissection)
- Re- intervention rates

Chapter Two

Methodology

2.1 Study Design and Population

Single centre retrospective descriptive study of all patients treated by the Vascular Unit at Groote Schuur Hospital.

2.2 Study Setting

This study was conducted at Groote Schuur Hospital in Cape Town, South Africa. Groote Schuur Hospital is a tertiary referral hospital and currently the main Teaching Hospital for the University of Cape Town, Faculty of Health Sciences. It serves patients from Cape Town and its catchment areas in Western Cape Province.

2.3 Inclusion and Exclusion Criteria

We included all patients aged over 18 years who were admitted to our Vascular/Trauma units with TTAI confirmed on CT scan on admission who were treated with TEVAR from December 2006 to December 2016.

2.4 Baseline Characteristics

Patients were assigned a study number. Baseline demographic and clinical characteristics, imaging and treatment data were extracted from trauma registry, vascular registry and theatre registry.

2.5 Injury circumstances

Mechanism of injury was recorded as blunt or penetrating. Information relating to whether safety belts (restrained) or helmets for motorcyclists were used was also obtained from the pre-hospital and trauma registry. Civilian injury circumstances recorded were either motor vehicle accidents

(MVAs), pedestrian vehicle accidents (PVAs), falls, motorcycle, gunshot wounds (GSW) or stab wounds.

2.6 Clinical Measurements

Patients' hemodynamic status on arrival to the hospital (systolic blood pressure, the need for inotropic support or ventilator support) was recorded. The severity of head injury was recorded as the Glasgow Coma Scale (GCS). The Injury Severity Score, an anatomical scoring system that provides an overall score for patients with multiple injuries, was calculated for each patient. Each injury was assigned an Abbreviated Injury Scale (AIS) score and was allocated to one of six body regions (Head, Face, Chest, Abdomen, Extremities (including Pelvis), and External). Only the highest AIS score in each body region was used. The 3 most severely injured body regions have their score squared and added together to produce the ISS score (20).

2.7 Laboratory Measurements

The Hemoglobin (Hb), Creatinine and HIV status, was obtained from the National Laboratory Health System (NHLS) database. An Arterial Blood Gas (ABG) recording pH and lactate was also recorded.

2.8 Imaging

A chest X-ray (CXR) was performed on all patients. For patients seen before 2012 a documentation of x-ray findings was extracted from the trauma registry. Patients seen in 2012 and thereafter, all CXR images were available on i-SITE for review. A Widened mediastinum was defined as a measured width of >8 cm, a mediastinal-chest width ratio of >0.38 (measured at the level of the aortic arch), or simply the physician's impression that the mediastinum is widened (20). A computed tomographic angiogram (CTA) was performed on all patients with suspected thoracic aortic injuries or for other trauma indications. These were reviewed and the aortic injuries were

severity-graded according to recommended classification systems accordingly: type I (intimal tear), type II (intramural hematoma or intimal flap), type III (pseudo aneurysm), or type IV (rupture) (21). Intra-operatively an angiogram was performed and the reported findings were obtained from the operative notes and recorded vascular C-arm images, captured in theatre. The type of aortic injury was noted. The arch type was recorded, measured as the vertical distance from the origin of the innominate artery to the top of the arch, type 1(distance < 1 common carotid diameter (CCA), type 2(between 1 and 2 CCA diameters) and type 3 (> 2 CCA diameters) (22). Arch anomalies were also identified and recorded.

2.8 Intraoperative data

The time from injury to surgery was deduced from the trauma admission and operative notes. The anesthetic notes were also perused to obtain information on the use of heparin, ASA classification and the total duration of surgery. The type and size of device used and the access vessels were also recorded. The proximal landing zones were recorded as; Zone 0- the ascending aorta proximal to the innominate artery; Zone 1- between the innominate and left common carotid artery; Zone 2 - between the left common carotid artery and the left subclavian artery; Zone 3 -descending thoracic aorta distal to the left subclavian artery; Zone 4 - the proximal descending thoracic aorta > 2cm distal to the left subclavian artery (15). Information regarding intentional coverage of the left subclavian artery (LSCA), embolization of the LSCA, hybrid procedures, or any additional vascular or non-vascular surgical procedures were obtained from the operative notes. Technical success was defined as complete aortic stentgraft coverage of the thoracic aortic lesion.

2.9 Follow up

Data reporting on post-operative adverse events, the length of hospital stay and ICU stay were obtained from patients' files. The CTAs were scheduled at 1 month, 6 months, 12 months and annually thereafter. Regular clinical reviews reported on symptomatology (left upper limb ischaemia, chest discomfort, chest pain, cerebrovascular symptoms) and imaging for device related complications (stent configuration and wall apposition-arch, stent fracture, stentgraft migration, endo-leak or stentgraft sepsis).

2.10 Search Methods

A literature search of relevant literature was performed initially in August 2015 and repeated for new references in August 2016 and August 2017. The literature search was conducted using PubMed (MEDLINE), PubMed Central and the Medical Subject Headings (MeSH) databases. The following search headings or terms were used: "BTAI", "TEVAR", "penetrating thoracic injury", "outcomes", "procedure related", "device related", "mortality", "paraplegia", "follow up" and "late complications". The search terms were used for all fields (including title, abstract, keywords and full text), and all results types were included. Further sources were identified by following up internal citations and references within the documents retrieved in the initial search. Due to the applied methodology, the review excluded research currently underway that is not available in certain databases, or studies which have not been published in English.

2.11 Ethical Clearance

Approval for this study was obtained from the Human Research Ethics Committee, Faculty of Health Sciences and University of Cape Town (REF: 635/2016).

2.12 Budget and Justification

The study did not need an extra budget as the results used were captured from hospital records by the principal investigator.

Chapter Three

Results

3.0 Demographics

A total of 34 patients were enrolled into the study. There were 31 males (91.2%) and three (8.8%) females. The mean age of enrolled patients was 35.1 +/- 11.5 (Range: 20 – 65 years). Twenty-six patients had no medical comorbidities. Three patients were RVD positive. The following comorbidities were also identified: one HPT; one HPT/DM; one HPT/DM/RVD; one epileptic; one previous PTB with pneumonectomy and one schizophrenic. Nineteen patients did not know their HIV status, 12 were negative and three were positive. All three HIV positive patients were on treatment. Fourteen patients were smokers and 20 patients were non-smokers. None of the patients had previous aortic surgery (open or endovascular). The median GCS was 15 (Range: 4-15). Twenty-six patients were not intubated and eight were intubated either at the scene or on arrival at the hospital. Table 1 summarizes the baseline characteristics.

Table 1: Baseline characteristics

Characteristics	N=34
Age	
Mean \pm SD	35.1 \pm 11.4
Median (range)	34 (20-65)
Gender	
Male	31
Female	3
ISS, median (range)	31 (13-66)
Ventilation	8
GCS, median(range)	15 (4-15)
Comorbidities	
Hypertension	3
Diabetes	2
Tuberculosis	1
Epilepsy	1
Cerebrovascular accident	0
Paraplegia	4
HIV status	
Positive	3
Negative	12
Unknown	19
Smokers	14
Previous aortic surgery	0

3.1 Vital signs

The pulse distribution is skewed to the right with the mean pulse rate of 112 ± 20 /minute and mean systolic pressure of 116 ± 25 mmHg. The systolic pressure distribution is normal and pulse distribution is skewed to the right as shown in figure 1 and 2 below.

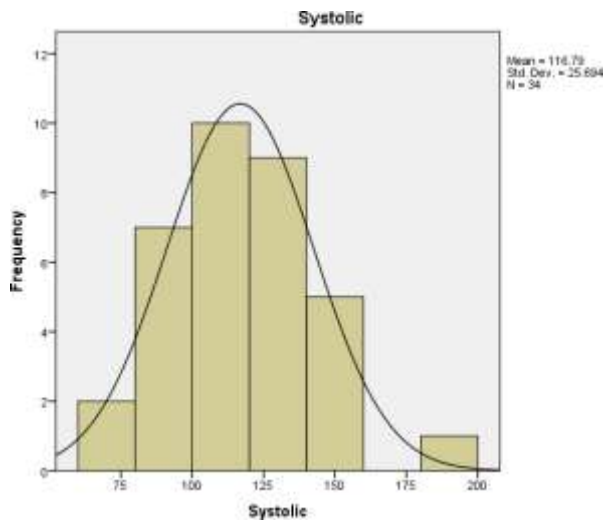


Figure 1: SBP distribution

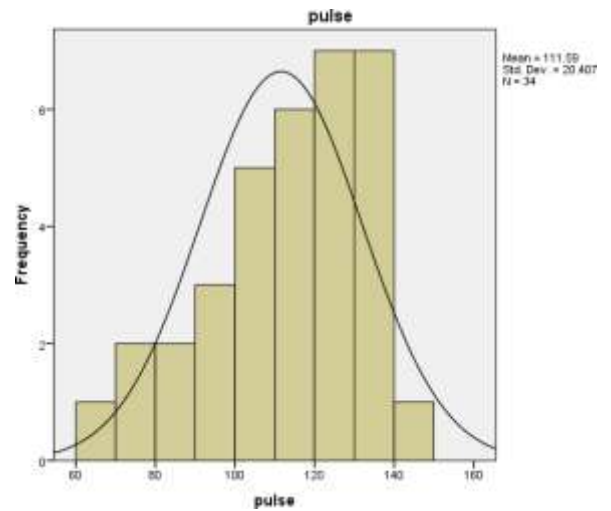


Figure 2: Pulse distribution

3.2 Biochemical variables

The average pH of patients on admission was 7.38 ± 0.06 ; minimum recorded pH 7.23 and maximum pH 7.47. The frequency distribution of some biochemical variables (lactate, Hb, creatinine) are as shown in table 2.

Table 2: frequency distribution of biochemical variables

		Ph	Lactate	Hb	Creatinine
N	Valid	28	23	33	28
	Missing	6	11	1	6
Mean		7.3829	1.7148	10.782	81.571
Median		7.3900	1.1000	11.000	79.000
Std. Deviation		.06024	1.86877	2.1809	29.8185
Minimum		7.23	.10	6.6	34.0
Maximum		7.47	9.00	15.0	167.0

Hb (g/dl); creatinine (Umol/L); lactate (mmol/L)

3.3 Mechanism of Injury

Thirty patients sustained blunt trauma and 4 patients sustained penetrating trauma. In the blunt trauma group, 28 patients sustained motor-vehicular accidents while 2 patients were involved in falls from a height.

In the group of patients that sustained motor vehicular accidents (N=28): seven were unrestrained drivers, four were motorcyclist (two with helmets on and two with helmet use information not documented), eight were unrestrained passengers and nine were pedestrians. In the group of patients that sustained injuries due to penetrating trauma, three were related to gunshot wounds and one was an iatrogenic injury sustained at thoracotomy. Comparatively, penetrating trauma patients were younger with a median age of 28 (range 22-56) and had a median ISS of 17. No grade IV aortic injuries were documented for penetrating aortic injuries. Table 3 summarizes the comparison between blunt and penetrating trauma.

Table 3: Comparison between blunt and penetrating trauma

Characteristics	Blunt trauma (n=30)	Penetrating trauma (N=4)
Age, median (range)	35 (20-65)	28 (22-56)
Gender		
Male	27	4
ISS, median (range)	33 (13-66)	17 (16-34)
Ventilation	8	0
GCS, median (range)	15 (4-15)	15 (In all four patients)
Comorbidities	2HPT/DM, 1HPT, 2Other	1PTB
ICU stay, mean \pm SD	8 (\pm 7.0)	2 (\pm 5)
Renal failure	1	0
Extent of aortic injury		
Grade I: intimal tear	0/30 (0.0%)	1/4 (25.0%)
Grade II: intramural hematoma	6/30 (20.0%)	2/4 (50.0%)
Grade III: pseudo-aneurysm	21/30 (70.0%)	1/4 (25.0%)
Grade IV: free rupture	3/30 (10.0%)	0/4 (0.0%)
Day of TEVAR, median (range)	2.0 (0-20)	13.5 (4-67)
Primary end points		
30day mortality	2/30 (6.7%)	0/4
Overall mortality	4/30 (13.3%)	0/4
Secondary end points(overall)		
Procedure related	13/30 (43.3%)	2/4 (50.0%)
Stent graft related	2/30 (6.7%)	0/4 (0.0%)
Technical success	28/30 (93.3%)	4/4 (100.0%)
Re-intervention rate	2/30 (6.7%)	0/4 (0.0%)

3.4 Imaging

On chest x-ray imaging 22 patients had a widened mediastinum and 12 patients had a normal looking mediastinum. The commonest aortic pathology was a grade III aortic injury (64.7%) followed by grade II aortic injuries (23.5%). Only one patient (2.9%) had a grade I aortic injury and three patients (8.8%) had grade IV aortic injuries. We found that 82.4% of our study population had a Type 1 arch on CTA imaging. We found this to be very deceptive during catheter angiogram where young aortic arches were found to be more angulated than expected resulting in challenging deployment of the aortic stentgraft during TEVAR. Eighty-two percent (28/34) of our patients had a normal aortic arch and supra-aortic vessel configuration. The commonest arch anomaly was a bovine arch (5/34 patients). Two patients had a left vertebral artery arising from the aortic arch between the origins of the left CCA and the left SCA. One patient had a bovine anomaly associated with an aortic origin of the left vertebral artery. (Table 4)

Table 4: Injury proportions grouped according to different classification schemes

CLASSIFICATION ACCORDING TO MECHANISM OF INJURY	COUNT	PERCENT (%)
Blunt Trauma	30	88.2
Motor-Vehicular Accidents (MVA)	28	
Fall	2	
Penetrating Trauma	4	11.8
Gunshot injuries	3	
Iatrogenic Penetrating injuries	1	
CLASSIFICATION SCHEME ACCORDING TO INJURY SEVERITY		
Grade I: intimal tear	1	2.9
Grade II: intramural haematoma	8	23.5
Grade III: pseudo-aneurysm	22	64.7
Grade IV: free rupture	3	8.8
ANATOMICAL RADIOLOGICAL CLASSIFICATION SCHEMES		
Arch Types		
Type 1	28	82.4
Type 2	4	11.8
Type 3	2	5.8
Arch Anomalies		
Bovine arch	3	8.8
Vertebral artery off the arch	2	5.9
Bovine arch and left vertebral artery off the arch	1	2.9

Extent of overall injuries

Assigned ISS

Mean ± SD

34.0 ± 14.9

Median (range)

31(13-66)

3.5 Time to TEVAR

Our protocol consisted of initial stabilization, blood pressure control, anti-impulse therapy where appropriate and treatment of associated injuries followed by delayed repair. This allowed for other

life-threatening injuries to be addressed first. No patient died secondary to aortic rupture while awaiting a TEVAR.

3.6 Procedure

All TEVAR procedures were performed under general anaesthesia using a vascular C-arm in the operating room (OR). The average length of operation was 323 minutes (Range: 85 – 700 minutes). Access was generally obtained via the femoral approach (groin cut-down with a contra-lateral femoral access sheath for imaging). Systemic heparinization was used in 82.4% (28/34) of patients prior to the deployment of the stent graft. These patients did not have any compelling contra-indication to systemic anti-coagulation. The left subclavian artery was intentionally covered in 47.0% of patients (16/34), with complete coverage in 23.5% (8/34). Only two (2/16), with intentional coverage of the LSCA had hypoplastic right vertebral arteries requiring LSCA revascularization. Four (4/16) had anomalous arch configuration, three with bovine arch and left vertebral artery coming off the arch and one with an isolated vertebral artery coming off the arch. None of these patients required revascularization. Two patients had a left carotid – LSCA bypass, both these patients had their left SCA intentionally covered. Three patients had a hybrid arch procedure: right common carotid- left common carotid bypass and a left common carotid-LSCA bypass. The proximal stump of the left CCA was ligated in these cases. Cases requiring a left CCA – LSCA bypass generally had an Amplatzer embolic plug deployed in the proximal LSCA close to the aortic arch.

Seventy percent (24/34) of the thoracic aortic devices were 26 mm or less in diameter. Thirty-two (94.1%) of the TEVAR procedures were technically successful. One patient had a small type II endo-leak via the left SCA. This was addressed immediately with a left SCA plug. One patient had an inner curve mal-apposition of the aortic stentgraft (bird-beaking). Eight patients had an

additional vascular procedure. Table 5. The mean hospital stay was 23 ± 14.5 days (Range: 7 – 65 days). The mean ICU stay was 7 days (Range 0- 28 days)

Table 5: Additional vascular procedures

Procedure	Left common carotid -LSCA bypass (N=2)	Right CCA-left CCA + left CCA -LSCA bypass (N=3)	IVC filter N=2
LSCA	Intentionally covered both patients	2 not covered 1 intentionally covered	

3.7 Primary end points

The 30- day mortality rate was 5.8% (2 patients), all related to fatal major strokes. One of these strokes was secondary to a blunt carotid dissection that was related to trauma. One patient had an uneventful early post-operative course but developed a fatal major stroke on day 15 post TEVAR. Non-of these strokes were related technically to the TEVAR procedure. The overall mortality rate was 11.8% (4/34): three deaths were secondary to fatal strokes and one death was secondary to pulmonary complications.

Early deaths

Patient #21: 30year old male. Previously healthy. Unrestrained MVA passenger. On arrival GCS- 15/15, with an injury severity score (ISS) of 31. No focal neurological deficit. No carotid bruits. CXR – widening of mediastinum (figure 3). CTA- Pseudo-aneurysm (figure 4). TEVAR done on

Day 4 of admission. Access through the common femoral artery (CFA). LSCA not covered. With good technical success. Length of surgery 320mins.

Post-operative course:

- Day 1 in ICU- doing well with no immediate complications
- Day 2 -discharged from ICU
- Day 3- stable in the ward
- Day 4 – suffered a massive stroke and died.

Post mortem- blunt left carotid artery dissection with a fatal CVA.



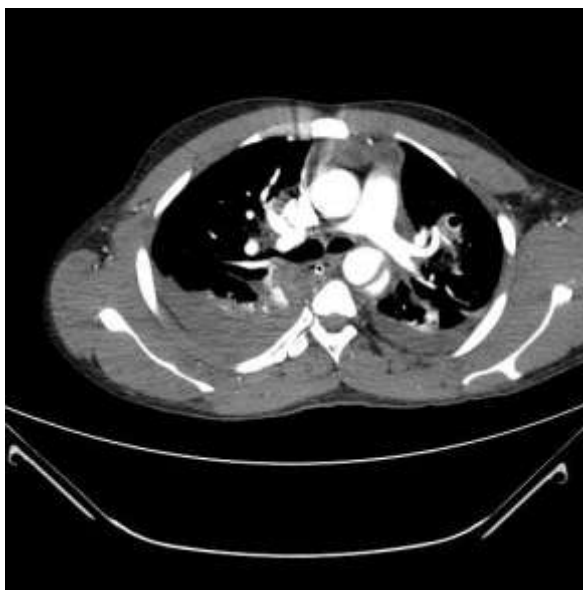
Figure 3: initial CXR showing widened mediastinum



(a)



(b)



(c)

Figure 4 (a,b,c): CTA showing grade IV aortic injury (patient #21)



Figure 5: day 1 post TEVAR – stent graft in place (patient #21)

Patient #14: 37-year-old male. Background of hypertension. MVA unrestrained passenger. On arrival GCS -15/15, ISS-29. Widened mediastinum on CXR. CTA showed anatomical class 3 aortic injury. TEVAR done day 5 of admission. Access through the common femoral artery (CFA). LSCA not covered. With good technical success. Length of surgery 270mins

No available images

Post-operative course was relatively unremarkable for a trauma patient.

- Fatal CVA –day 15 (post mortem report not available)

3.8 Secondary end points

There was one recorded common femoral artery dissection. This was identified and repaired at the time of the TEVAR procedure. Six patients developed pneumonia. One patient developed renal failure requiring dialysis. Two patients developed groin wound infection. One patient developed a urinary tract infection. Three patients developed a stroke while in the intensive care unit. Two of the three were fatal strokes. One patient had a confirmed deep venous thrombosis. One patient developed a pulmonary embolism. One patient post TEVAR required a thoracotomy for evacuation of a massive mediastinal haematoma during the first 30 days. This patient had a persistent left main bronchus compression and failure to wean off the ventilator.

Surveillance imaging was performed at 1 month; 6monthly then annually post-TEVAR and reviewed. One patient had “bird-beaking”, without stentgraft compression, after deployment which was managed expectantly.

A total of 28 patients (82.36%) availed themselves for late follow-up. The average duration of follow-up was 25±23 months (Range: 12 – 96 months). Six patients were lost to follow-up. One patient presented a few months later with a saccular aneurysm at the proximal landing zone extending into the distal arch. This patient had significant crowding of the supra-aortic vessels. A hybrid arch procedure was performed, involving total arch debranching and translocation of the vessels to the ascending aorta with retrograde extension of the aortic stentgraft. The patient developed a major post-operative stroke and demised. Following this case, we currently routinely occlude the proximal LSCA with an Amplatzer plug when we revascularize the LSCA.

No further device related complications (stent graft migration, oesophageal or mediastinal erosion, stentgraft sepsis, stentgraft collapse or compression, stent fractures, etc.) was documented on

follow-up in the remaining patients. Four patients died on late follow-up. Table 6 summarizes the study end points.

Table 6: Study end points

Primary end points	
30day mortality	2/34 (5.8%)
Overall mortality	4/34 (11.7%)
Secondary end points	
Early outcomes (30-day results)	
Systemic complications (pneumonia 6; renal failure 1; wound sepsis 2; urinary tract infection 1; DVT 1; pulmonary embolism 1)	12/34 (35.3%)
Procedure related	3/34 (8.8%)
Technical success	32/34 (94.1%)
Late complications (>30-day results)	
Clinical outcomes	1 arm claudication
Technical success	32/34 (94.1%)
Stent graft related complications	1 saccular aneurysm at proximal landing zone
Re-operations	2/34 (5.8%)

Table 7: Comparison of survivors and non-survivors

Characteristics	Survivors (n=30)	Non-survivors (N=4)
Age, median (range)	34 (20-65)	32.5 (27-56)
Gender		
Male	27	4
ISS, median (range)	33 (13-66)	25 (16-31)
Ventilation	7	1
GCS, median (range)	15 (4-15)	15 (9-15)
Comorbidities	2HPT/DM, 1PTB, 2Other	1HPT
ICU stay, mean \pm SD	7 (7.5)	6 (\pm 6.9)
Renal failure	0	1
Day of TEVAR, median (range)	2.5 (0-67)	3.5 (2-5)
LSCA covered	14	0
LCCA covered	0	0
Inner-curve mal-apposition of TEVAR device	1	1
stentgraft collapse / compression	0	0
Leg ischemia	0	0

3.9 Neurologic outcomes

Upon admission, none of our patients had neurologic deficit attributable to associated head injury. Four patients presented with trauma-related paraplegia, 3 of these patients had paraplegia secondary to spinal cord injury and one patient had established lumbosacral radiculopathy (HIV – related). No patient had a pre-interventional history of a stroke. There were no cases of spinal cord ischemia or strokes related to the TEVAR procedure.

Chapter Four

4.0 Discussion

Nearly twenty-five years ago, Volodos et al. (9) performed the first thoracic endovascular aortic repair (TEVAR). The same year Parodi et al. (23) performed the first endovascular aortic repair (EVAR). It was in 1999 when the U.S Food and Drug Administration (FDA) approved the use of endografts for abdominal aortic aneurysm repair and EVAR was rapidly adopted. However, it was not until 2005 when the FDA also approved the use of endografts for descending thoracic endovascular repair (TEVAR)

Since the introduction of commercially available aortic stentgrafts, TEVAR has been increasingly used as a primary treatment option for BTAI. There is little doubt that TEVAR offers several advantages over open surgical repair, including minimally-invasive peripheral access obviating thoracotomy; avoidance of single-lung ventilation, avoidance of cardiac bypass and aortic cross-clamping and avoiding interfering with the mediastinal hematoma (3). In the 2008 AAST-2 study, TEVAR was associated with significantly lower procedural and post-operative morbidity and mortality compared to open repair (12).

We retrospectively looked at the outcomes of TEVAR in TTAI (both blunt and penetrating) at a single center. Our 30-day all-cause mortality was 5.8%, better than the 8% reported in the RESCUE trial which was designed as a descriptive study focused on safety outcomes. The RESCUE trial prospectively investigated the outcomes of TEVAR in multiple centers using the Medtronic Valiant Captiva stent graft (Medtronic, Inc.) in patients with BTAI and reported a 30-day all-cause mortality of 8.0% and 12.0% at 1 year (13). It is noteworthy that the RESCUE trial investigators were selected from high volume centers experienced with TEVAR. Demetriades et.al reported a significant reduction in the early operative mortality rates from 22% with open surgery to 13%

using TEVAR (12). The overall all-cause mortality of 11.8% is reported in our series to date noting that six of our patients were lost to follow up (the regional birth and deaths registry did not record deaths in these 6 patients). Follow up is poor in post trauma patients. A local retrospective study by Pillai et.al, reported 42 survivors after TEVAR, with 19 follow-up CT scans available at 6 months, 6 at 1 year and 2 at 2 years (24).

The secondary end points in this review were the incidence of nonfatal adverse events related to the device, procedure, and re-intervention rates. Delivery and deployment was successful in 94.1% of cases, lower than the 100% technical success reported in the RESCUE trial (13). One patient had bird-beaking after deployment and one had a type I endo-leak managed with a left SCA plug. Forty- four percent (15/34) of patients had systemic and procedure related adverse events, a very high rate compared to that quoted in the literature (13,17). Six of the fifteen patients had pneumonia which was managed medically. The incidence of postoperative atelectasis and pneumonia in patients undergoing non-cavitatory surgery is reported to be 1% (25) but Antonelli et al. (26) documented 33% of trauma patients developed early onset pneumonia. Patients' HIV status did not seem to influence these septic complications. Only one patient who was HIV positive in our series had pneumonia. All three patients with HIV in our series were on treatment (HAART). The benefit of antiretroviral therapy in HIV positive patients cannot be overemphasized.

Partial or complete coverage of the left subclavian artery was documented in 47.0% (16/34) of our patients. None of these patients developed significant arm ischemia. One patient developed non-disabling left arm claudication and was managed expectantly. This result is in keeping with reports of 41% (24), 58% (13) and 61% (25) of intentional left subclavian artery coverage. There was no reported paraplegia in our patients post TEVAR, which is in keeping with low paraplegia

rates reported in the RESCUE trial. Demetriades et.al also reported a significant reduction in spinal cord injury from 8.7% with open surgery to 1.6% using TEVAR (12)

The Society for Vascular Surgery (SVS) 2011 guidelines suggests expectant management with serial imaging for type I injuries, while types II to IV should be repaired (19). Only one patient (2.9%) with grade 1 aortic injury had TEVAR at our institution. A 23year old male with transthoracic GSW and a grade I aortic dissection of the descending thoracic aorta on CTA imaging. The decision was made by the operating vascular surgeon to perform a TEVAR. An intimal flap was identified with the use of intravascular ultrasound (IVUS). The RESCUE trial on the other hand selected 18% of patients with grade 1 aortic injuries for TEVAR (13). Lee et al. (19) reported that 21% of BTAI patients with minimal aortic injuries undergo TEVAR despite these clinical practice guidelines.

Patients who had penetrating trauma, in our series, had more favourable results with no deaths reported. This is probably due to natural selection as these patients were younger, had low ISS scores and lower grades of aortic injuries associated with penetrating trauma. The time to TEVAR in this group of patients was longer, 13.5 days (range 4-67 days). Pacini et al. evaluated the timing of aortic repair and found improved survival among patients undergoing delayed repair (27).

The limitations of this study include its retrospective design, the period of follow-up to date and loss of follow up. Missing data is also a major issue.

Chapter Five

5.0 Conclusion and Recommendations

TEVAR after TAI is associated with significantly lower procedural and post-operative mortality. The 30 day and overall mortality after TEVAR in our unit, despite resource constraints in an African setting, is comparable to international standards. The morbidity associated with TEVAR is higher in our institution mostly due to pulmonary complications. Even though our sample size for PTAI was very small and no conclusion can be drawn from this, TEVAR has low peri-procedural adverse events and is safe in selected patients. From this audit, we recommend TEVAR for both blunt and penetrating thoracic aortic injury.

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Appendices

Appendix A: Study Protocol

Title:

OUTCOMES AFTER THORACIC ENDOVASCULAR ANEURYSM REPAIR (TEVAR) IN PATIENTS WITH TRAUMATIC THORACIC AORTIC INJURIES (TTAI) - A single centre retrospective review

BACKGROUND

Blunt traumatic thoracic aortic injury (BTAI) caused by motor vehicle accident and blunt thoracic trauma is a surgical emergency with high mortality rates. Most patients do not survive long enough to reach the hospital. Two main treatment options for BTAI are open surgery and thoracic endovascular repair (TEVAR). Penetrating thoracic aortic injuries have a higher mortality than blunt trauma, with patients reaching the hospital in extremes. Most will require early intervention with a mortality as high as 80%. TEVAR has been accepted as the standard of care for thoracic aortic injuries (TAI) at many centers, primarily due to the convincing evidence of lower mortality and morbidity in comparison to open surgery ⁽¹⁾⁽²⁾⁽³⁾⁽⁴⁾⁽⁵⁾⁽⁶⁾. The RESCUE trial was a prospective, non-randomized, multi-centre device trial that enrolled 50 patients with BTAI and reported one year follow-up data. Major procedural and long-term device complications were infrequent, and no patients required aortic re-intervention or had neurologic complications. Overall mortality at 30 days and 1 year was 8 and 12 %, respectively; two deaths (4 %) were adjudicated as aortic-related ⁷.

TEVAR was only adopted in Groote Schuur Hospital (GSH) in 2009.

AIM

The aim of this study is to evaluate the outcomes (early and intermediate) of TEVAR after TTAI (both blunt and penetrating), and to compare to international standards

METHODS

Working hypothesis and study objectives:

Our hypothesis is that TEVAR after TAI is associated with significantly lower procedural and post-operative morbidity and mortality. We postulated that the 30-day mortality after TEVAR will be comparable to international standards.

The study specific objectives are to look at the outcomes after TEVAR in patients with TTAI

Types of outcome measures

➤ Primary outcomes

- 30 day and overall mortality

➤ Secondary outcomes

- Procedure related (endo-leak, pseudo-aneurysm formation, paraplegia, cerebrovascular accident, recurrent laryngeal nerve injury, acute renal failure, conversion to open repair, pulmonary complications)
- Device related (stent configuration and wall apposition-arch, stent fracture, stent migration, endo-leak; stent-graft sepsis);
- Reintervention rates

Study design

Single center Retrospective study in the Vascular Unit, Groote Schuur Hospital

Selection of patients and data collection

All the endovascular repairs of the TAI performed at our institution between January 2009 and December 2015 will be reviewed. Data will be reviewed from trauma registry, vascular registry and theatre registry.

The medical records of the patients will be identified and reviewed with respect to

- Baseline demographics, mechanism of injury, haemodynamic status of the patient, Glasgow Coma Scale(GCS), concurrent injuries with assessment of the Injury Severity Score (ISS), time to surgery
- Operative variables including the proximal landing zone, left subclavian artery status, access vessels, technical success
- Imaging studies including CXR (erect AP film) for widening of mediastinum (>8cm), CT scan and intraoperative angiogram for anatomical grading of injuries, arch anomalies, arch configuration/type.

Post-operative events and complications will be recorded.

- Procedure-related (endo-leak, pseudo-aneurysm formation, paraplegia, cerebrovascular accident, recurrent laryngeal nerve injury, acute renal failure, conversion to open repair, pulmonary complications)
- Device-related (stent configuration and wall apposition-arch, stent fracture, stent migration, endoleak; stentgraft sepsis)

Any readmissions, reoperations and mortality will also be audited.

Postoperative CT scans will be reviewed and complications on follow up will also be audited

Inclusion Criteria

- Patients with traumatic aortic injury confirmed on CT scan on admission who were treated with TEVAR
- >18 years
- period February 2009 to January 2016

Exclusion Criteria

- Open repairs

Statistical methods

The base proportion used is the international post-operative outcome (30-day and overall mortality of 8 and 12% respectively). Standard statistical systems will be utilized to analyze accumulated data.

Risks and benefits to patients

There will be no risks involved

We believe that this study could produce data and stimulate further research that may be of real benefit to patients including long term outcomes, durability of stent grafts, and the use of stent grafts in the younger population, CT angiography surveillance and exposure to radiation.

Data Safety and Reimbursement

All patients' names as well as their folder numbers will be removed from the data stream. The study adheres to the Declaration of the Helsinki 2013. There will be no reimbursement.

Timeline /Schedule

Time period	
July - October 2016	Literature review
November- January 2017	Data collection
February- April 2017	Results and write up
May 2017	Submission of 1 st draft

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Appendix B: Ethical approval letter from University of Cape Town



UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee



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13 September 2016

HREC REF: 635/2016

Dr NG Naidoo
Vascular Surgery
345, Old Main Building

Dear Dr Naidoo

PROJECT TITLE: OUTCOMES AFTER THORACIC ENDOVASCULAR ANEURYSM REPAIR (TEVAR) IN PATIENTS WITH TRAUMA-RELATED THORACIC AORTIC INJURIES (MMed candidate- Dr N Chinyepi)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th September 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.

(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval before the research may occur.

We acknowledge that the student Dr N Chinyepi will be involved in this study.

Please quote the HREC REF in all your correspondence.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

HREC 635/2016

Appendix C: Data collection sheet

Patient Number:

Demographics

Gender: male female:

Age: _____

Comorbidities:

Medications:

HIV: unknown__positive__negative__

HAART: yes__no__

Smoker: yes__no__

Previous vascular surgery: yes__no__if yes_____

Initial assessment

GCS: _____

Intubated: yes, at scene____yes, in hospital____no____

SBP:_____ Pulse: _____

Ph:_____Lactate:_____Creatinine:_____hb: _____

Injury circumstances

Date of injury: / / _____

Mechanism of injury: blunt:_____penetrating: _____

Circumstances: MVA____Fall____motorcycle____Stab____GSW____other _____

Restraints: yes____no____if yes type _____

ISS: _____

Imaging

CXR: widened mediastinum yes__no__

CXR Index: _____

Anatomical classification: grade I__grade II__grade III__grade IV__

Arch type: type 1 ___ type 2 ___ type 3 ___

Arch anomalies: _____

Intra- operative data

Day of TEVAR: ___/___/___

ASA: ___

Access vessels: _____

Device size: ___

Landing zone: _____

LSCA covered: yes ___ no ___

LSCA plugged: yes ___ no ___

Hybrid procedure: yes ___ no ___ if yes additional vascular procedure _____

Heparin used: yes ___ no ___

Length of surgery: _____

Other surgery done same setting: _____

Technical success: yes ___ no ___

Post-op

ICU stay: ___

Hospital stay: ___

Mortality

30-day: yes ___ no ___

Cause of mortality: _____

Overall: yes ___ no ___

Cause of mortality: _____

Complications

Procedure related:

Pneumonia ___

Renal failure ___ Dialysis ___

MI ___ VTE ___ UTI ___ Bacteraemia ___ Wound complications ___

Paraplegia ___ level ___

Other: _____

Stent graft related:

Endo-leak __

Endo-tension__

Other: _____

Re-intervention: _____

Follow-up imaging

At 1 month:

At 6 months:

At 1 year:

Yearly after:

Late complications:

Follow up lost: yes__no__

If yes after how long_____months