SHORT AND MID-TERM RESULTS OF STATE-OF-THE-ART ENDOVASCULAR AND HYBRID TECHNIQUES FOR TREATMENT OF THORACIC AORTIC PATHOLOGIES

THESIS

Submitted in partial fulfilment

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of the institute

By

Dr SIDHARTH VISWANATHAN

MCh Vascular Surgery Resident

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DIVISION OF VASCULAR SURGERY, DEPARTMENT OF CVTS

SREE CHITRA TIRUNAL INSTITUTE FORMEDICAL SCIENCES AND TECHNOLOGY

Thiruvananthapuram – 695011, India

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Known for their munificence, the royal family of Travancore considered themselves ‘dasas’ (servants) of Lord Padmanabha, the reigning deity of Travancore. Interestingly, they wore turban instead of a crown as a mark of respect to the Lord. Their philanthropy finds expression in their countless contributions to the country, then and now.

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10/10/2014 ***Dr Sidharth Viswanathan***

Thiruvananthapuram

DECLARATION

I, **Sidharth Viswanathan**, hereby declare that the project in this book was undertaken by me under the supervision of Prof M Unnikrishnan MCh, Professor and Head of Division of Vascular Surgery, Dept of CVTS, and Prof TR Kapilamoorthy, Head of Dept of Imaging Sciences and Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram

Sidharth Viswanathan

Date: Resident, Vascular Surgery

Forwarded

The candidate, **Sidharth Viswanathan**, had carried out the minimum required work in this project

Prof Unnikrishnan M

Head, Division of Vascular Surgery

Dept of CVTS

SCTIMST, Thiruvananthapuram

Prof Jayakumar K

Head of the Department

Dept of CVTS

SCTIMST,Thiruvananthapuram

CERTIFICATE

Certified that this thesis entitled "Short and Mid-term Results of State-of-the-art Endovascular and Hybrid Techniques for Treatment of Thoracic Aortic Pathologies" is the bonafide work of ***Dr Sidharth Viswanathan,*** *MCh Vascular Surgery Resident, done under our supervision at Division of Vascular Surgery - Department of CVTS, and Department of Imaging Sciences and Interventional Radiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram.*

Prof Unnikrishnan M

Head, Division of Vascular Surgery, Dept of CVTS

SCTIMST, Thiruvananthapuram

Prof Kapilamoorthy TR

Head, Dept of Imaging Sciences and Interventional Radiology

SCTIMST, Thiruvananthapuram

Prof Jayakumar K

Head, Dept of CVTS

SCTIMST, Thiruvananthapuram

TITLE

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INTRODUCTION

Diseases of the arch and descending thoracic aorta that include aneurysms, dissections and traumatic injuries require intervention in a timely basis to abate fatal rupture. The conventional open surgical procedures like inclusion graft replacement and elephant trunk procedures require cardio-pulmonary bypass (CPB), often with deep hypothermic circulatory arrest (DHCA) or at times distal aortic perfusion strategies that substantially increase the morbidity & mortality in this group of patients who are by and large of advanced age with high morbidity index

TEVAR is fast emerging as front-line and less invasive endovascular option in the thoracic aortic domain with drastically reduced morbidity and mortality.

Initially designed for endovascular repair of thoracic aortic aneurysms, it is also being widely applied for treatment of aortic dissections and blunt aortic injury. This minimally invasive approach has particularly provided dramatic results in the setting of ruptured pathologies for the salvage of these unstable patients often on the verge of fatal end.

AIMS OF THE STUDY

1. To analyse the peri-operative and short term results regarding the safety and efficacy of state-of-the-art Thoracic endovascular aortic repair (TEVAR) for thoracic aortic pathologies in both elective and emergent settings at our institute

2. To determine the mid-term survival and positive aortic remodelling on imaging after TEVAR

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REVIEW OF LITERATURE

Arterial aneurysms have been known to physicians from time immemorial. The Ebers papyrus (2000 BC) mentions about aneurysms. Galen (131-200 AD) also described aneurysms[1]. The ancient Indian surgeon of repute Sushruta in his book *Sushruta Samhita* describes vascular malformations including aneurysms (Chapter 11, Nidana Stana, Slokas 8 and 9).[2] The earliest report of surgery for an aneurysm is from the 3rd century, and numerous surgeons thereafter have reported performing ligation of feeder and run-off vessels from aneurysms in the 17th and 18th centuries.

With John Hunter (1728-1793), surgery began to emerge as a scientific discipline on the basis of anatomy and physiology. He is well known for successful ligation of superficial femoral artery in the thigh in a anatomical canal that now bears his name to treat a popliteal aneurysm. Astley Cooper (1768-1841) was the first to ligate the abdominal aortic for a ruptured aortic aneurysm. Rudolph Matas, in 1888, performed the first definite repair of a brachial artery aneurysm by endoaneurysmorrhaphy[3], a technique that is still in vogue for aortic aneurysms. It was Charles Dubost in 1951 who repaired an abdominal aortic aneurysm by replacing the segment with a thoracic aortic homograft harvested from a recently deceased 20-year-old patient. This patient lived for 8 years post-operatively.[4] In 1954, Blakemore and Voorhees published their series of 17 aortic and 1 popliteal aneurysm repair with Vinyon'N' cloth prosthesis.[5] This launched the modern age of synthetic replacement of aneurysms. The following year, Cooley and DeBakey presented their work on repair of thoracic aneurysms with homografts.[6]

Thoracic aneurysms including the arch and thoraco-abdominal domains had presented a challenge for many years. DeBakey and Cooley reported the first case of a successful resection and grafting of a fusiform thoracic aneurysm in 1953. Since then all sections of the thoracic aorta from arch to the diaphragm have been resected successfully and replaced by grafts of various sorts.[7] In 1974, Stanley Crawford reported his experience with inclusion technique with reattachment of visceral branches to an opening created in the graft wall.[8] Operations on the formidable domain of the aortic arch was further refined by the adoption of Deep hypothermic circulatory arrest (DHCA) by Randall Griepp in 1975[9] and the elephant trunk grafting (ETG) technique described by Hans Borst in 1983.[10]

Shortly after Parodi and colleagues' first report of endovascular abdominal aortic aneurysm repair (EVAR),[11]Dake and coworkers introduced the same concept of stent-graft exclusion for the thoracic aorta in December 1994.[12] The stent-grafts were custom-designed for each patient and were constructed of self-expanding stainless steel stents covered with woven Dacron grafts. Ten years later, thoracic endovascular aortic repair (TEVAR) for descending thoracic aortic aneurysms (DTAAs) became a mainstream technology with the release of commercial endografts starting with the TAG device (W. L. Gore and Associates, Flagstaff, AZ) in early 2005. TEVAR is fast emerging as a less invasive endovascular and hence first line option in the thoracic aortic domain with drastically reduced morbidity and mortality. The most commonly used stent-grafts for TEVAR that have been commercially available in India are the Medtronic Valiant Thoracic device, the Cook Zenith TX2 TAA device and the Gore TAG device (Figure 1).

All have shown equally good results and the choice of device is primarily operator/institutional preference.

Figure 1. Various commercially available endoprostheses for TEVAR

The main considerations in the preferential choice of TEVAR over open repair are anatomic. An appropriate landing zone should be available both proximally and distally to allow sealing and exclusion of the aneurysm from the circulation, as well as appropriately sized arterial access to deliver the stent-graft to its desired location. Anatomy, however, is not the only overriding parameter in treatment planning; age and risk assessment also play a significant role in selecting the appropriate treatment modality.

In the presence of suitable anatomy, TEVAR seems to be the logical choice in most patients because of its lower morbidity and mortality. However, even in these patients, the decision should be tempered by the paucity of extended follow-up data for TEVAR and the requirement for lifelong clinical and imaging follow-up. Yet for high-risk individuals, the decision is simple given that clinical results clearly favour endovascular approach.

Multiple comparative studies have shown a significantly larger mortality benefit with TEVAR as compared to open surgery in thoracic aortic aneurysms (2% versus 12% for the TAG study, 1.9% versus 5.7% for the STARZ trial, and 2.1% versus 7.9% for the VALOR trial).[13-16]

In the setting of Type B aortic dissections (TBAD), intervention is warranted in acute setting when patient presents with malperfusion, intractable pain, uncontrolled hypertension, acute expansion or rupture. Indications in the chronic phase include aneurismal degeneration or the rare instances of malperfusion and rupture. Open surgical correction of type B aortic dissection carries a very high mortality risk ranging from 6% to 69% in several large series and higher still in acute setting.[17,18] Stent-graft repair of the aortic entry tear potentially provides the means to accomplish the short- and long-term goals of central aortic repair of the entry tear while obviating the substantial morbidity associated with conventional surgical repair.

Patients who present with ruptured aortic pathologies and traumatic aortic injuries are a particularly high risk group with a surgery-related mortality rate of 30-40%. In this patient subset also TEVAR is a life-saving treatment modality without adding significant morbidity to this unstable patient group.[19-20]

Adequate fixation of a stent-graft to both proximal and distal landing zones is essential for successful outcome of TEVAR. To standardize comparisons, Ishimaru's group classified the thoracic aorta into five landing zones - Zones 0 to 4[21](Figure 2). Hybrid procedures involving debranching the arch can be performed with acceptable risks to extend the therapeutic domain of TEVAR to the region of aortic arch. To treat a disease involving the aortic arch with a stent-graft it is necessary to “debranch” the great vessels that would need to be covered for effective proximal sealing of the endograft.

Figure 2. Ishimaru Zones for TEVAR

Advancement in endovascular technology has made total endovascular solutions in the repair of arch pathologies a reality. These predominantly include the custom-made or physician-modified fenestrated devices and the branched stent-grafts. Although it carries the advantage of complete avoidance of open surgical procedures, the complicated technical steps involved in executing such repairs and the potential risk of jeopardising the branch placement with attendant risk of stroke along with exorbitant cost of these devices pose a major trade-off.Although scrutiny of the hybrid approach vis-à-vis total endovascular repair has not been conclusively brought out[22,23], the potential of hybrid techniques to reduce the complexity of endovascular repair with more durable results and at a lesser cost to our patients, makes it a more attractive approach.[24,25]

There are several options for revascularization, depending on which great vessels need to be covered. Zone 0 landing mandated total arch debranching from ascending-aorta to both carotids. Hemi-arch debranching can be accomplished by an extra-anatomical carotid-carotid bypass in the neck for Zone 1 proximal landing. Coverage of Zone 2 has been combined with left subclavian transposition or bypass by some authors, while others have indicated that non-revascularisation of left subclavian artery produces no adverse consequences.[26]

Being a relatively new technology with mass utilization only in last 2 decades, data on long-term results are lacking. With growing clinical experience in the application of TEVAR for pathologies of the aortic arch and descending thoracic aorta, long-term efficacy and durability will be understood and newer insights on factors influencing these outcomes can help tailor modifications in the planning and operative technique to achieve better results with reduced stress for the patient.

MATERIALS AND METHODS

Over a period of 7 years from September 2007 to August 2014, 68 patients who underwent endovascular repair of thoracic aortic pathologies were included in this retrospective study with a minimum follow-up of 1 month. Pathologies treated included thoracic aortic aneurysms, aortic dissections and traumatic thoracic aortic injuries, both in elective and emergent setting. Open repair of aortic pathologies and EVAR for abdominal aortic aneurysms were excluded from the study. Approval was obtained from the Technical Advisory Committee (TAC) and Institutional Ethics Committee (IEC) for the conduct of the study.

Demographics, preoperative, perioperative and postoperative data and follow-up details were recorded in a structured data collection sheet after reviewing patient records and institutional electronic medical records. Patients undergoing elective repair underwent diagnostic work-up with chest radiograph, computed tomography (CT) angiography and work up for fitness included, complete hemogram, renal and liver functions test, coagulation profile, pulmonary function test and basic cardiac work-up with electrocardiogram (ECG) and echocardiogram. Routine testing was abbreviated in patients who presented in rupture for executing expeditious management

Renal insufficiency was defined as serum creatinine greater than or equal to 1.5mg/dl. Coronary artery disease was defined as history of acute coronary syndrome, prior coronary angioplasty or CABG or indirect evidence of myocardial ischemic damage in ECG or Echo

Operative planning

All patients underwent CT angiography, most of which were done using the institute's 256-slice Philips Multidetector CT scanner. Axial, multiplanar reconstruction (MPR) and Volume-rendered technology (VRT) images were examined by the radiologists and exact measurements of length and maximum diameter of the aortic aneurysm, site of entry tear/rent and luminal characteristics in aortic dissection and traumatic pathologies were recorded as well as the length and diameter of available landing zones for selecting the appropriate size of aortic stent-graft, considering an oversizing of 20% for aneurismal pathologies and 10% for dissections and trauma. Careful measurements of the ilio-femoral vessels were also taken to ensure adequate size, absence of undue tortuosity or calcification for smooth and hassle-free passage of device (often 22-24Fr) into the aorta.

Interventional procedure

TEVAR was done in the endovascular suite (DSA lab) under fluoroscopic guidance. Procedure was done under GA or LA with conscious sedation after securing venous access including a central line, arterial line for continuous blood pressure (BP) monitoring and urinary catheterisation of assessment of urine output. Lumbar CSF drainage catheters were placed in selected patients who were at high-risk for spinal cord dysfunction due to extent/location of thoracic coverage by endograft particularly in patients who present in hemodynamic shock, history of prior abdominal aortic repair or presence of occluded hypogastric arteries, all of which could lead to jeopardized spinal cord collateral blood supply.

A standard surgical exposure of common femoral artery (CFA) is initially performed. CFA was punctured under vision and 6Fr vascular sheath placed. After advancing 0.035-inch hydrophilic guidewire to the proximal aorta beyond the pathological domain, a marker pigtail catheter is placed and aortogram obtained using pressure injector using diluted Visipaque contrast to define the pathoanatomy and identify appropriate landmarks for executing the endo-repair. Brachial access was taken occasionally, particularly in dissection cases to ensure true lumen access and for obtaining intra-operative injections.

After confirming the optimal landing sites, the hydrophilic guidewire is exchanged with superstiff Archer or Lunderquist guidewire. The stent-graftof appropriate size and length is taken and prepared by flushing through its ports. The stent-graft delivery system was introduced over the wire through the femoral artery by extending arteriotomy while the tapered tip (nosecone) engages the puncture site. The stent-graft is advanced with a controlled rotational and pushing motion, avoiding excessive force

An optimal proximal landing zone (PLZ) of 2-3cm and with a horizontal lie particularly in the arch of aorta is ensured and the stent-graft system is positioned appropriately. It is suggested to position the device a few millimetres proximal to the target landing zone, as the stent-graft may move distally when graft cover is initially pulled back and from the ‘wind-sock’ effect of the aortic jet of blood with each cardiac systole. The position of stent-graft is confirmed angiographically with proximal markers indicating the top edge of the fabric. While the anaesthesiologist brings down the sysolic arterial pressure to 70-80mmHg using vasodilators (sodium nitroprusside or nitroglycerine), the stent-graft is deployed in a controlled fashion using the standard deployment mechanisms of the delivery system as mentioned in the device's instructions for use (IFU) with tip release completing the deployment sequence. Following that the entire system is now pushed proximally so that the tapered tip and spindle are completely clear of proximal springs. Spindle is recaptured in the tapered tip and nose-cone is retracted into the graft cover under continuous fluoroscopy to ensure that the stent-graft is not inadvertently caught and pulled down. After completion of deployment, ballooning of the proximal and distal ends (and overlapping segments if more than one stent-graft was used) is done to enhance radial sealing by modelling of the covered springs. A check angiogram is taken at end of procedure by reintroducing the pigtail catheter to ensure exclusion of aneurysm, false lumen entry tear or injury site, rule out endoleaks and confirm normal flow in neighbouring aortic branch vessels. On completion, the catheter and guidewire is removed and femoral arteriotomy is closed in a standard manner using 5-0/6-0 polypropylene suture.

Surgical conduit placement

In case when the femoral artery is too accept the 22-24Fr sheath of the device or when intra-operative difficulty innegotiating the system was encountered, an additional 9 or 10mm polyester graft is attached to the common iliac artery or terminal aorta through an extra-peritoneal approach and brought out through femoral wound or separate stab wound to exterior. Graft access is done through a stab graftotomy rather than end of the graft for better hemostatic control. At end of the procedure, graft may be transected with a short stump or converted to ilio-femoral bypass graft in case the ilio-femoral arteries was significantly traumatized.

Hybrid procedures

For optimal proximal sealing in the transverse arch or ascending aorta with adequate proximal landing zone length of 2-3 cm, prior elective 'debranching' and bypass of one or more brachio-cephalic vessels will be necessary preceding TEVAR. Totally cervical approach is employed with extra-anatomical carotid-carotid or carotid-subclavian bypass for Zone1 and Zone2 landing respectively, while Zone0 deployment necessitates bypass inflow from ascending aorta through sternotomy approach by ascending aorto-bicarotid bypass. The surgical debranching procedure and TEVAR are usually staged by 1-2 days for initial physiological and wound stabilisation, unless there is an emergency indication or when a graft conduit has been was required for access.

Carotid-carotid bypass: Bilateral common carotid arteries (CCA) are exposed by a vertical incision anterior to sternomastoid. After deepening the wound through platysma and deep fascia, the carotid sheath is incised and internal jugular vein retracted laterally. CCA is then dissected and looped for adequate distance above the level of superior belly of omohyoid. A tunnel is created in over the trachea within the subfascial plane. After heparinisation, an 8mmpolyester graft is anastomosed end-to-side to both CCAs sequentially, allowing 10-15 minute interval between each carotid clamp. Proximal end of left CCA is ligated.

Carotid-subclavian bypass: A transverse supraclavicular incision is placed and deepened through platysma and deep fascia. Clavicular head of sternomastoid is divided and inferior belly of omohyoid retracted. The carotid sheath is incised and CCA is then dissected and looped. Supraclavicular fat pad is taken off the clavicle and retracted away. Safeguarding the subclavian vein and brachial plexus, the 3rd part of left subclvian artery

(LSA) is dissected and looped. After heparinisation, an 8mm polyester graft is anastomosed end-to-side from left CCA to LSA.

Aorto-bicarotid bypass: Standard median sternotomy is placed. After partially thymic dissected and mobilisation of left innominate vein, pericardium is opened over the proximal ascending aorta and aorta dissected on either side for a side-biting Satinsky/Lemole clamp. Both CCAs are exposed as described earlier. If bypass is planned for LSA, the same may be dissected within the chest or through separate incision in the supraclavicular area as described. After heparinisation, side-biting clamp is placed as low on the ascending aorta as possible to keep the anastomosis maximum proximally so as to permit more proximal landing area for TEVAR. Either an inverted bifurcated 16/8mm pr a 10mm polyester graft is attached to ascending aorta using 4-0 polypropylene with the distal anastomosis on either carotid using a separate 8mm graft to left CCA attached to the side of the 10mm graft anastomosed to right CCA. A separate 8mm graft can be attached to bypass LSA if indicated. The proximal parts of the 3 great vessels is then ligated within the chest.

Management of Left subclavian artery

In patients in whom Zone 0 to Zone 2 proximal landing is required, the subclavian artery is usually intentionally covered without prophylactic revascularisation, considering the abundant collaterals feeding the artery and the reversal of vertrbral artery flow. On the contrary, in selected patients subclavian bypass is undertaken to maintain antegrade subclavian flow if there is high risk for posterior-circulation, spinal cord or upper limb ischemia.

These include:

a) Extensive coverage of DTA (>20cm)

b) Previous abdominal aortic grafting

c) Occluded hypogastric arteries

d) Dominant left vertebral A or left vertrbral A terminating into PICA without basilar A continuity

e) Hypoplastic/absent right vertebral A

f) Anomalous arch origin of left vertebral A

g) Aberrant right subclavian A

h) Patent LIMA bypass graft

i) Functioning left upper limb AV fistula

Complete assessment of cerebral vasculature and posterior circulation in particular is important prior to considering intentional coverage of LSA lest disastrous complications could ensue.

Follow-up protocol

All patient were evaluated for minor/major complications during the procedure and at discharge and within a month CT angiogram was done to assess immediate technical success of endovascular repair and evaluate for presence of endoleaks. Patients are then followed-up at 6 months to 1 year intervals within a repeat CT after 1 year to document positive aortic remodelling and exclude occurrence of late complications like endoleaks or migration. Apart from routine cardiovascular examination, chest radiographs in antero-posterior and lateral projections are taken to visualise the position of stent-graft and rule out gross abnormalities.

Data recording and analysis

Peri-operative, short-term and mid-term events were identified and recorded through review of patient records and the hospital's electronic medical records (EMR).

Additional information about survival and freedom from symptoms and re-interventions was obtained from telephonic and letter communications. Aortic disease related mortality included death from any cause within 30 days of the primary procedure or any secondary intervention. Subset analysis of mortality and complications rates was done (Elective vs Emergency and Hybrid repairs vs TEVAR alone). Categorical variables were investigated using Fisher's exact test and continuous variables using the Student *t* test. Overall survival was analysed using Kaplan-Meier survival estimation and occurrence of complications during follow-up was documented. All statistical analysis was performed using MS Excel and SPSS 17.0, with p value of <0.05 considered significant

Procedural details noted were:

1. Nature of procedure (elective vs emergency)
2. Size and number of aortic stent-grafts used
3. Anaesthesia employed
4. Access vessel

5. Landing zone
6. Intentional coverage of LSA
7. Type of hybrid procedure
8. Time interval between open and endovascular component
9. Use of CSF drainage

Outcomes analysed:

1. Technical success
2. Access related complications
3. Subsystem complications
    a. Cardiac
    b. Respiratory
    c. Renal dysfunction (transient/permanent)
    d. Paraplegia/paraparesis
    e. Visceral ischemia
4. Endoleaks
5. Length of hospital stay
6. 30-day mortality

Follow-up analysis:

1. Survival
2. Aneurysm/endograft related morbidity
3. Positive aortic remodelling and patency on CT
4. Re-interventions

Definitions

Technical success: relates to peri-procedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period. Primary technical successis defined as the successful introduction and deployment of the device in the absence of surgical conversion or procedural mortality, type I or III endoleaks, or graft limb obstruction. A technical success thus implies the following qualifying details:

1. Successful access to the arterial system using a remote site (ie, the femoral, external iliac, common iliac, or brachiocephalic arteries with or without use of a temporary or permanent prosthetic conduit to access these arteries
2. Successful deployment of the endoluminal graft with secure proximal and distal fixation
3. Absence of either a type I or III endoleak
4. Patent endoluminal graft without significant twist
5. Kinks, or obstruction (>30% luminal stenosis or a pressure gradient >10 mm Hg) by intraoperative measurements

Initial or 30-day clinical success encompasses 30-day data. Short-term clinical success includes outcome measures reported within a 30-day to 6-month time frame. Mid-termclinical success refers to all outcome measures that are statistically significant up to 5 years after endograft implantation. Long-term clinical success includes all outcome measures that are statistically significant beyond 5 years.

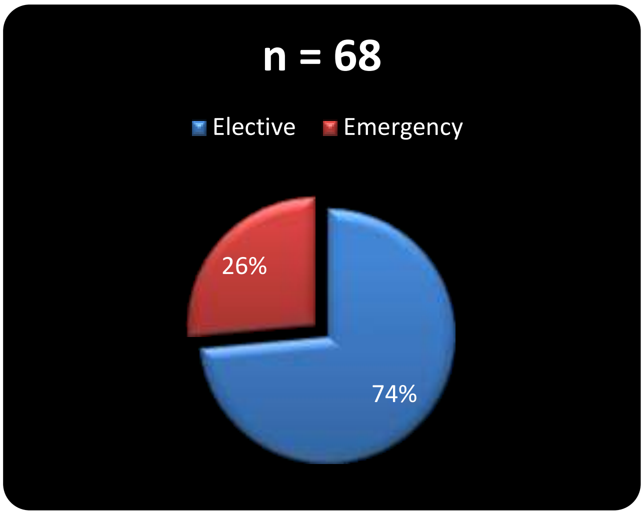
Endoleaks: is defined by the persistence of blood flow outside the lumen of the endoluminal graft but within the aneurysm sac, as determined by an imaging study

<u>Classification of endoleaks:</u>

Type	*Cause of perigraft flow*
I	A: Inadequate seal at proximal end of endograft B: Inadequate seal at distal end of endograft
II	Back-flow from branch vessels without attachment site connection
III	A: Modular disconnection B: Fabric disruption
IV	Flow from porous fabric (<30 days of graft placement)
V (Endotension)	Aneurysm expansion without detectable flow

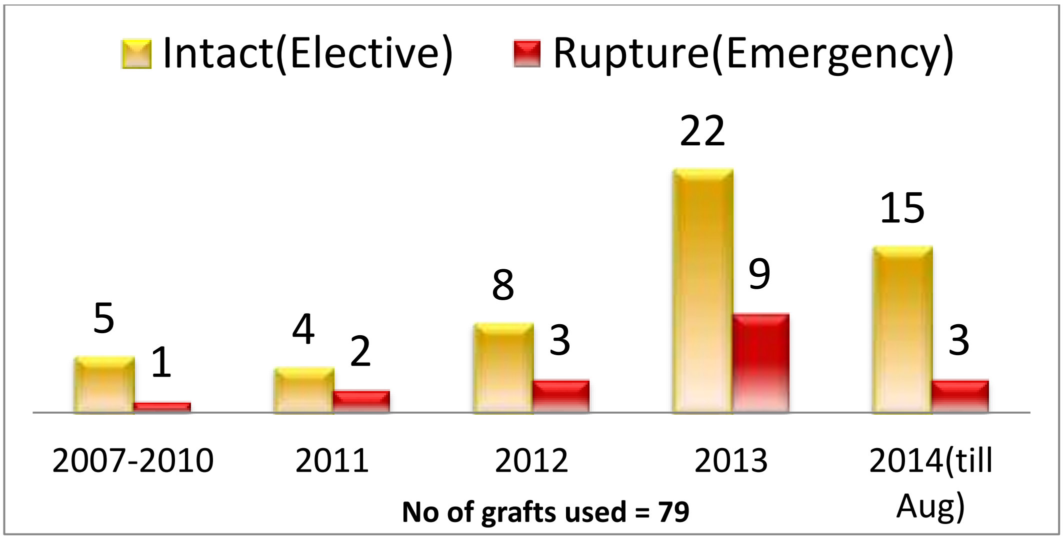
RESULTS

During the study period, 68 patients underwent TEVAR with or without hybrid strategies for repair of various thoracic aortic pathologies. 18 cases were emergent repairs for aortic rupture while 50 were elective procedures (Graph 1).



Graph 1: Division of cases based on timing of procedure

Graph 2 depicts the year-wise distribution of cases, evidencing an increasing trend in the utility of endovascular repair in the thoracic domain.



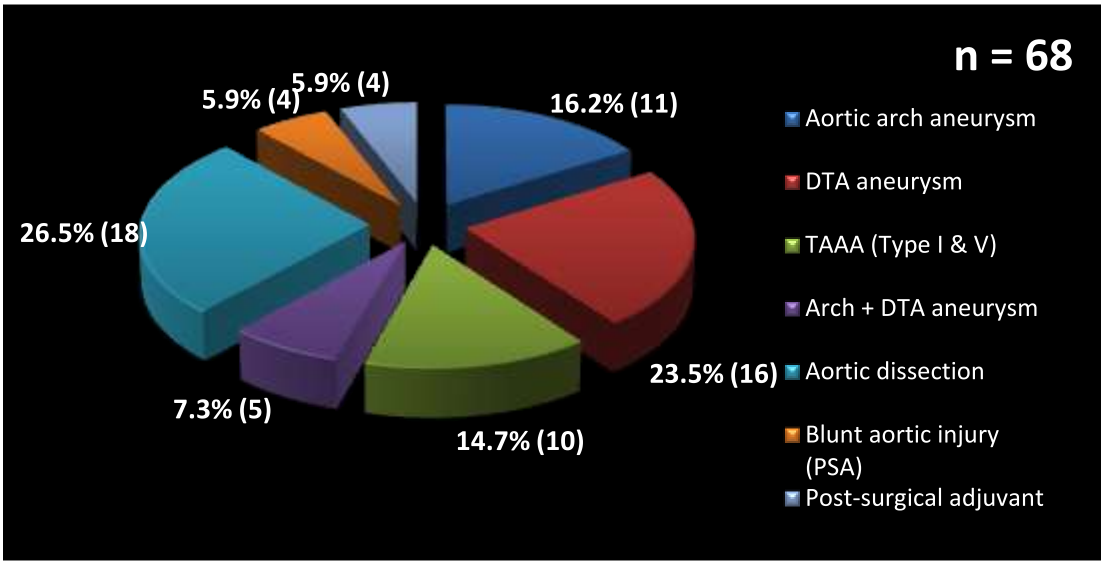
Graph 2: Year-wise distribution of TEVAR procedures at our institute

Demographics and clinical details are summarised in Table 1.

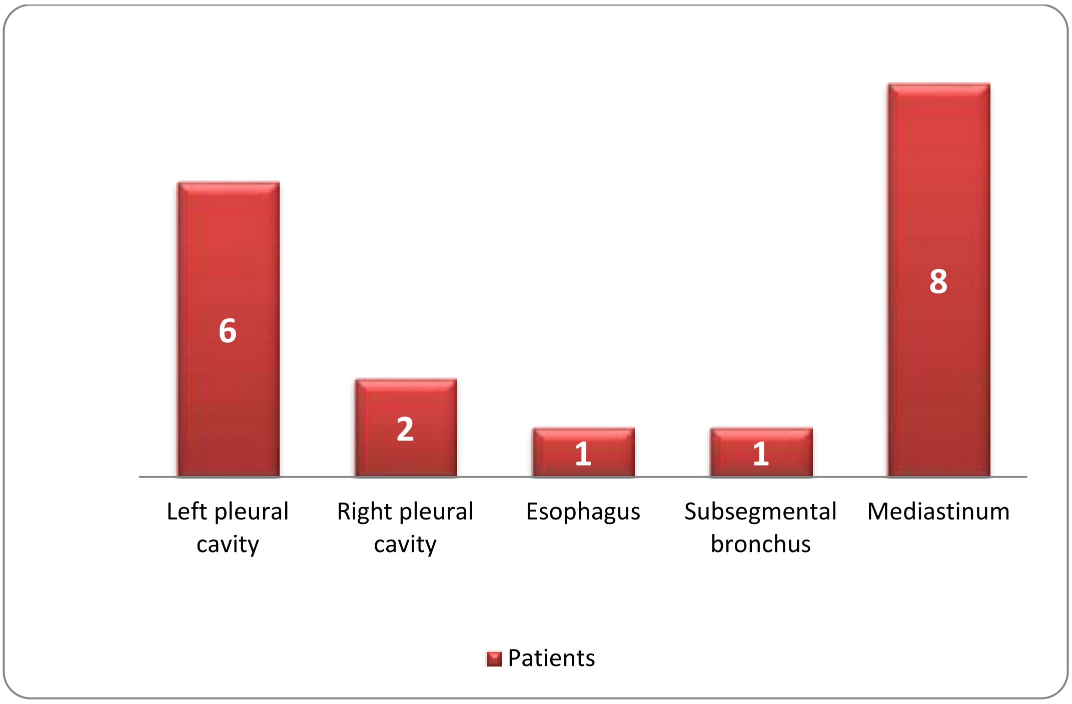
No. of patients	68
Age in yrs (mean)	20-87 (59.9)
Mean aortic diameter (in mm)	58.5
Male : Female	6.5:1 (59:9)
Smoking	45 (66.2%)
Hypertension	52 (76.4%)
Diabetes mellitus	8 (11.7%)
Dyslipidemia	29 (42.6%)
CAD	10 (14.7%)
COPD	9 (13.2%)
Renal insufficiency	10 (14.7%)
CVD	3 (4.4%)
PAD	5 (7.3%)
Previous aortic surgery	6 (8.8%)
Hemodynamic instabilityat presentation	4 (5.8%)

Table 1. Demographics of study population. CAD = coronary artery disease, COPD = chronic obstructive pulmonary disease, CVD = cerebrovascular disease, PAD = peripheral artery disease

The pathologies treated included aneurysms of the aortic arch, descending thoracic and supraceliac thoraco-abdominal aortic aneurysms in 42 patients (61.7%), thoracic aortic dissections in 18 (26.5%) and traumatic aortic injuries in 4 (5.8%) (Graph 3). TEVAR was employed as a post-surgical adjuvant in 4 patients, 2 cases following surgical repair of Type A aortic dissection, 1 after repair of Type B aortic dissection and 1 after open repair of DTA aneurysm for distal anastomotic pseudoaneurysm. Among the 18 ruptured aortic pathologies, 2 (11.1%) were arch aneurysms, 4(22.2%) were DTA aneurysm, 5(27.8%) were Crawford type V TAAA (supra/juxta celiac), 3(16.7%) were acute aortic dissections with pleural rupture and 4(22.2%) were post-traumatic aortic psuedoaneurysms. Sites of rupture are shown in Graph 4.



Graph 3. Distribution of cases based on treated pathology



Graph 4. Sites of aortic rupture

Procedural details:

The common femoral artery (CFA) was utilised as access vessel for delivery of the endoprosthesis in 59 (86.7%) patients, while 6 (8.8%) cases required additional conduit placement to common iliac artery (CIA) or terminal aorta due to inadequate calibre of CFA or due to intra-operative inability to negotiate the delivery system due to vessel spasm. The femoral limb of a prior aorto-femoral bypass graft was using in 2 cases. 1 patient had a CIA stenosis that had to be stented using a self-expanding bare metal stent prior to passage of the device.

29 (42.6%) cases were performed under local anaesthesia with conscious sedation, predominantly in the elective group; while GA was employed in 39 (57.3%) cases for reasons of hemodynamic instability, obesity, patient anxiety or when a conduit placement or synchronous hybrid repair was required. Lumbar intrathecal catheter was placed for CSF drainage in 10(14.7%) cases that posed high risk for spinal cord ischemia

Out of the 79 aortic stent-grafts used, majority (70) were Valiant Thoracic endoprosthesis with Xcelerant or Captivia delivery system (Medtronic Inc, Minneapolis, MN, USA), Zenith TX2 TAA endoprosthesis (Cook Medical Inc., Bloomington, IN, USA) was used in 6 while 2 cases were performed using the TAG endoprosthesis (W.L Gore, Flagstaff, AZ, USA). 11 cases required the deployment of 2 stent-grafts on account of the sheer length of the aneurysm or to tackle endoleak. Graft diameters employed ranged from 24 to 46mm (median; 35mm)

PLZ in which deployment was executed involved Zone 0 in 9, Zone 1 in 21, Zone 2 in 5, Zone 3 in 4 and Zone 4 in 29 patients. Hybrid debranching procedures were undertaken in those patients requiring Zone 0 and 1 deployment for preserving carotid flow. Details of the arch debranching procedures are mentioned in Table II. Most of the procedures were staged except in emergent setting that required expeditious TEVAR.

Hybrid arch repairs	**n = 31**
Hemiarchdebranching procedures	
Aorto-left carotid bypass	10
Carotid-carotid bypass	10
Carotid-Subclavian bypass	1
Total arch debranching procedures	
Ascending-bicarotid bypass	3
Pan supra-aortic bypass	5
Carotid-carotid bypass + innominate chimney (endodebranching)	2

Table II. Details of hybrid arch debranching procedures

The left subclavian artery was intentionally covered in 29 (42.6%) patients while prophylactic bypass on indications were given in 6 patients. No neurological or upper limb ischemic sequelae were noted in any of the former patients.

Early outcomes:

Technical success was achieved in 65 patients (95.5%).Overall 30-day mortality was 7.3% (n=5) (Table III), Mortality was marginally higher in the hybrid group was 12.9% (n=4) compared to 2.7% (n=1) in TEVAR alone group (p=0.25). On comparing the elective and emergent treatment group, mortality was 6.0% (n=3) in elective setting while it was 11.1% (n=2) among patients treated in emergency (p=0.79).

Cerebrovascular accident	1
Visceral malperfusion	1
Renal failure	1
Respiratory failure	1
MODS	1

Table III. Causes of perioperative mortality

Early major post-operative complications are listed in Tables IV and V. Complication rates were higher in the patients treated with hybrid repair than those requiring only TEVAR, and were also higher in emergent group in comparison with elective group. Most commonly encountered were respiratory and renal complications.

	Hybrid group (n = 31)	TEVARalone (n = 37)	*p* value
Mortality	4 (12.9%)	1 (2.7%)	0.25
Neurological complications			
Stroke	2 (6.4%)	0 (0%)	0.40
Paraplegia	1 (3.2%)	1 (2.7%)	0.99
Cardiac complications	1 (3.2%)	1 (2.7%)	0.99
Respiratory complications	10 (32.2%)	3 (8.1%)	0.02
Renal dysfunction			
Transient dysfunction	7 (22.5%)	10 (27.0%)	0.89
Renal failure	1 (3.2%)	1 (2.7%)	0.99
Visceral ischemia	1 (3.2%)	0 (0%)	0.91
Venous thromboembolism	0 (0%)	0 (0%)	-
Wound/access related complications	5 (16.2%)	4 (10.8%)	0.77
Endoleaks (I or III)	2 (6.4%)	2 (5.4%)	0.99
Mean length of hospital stay (in days)	12.7	7.3	0.05

Table IV. 30-day postoperative outcomes comparing TEVAR alone and hybrid groups.

	Elective (n = 50)	Emergency (n = 18)	*p* value
Mortality	3 (6.0%)	2 (11.1%)	0.79
Neurological complications			
Stroke	1 (2.0%)	1 (5.5%)	0.92
Paraplegia	1 (2.0%)	1 (5.5%)	0.92
Cardiac complications	1 (2.0%)	1 (5.5%)	0.92
Respiratory complications	8 (16%)	5 (27.7%)	0.45
Renal dysfunction			
Transient dysfunction	14 (2.8%)	3 (16.6%)	0.53
Renal failure	1 (2.0%)	1 (5.5%)	0.92
Visceral ischemia	1 (2.0%)	0 (0%)	0.99
Venous thromboembolism	0 (0%)	0 (0%)	-
Wound/access related complications	6 (12%)	3 (16.6%)	0.88
Endoleaks (I or III)	3 (6.0%)	1 (5.5%)	0.99
Mean length of hospital stay (in days)	8.0	13.1	0.03

Table V. 30-day postoperative outcomes comparing elective and emergency groups.

Respiratory complications mainly involved bronchospasm, atelectasis or pneumonia occasionally requiring prolonged ventilation (>48 hrs) or re-intubation. Renal complications were predominantly transient rise in S. creatinine> 0.5mg% largely related to contrast-induced nephropathy (CIN) that subsided with conservative management within a week or two. Wound complications comprised of wound infection in 5 patients , neck hemotoma in 2 patients following subclavian bypass and groin lymphorrhoea in 2 patients.

Length of hospital stay was significantly shorter in TEVAR alone group compared to hybrid group as was the case with elective group in comparison to emergency group. ($p < 0.05$)

Visceral ischemia occurred in a patient, in whom the stent-graft was accidentally deployed into the false lumen in a case of aortic dissection, following which the patient ultimately succumbed. Yet another patient developed cerebral ischemia following thrombosis of parallel graft (chimney) placed in the innominate artery that was the sole brachio-cephalic inflow vessel though necklace bypass to opposite carotid artery. Acute thrombosis of aorto-left carotid bypass graft in first post-operative day occurred in 2 patients both of which were immediately revised and flow re-established, ensuing in major stroke in one patient. Barring this patient, other patients who developed major neurological complications (stroke/paraplegia) and renal failure eventually succumbed. No patients had to be discharged to a high-dependency centre as a result of major debility.

Outcomes on short and mid-term follow-up

Completeness of follow-up was 100%. Follow-up ranged from 1 to 84 months (mean, 18.4 months).10 patients expired during the follow-up period. Causes of death included 4 massive gastro-intestinal bleeding, 4 from myocardial infarction, 1 from cerebrovascular accident and 1 from neuro-degenerative disease.6-month, 1-year and 2-year survival rates were92.0%, 88.8% and 85.7% respectively (Figure 3).

Aorta-related re-interventions were required in 2 patients. 1 patient, who had undergone a hybrid repair of a distal bovine arch aneurysm with a ‘necklace’ procedure, had a Type IA endoleak detected a month later, that was salvaged by an extension TEVAR to Zone 0 with chimney graft to innominate artery. The other patient developed a secondary aorto-esophageal fistula, detected after he presented with hematemesis 6 months following emergency TEVAR for ruptured DTA aneurysm, requiring esophageal covered stent placement. 1 patient developed a pseudoaneurysm at femoral anastomosis of an aorto-femoral bypass that was repaired subsequently.

On follow-up CT imaging positive aortic remodelling was noted in all cases (100%) in the form of partial/total shrinkage of aneurysm sac or reduction in aortic/false lumen diameter in cases of aortic dissection. Among the 18 patients treated for aortic dissection, complete thrombosis of false lumen (FL) was noted in 3 patients (16.7%), partial thrombosis in 14 (77.8%) while the FL remained patent although decreased in size in 1 patient (5.5%). Secondary (delayed) endoleak was present in 3 patients – one had a type IA endoleak that required reintervention, while the others were a faint type IB endoleak in 1 patient and type II endoleak (at base of subclavian artery) in another, that are kept under follow-up. 1 patient had short retrograde dissection without any symptoms and is also under close surveillance. All bypass grafts were patent on follow-up. There were no stent-graft migrations or late aneurysm ruptures.

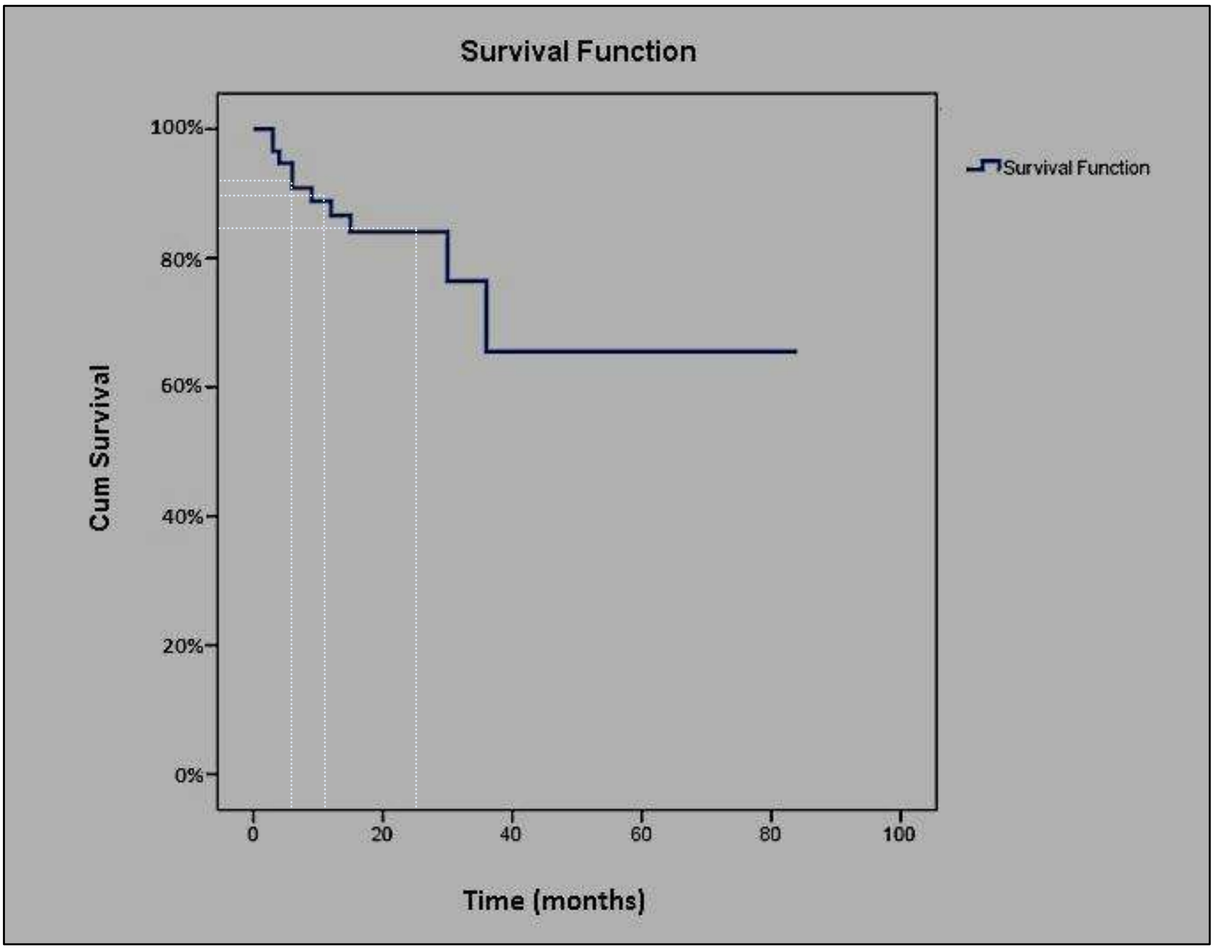


Figure 3. Kaplan-Meier life table analysis of mid-term survival after endovascular and hybrid repair of thoracic aortic pathologies. Survival rates at 6 months, 1 year and 2 years were 92.0%, 88.8% and 85.7% respectively

DISCUSSION

TEVAR has revolutionized the management of thoracic aortic disease. Advantages of a minimally invasive endovascular approach are the avoiding of thoracotomy and aortic cross-clamping, reduced operating times, and minimal additional blood loss, which are particularly important in rDTAA patients in critical condition. TEVAR is emerging as the preferred treatment for patients with thoracic aortic pathologies both in the elective and emergent setting, although there is currently a scarcity of Level I evidence that an endovascular approach improves survival compared with traditional open surgery.

The largest RCTs to date on the utility of TEVAR for thoracic aortic diseases are the TAG trial, the VALOR trial and the STARZ trial, all of which showed favourable peri-operative results with TEVAR compared to open repair (2% versus 12%, 2.1% versus 7.9% and 1.9% versus 5.7% respectively).[13-15] Since then numerous prospective studies have been published on the safety of TEVAR for various pathologies of the thoracic aorta. Hybrid procedures have been developed to lessen the potential morbidity associated with aortic arch surgery by combining extra-anatomic debranching of aortic arch branch vessels with endovascular exclusion of the aortic arch. Encouraging results have been reported in limited series of patients having various aortic arch pathologies.[27-35]

This study on TEVAR and hybrid procedures demonstrated a overall 30-day mortality of 7.3%, with 2.7% mortality for cases that required TEVAR alone for DTA pathologies, comparable to the results of the above-mentioned trials. Renal dysfunction predominated among the early post-operative complications (27.9%) that were mostly transient derangements in serum creatinine from contrast induced nephropathy. Pre-operative renal dysfunctionwas a major predictor of this complication apart from advanced age and co-existence of diabetes mellitus. Overall the results were similar to the recently published VALOR II trial results of Medtronic Valiant Thoracic endoprosthesis for DTA pathologies.[36] This trial reported a peri-operative mortality of 3.1% with net complication rate of 38.1%. This study had a major adverse event rate of 39.7% including neurological, cardiac, respiratory, renal and visceral complications. These figures compare favourably with results of open repair of thoracic aortic aneurysms, reported at 3-12%, with 50% major adverse event rate.[37-40] Apart from the reduced cardio-respiratory stress, the improved outcomes related to spinal cord ischemic complications after TEVAR (2.9% in this study, 2.5% in VALOR II trial) has been a major plus-point over open aneurysm repairin which paraplegia. Few articles in literature have focused uponcomparing endovascular stent grafts for repair versus thetraditional open technique. These reports include singleinstitutional experiences as well as two multicenter comparative trials. One such institutional study by Stone et al[41]reported a peri-operative mortality of 15.1% overall and 9.6% forintact DTA repairs. Complications included 8.6% paraparesis, 4.5% paraplegia, and 8% intra-operative stroke. Multicenter trials include those published by Bavaria et al[42] and Matsumura et al.[14] The former had an open cohort of 94 patients and a peri-operative mortality of 11.7% while the latter had an open cohort of 70 patients and a perioperative mortality of 5.7%. Complications reported by Bavaria et al included 20% respiratory, 13% renal, 1% myocardial infarction, 4% CVA, and paraplegia/paraparesis of 14%. Matsumura et al reported complication rates of 44% pulmonary, 14% renal, 44% cardiac, 8.5% CVA, and 6% paraplegia.

The feasibility of arch vessel debranching followed by thoracic endovascular aortic repair (TEVAR) as a less invasive alternative approach for treatment of arch diseases in high-risk patients has been supported by several reports and recent systematic reviews.[43-46] Approach to the aortic arch, regardless of the technique, cannot be achieved without risks. For open aortic arch replacement, an operative mortality ranging from 0.9% to 9.3% has been reported in single series from high-volume centers.[47,48] However, according to data from the National Inpatient Sample database[49] and the Medicare Provider Analysis and Review,[50] reflecting the real world experience, operative mortality as high as 15% to 20% has been shown. This mortality rate of hybrid procedures in this study was 12.9%, although slightly higher than the reported rates of 6-8%, is still satisfactory when weighed against open arch repair. Requirement of sternotomy for ascending aorto-carotid bypass was found to be risk factor for major respiratory complications and mortality in this group as shown by Anderson et al.[51] The recent availability of branched or chimney graft to allow partial or total supra-aortic vessel revascularization, limiting the invasiveness of the surgical access, may be a valid alternative to decrease intraoperative mortality. By this it is possible to 'endo-debranch' the innominate artery by a parallel (chimney) graft or a single branch on the endoprosthesis, left carotid and subclavian arteries can be bypass through a totally cervical approach. In this surgical cohort, this technique was used in 2 patients, one for avoiding thoracic entry in a case of aortic rupture, the other for proximal extension for endoleak. Although a less morbid strategy, significant risk does exist by depending on a one stented vessel as single inflow for the entire cranial and upper limb flow, as was noted in one patient who succumbed from cerebral ischemia following stent thrombosis.

Primary and secondary endoleak rates were low in this study (5.5% and 2.9%). This improved results are attributable to our protocol of overzealous proximal extension and preferential utilisation of Zone 0 and 1 over Zone 2 and 3 (30 vs 9) for deployment, such that a close to 3cm of proximal seal can be achieved with horizontal lie in the transverse arch. in a review of Kotelis et al of 14 studies, patients undergoing hybrid arch repair in zone 0 had lower endoleak (3.97% vs 15.48%; P = .005) and reintervention rates (12% vs 25.8%, P = .032).[43]These data, as well as the nonexistence of stent graft migration recorded in this study, may support the finding of other authors in creating a longer and durable proximal landing zone with aggressive extent to zone 1 or 0 for arch endovascular procedures particularly in bovine arch,[52]but still, the improved durability should be balanced with the higher perioperative risks involved with total arch re-routing.

In this series, intentional blockade of left subclavian artery was performed in 29 patients (42.6%), without prophylactic bypass. A few studies report that intentional coverage is not associated with additional morbidity,[53-55]whereas other studies report a higher incidence of postoperative arm ischemia and posterior circulation strokes.[56,57] Routine revascularisation is not without risk. Wound hematomas, injuries to lymphatic, vascular and nervous structures are potential complications seen in around 5% cases.[58] Although the level of evidence to support either practise is low, data from this study indicates that risk of vertebra-basilar insufficiency or arm ischemia is low is most patients. Yet it is of paramount importance to assess the posterior circulation and branching patterns of arch vessels prior to the procedure and to identify particular situations that pose a threat for development of these devastating complications and provide prophylactic bypass to retain antegradesubclavian-vertebral flow in this subset of patients as was done in 6 cases in this study.

The principle of the endovascular approach to TBAD is to cover the entry tear and provide favourable aortic remodeling, thereby preventing early and late complications. In this series, 18 patients had aortic dissections, of which 16 were of Stanford B dissections. While the classical location in proximity to left subclavian artery was noted in 8 patients, 7 patients had atypical entry tears in variable locations along the DTA that required only straight-forward TEVAR. In all cases of post-subclavian dissections, Zone 1 deployment was accomplished after appropriate left carotid debranching. Acute dissections were treated in 4 patients due to complicated presentation of rupture or malperfusion. In-hospital mortality was 5.5%, encountered in 1 patient who developed mesenteric ischemia secondary to visceral malperfusion due to erroneous deployment of the stent-graft into the false lumen, highlighting the importance of careful access and confirmation of true lumen entry prior to executing the endo-repair.

In a report by Cochennec et al[59], in-hospital mortality for hybrid repair of arch dissection was noted to be 29% (5 out of 17 cases). In this series, mortality rates and incidence of retrograde aortic dissection were significant after hybrid repair of aortic arch dissections, especially in acute cases. 4 (24%) cases of retrograde aortic dissection were noted. This is contrary to the single case of retrograde dissection noted in this series (5.5%), which was an asymptomatic short dissection in DTA just proximal to stent-graft detected on follow-up scanning in a case of acute atypical TBAD in Zone 4. The preferential extension of proximal seal to Zone 1 in all cases is could be the basis for the reduction of this adverse aortic complication.[60]

Progressive residual dissection after surgical repair of Type A aortic dissection is a not so uncommon sequelae encountered in about 30% of patients on follow-up,[61] as noted in 2 patients in this study. Hybrid TEVAR with landing within the ascending aortic graft is the safest option for salvage of these patients with satisfactory results, avoiding the complications of re-operative open arch surgery.

On follow-up CT, positive aortic remodelling in the form of shrinkage of aortic size and some amount of thrombosis in false lumen was noted in all cases. Partial thrombosis of false lumen was the most frequent finding on follow-up (77.8%). This was probably related to higher proportion of chronic aortic dissections with aneurismal degeneration that was treated. Complete thrombosis, reported to be around 50% in literature, is more often associated with treatment of acute TBAD, small entry tears with limited re-entry points, larger true lumen to false lumen ratio and dissections limited to thoracic aorta not extending into abdominal aorta.[62]

Lot of debate has been generated off late regarding TEVAR versus best medical management for uncomplicated TBAD. Results of the INSTEAD-XL trial, show that thoracic endovascular aortic repair of uncomplicated type B dissections in addition to medical therapy is associated with improved five-year aorta-specific survival and delayed disease progression . Data from the study show that risk of all-cause mortality (11.1% vs. 19.3%; p=0.13), aorta-specific mortality (6.9% vs. 19.3%; p=0.04), and progression (27.0% vs. 46.1%; p=0.04) after five years was lower with TEVAR than with optimal medical treatment alone, hence supporting the proactive endovascular repair of aortic dissections.[63] A year later interim results were published of the Acute Dissection Stent-grafting OR Best medical therapy (ADSORB) trial which suggested safety in employing

TEVAR in the setting of uncomplicated acute TBAD. Remodelling with thrombosis of the false lumen and reduction of its diameter is induced by stent-graft, but long-term results are needed.[64]

TEVAR has been a breakthrough in the emergent treatment of ruptured aortic pathologies. While mortality after open surgical repair has been reported to be 22-45%[65-67], distinct survival benefit has been evident following TEVAR with lower peri-operative mortality rates of 11-18%.[68,69] This study has shown a mortality rate 11.1%. This strikingly low rate may be accounted by the relatively stable presentation of these patients with only 4 (22%) of the 18 patients requiring resuscitation for in hemodynamic shock. Improved survival after an endovascular approach compared with open surgery has been observed as well for other thoracic aortic catastrophes, including traumatic aortic injuries or complicated type B aortic dissections.[70,71]

Although mortality is a very important outcome measure, the quality of life of surviving patients is also essential when determining the preferred treatment. In descending thoracic aortic interventions, the most feared nonfatal complication is postoperative paraplegia due to interruption of the blood supply to the spinal cord. Open repair in the emergent setting of rupture poses increased risk for spinal cord ischemia with reported paraplegia rates of 8-14%. Conversely, as seen in this study paraplegia following TEVAR can be as low as 2-5%.[67] Theoretic explanations include no aortic cross-clamping during TEVAR, fewer periods of perioperative hypotension due to blood loss or hemodynamic shifts, and slow thrombosis of the aneurysm sac compared with acute occlusion of critical vessels during surgical repair.

Few limitations impede the widespread use of TEVAR in some patients, because of anatomical constraints related to the quality of the landing zones, difficult iliac access, and need to carry a wide range of stent graft sizes off-the-shelf for emergent use. Yet another cause for concern is the occurrence of endograft related complications. Jonker FH et al. reported diagnosing endoleaks in 17% within 30 days, and aortic reinterventions were required in 8% of patients during the first month.[67] Similarly, late device related complications were noted in 3 patients (16%) in this series. 1 patient had anasymptomatic retrograde aortic dissection following emergent TEVAR for ruptured atypical (Zone 4) acute TBAD. Another patient treated for traumatic aortic rupture has a small type II endoleak from the base of subclavian artery and is on follow-up. The third patient had a secondary aorto-esophageal fistula requiring re-intervention in the form of esophageal stenting.

TEVAR offers a new minimal invasive therapeutic option that could be beneficial in the urgent management of polytrauma patients, frequently presenting with concomitant organ injuries. 4 patients underwent TEVAR with or without debranching procedures for treatment of traumatic aortic injuries with a single mortality. Several series have demonstrated endovascular repair to be an efficient therapeutic option with promising results. Concerns do exist about the long-term effects of these smaller-sized grafts when used in young patients and extended follow-up is warranted.[72,73]

Most of the long-term results available represent those of the previous generation of aortic stent-grafts performed in the previous decade. Similar to the findings of EVAR and DREAM trials for abdominal aortic aneurysm, the survival benefit noted in short-term following TEVAR in comparison to open repair seemed to dwindle off over a follow-up of 5 years as shown in a large study by Goodney P et al[74] (72% after open repair versus 62% after TEVAR). These results suggest that higher-risk patients are being offered TEVAR and that some do not benefit in terms of long-term survival. Since the survival studies are not well designed RCTs, a selection bias could exist since patients treated by open repair are generally of lower morbidity index compared to patients treated by TEVAR. Nonetheless, these differences in survival could be explained by device-related complications occurring within the first 5 years after surgery. Though evaluated over a shorter time frame, the present study depicted survival rates of 88.8% and 85.7% at 1 year and 2 years respectively, which fairly related to published data of about 80-90% mid-term survival.[75] Long-term results need to be analysed by following this cohort for >5 years.[76]

Although significant aortic sac shrinkage and false lumen thrombosis was present on follow-up imaging, residual thrombosed sac or patent retrograde false lumen filling continue to pose a risk of future aneurysm-related complications associated with device migration, fatigue and endoleaks. Hence is the need for prolonged surveillance imaging on a regular basis.[77]

With the advent of newer technology capable of delivering total endovascular solutions like fenestrated and branched endografts for arch and descending thoracic aortic diseases, complimented by better understanding of the dynamics of thoracic aorta with resultant improvement in device fabrication, the scope of TEVAR and hybrid repair is likely to expand further with added refinements in the therapy of thoracic aortic pathologies providing results with lesser morbidity and better long-term survival.

CONCLUSION

Short-term and mid-term results of TEVAR and hybrid procedures compare favourably with historic results for open surgical procedures for various pathologies of arch and descending thoracic aorta. Hybrid procedure for aortic arch aneurysms and dissections is a safer alternative, both for low risk and high risk patients, and has turned out to be the preferred therapeutic modality in this domain. Emergent TEVAR has become the treatment of choice for acute surgical emergencies of the thoracic aorta, and should be considered the first line of therapy for all ruptured and traumatic aortic pathologies.

Endoleaks and secondary interventions, although limited in the present study, remain the major trade-off of this procedure and continued post-hoc clinical and imaging surveillance is compulsory. Long-term outcomes are still poorly defined and results of long-term studies are awaited to ensure durability of this state-of-the-art endovascular technique.

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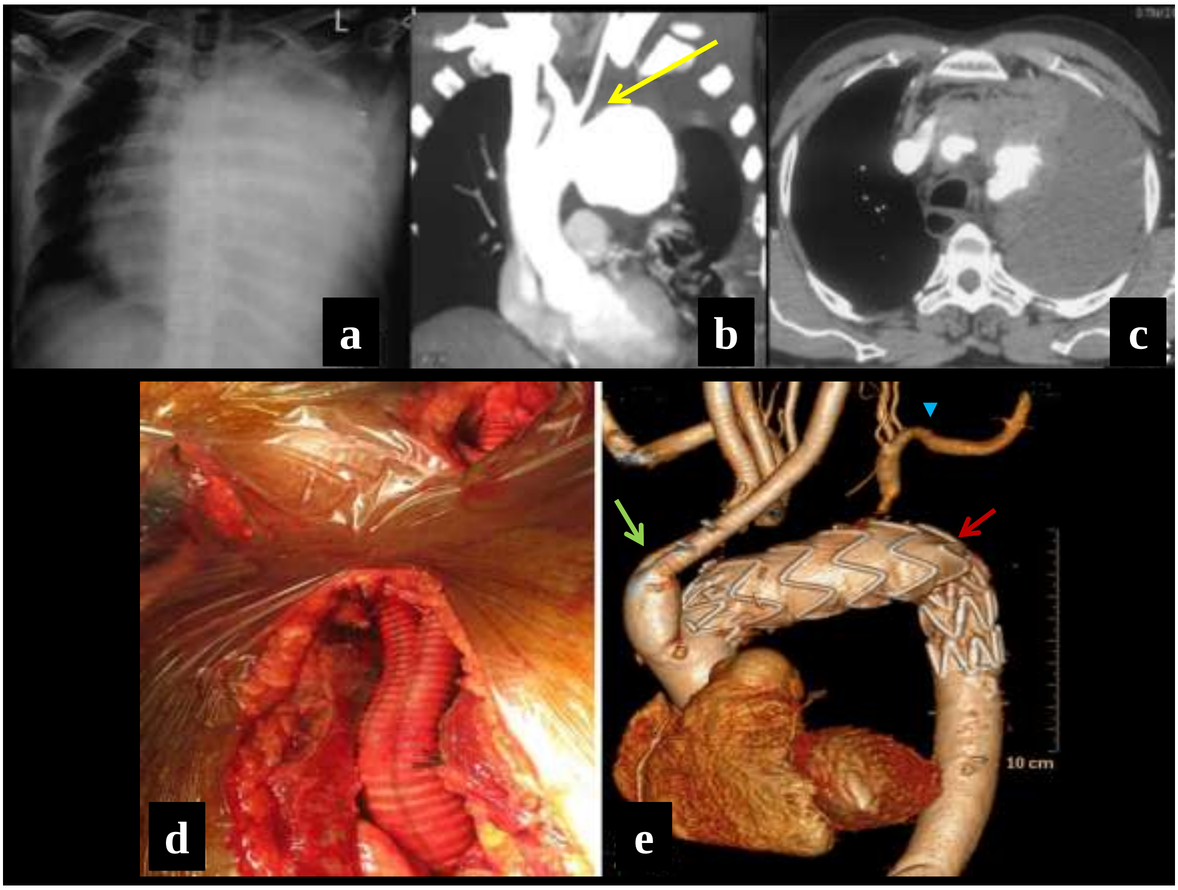
CLASSICAL CASES

Figure 1: Hybrid repair for ruptured bovine arch aneurysm in a 75-yr old patient



A: Chest radiograph showing total opacification of the left hemithorax with mediastinal shift.

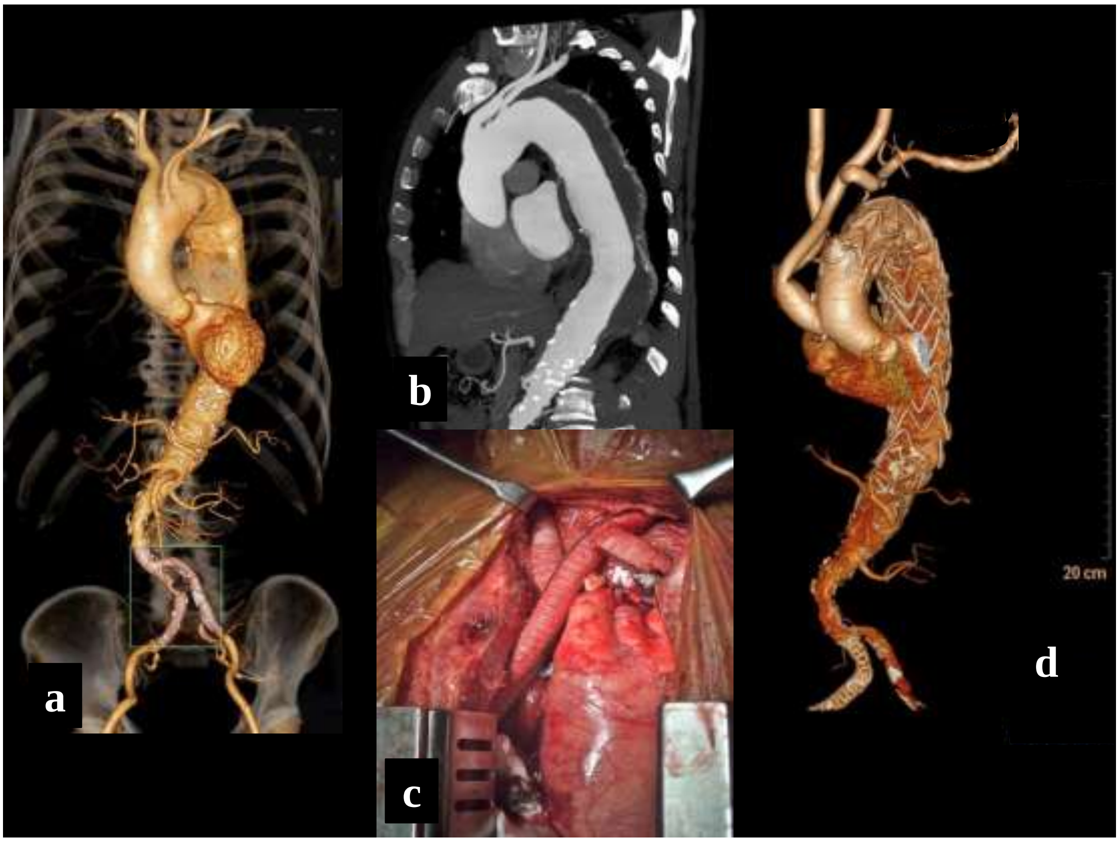
B: Coronal CT depicting an aneurysm of the arch immediately after the innominate ostium in bovine arch (yellow arrow).

C: Axial CT showing rupture of the arch aneurysm and massive left hemothorax.

D: Completed supraaortic debranching with ascending aorta-bicarotid bypass using a 16x8-mm inverted albumin-coatedknitted polyester graft.

E: CT-angiogram, volume-rendered 3-dimensional image, at 2-year follow-up, showingpatent bypass grafts (green arrow) and good stent-graft apposition with no endoleak (red arrow), and the occluded left subclavian artery with retrograde fillingfrom the left vertebral artery (blue arrowhead)

Figure 2: Hybrid repair for extensive aneurysm from distal ascending aorta upto hiatus



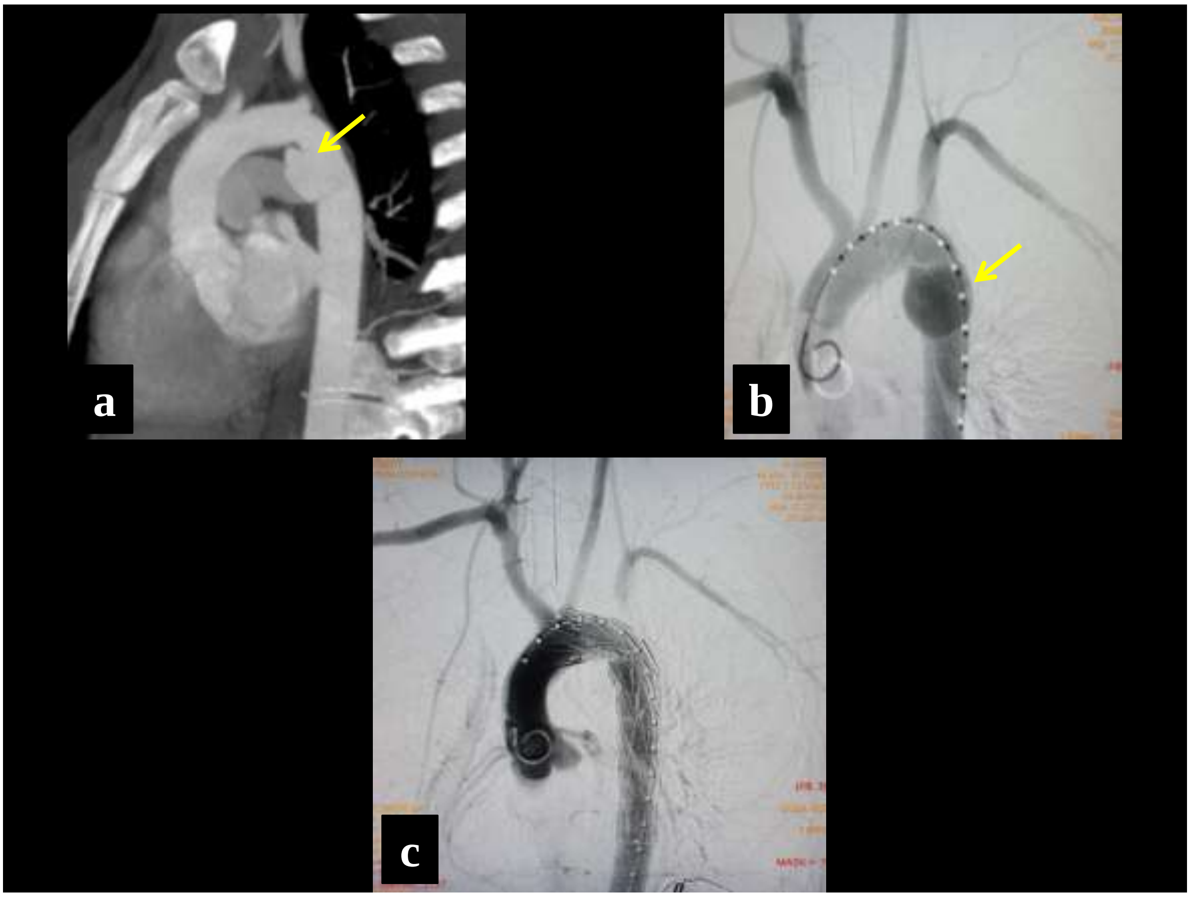
A: CT-angiogram, volume rendered 3-dimentional image, showing the extent of the aneurysm from distal ascending aorta upto supraceliac thoracic aorta

B: CT-angiogram, multiplanar reconstructed image, showing large aneurysm of maximum diameter of 8.5cm with thrombus

C: Intra-operative photograph showing the re-reouting of all supra-aortic trunks taking inflow from proximal ascending aorta, along with the debranding (ligation) of the native arteries

D: CT-angriogram, volume-rendered 3-dimensional image, 6 months after endorepair using 2 Medtronic Valiant thoracic stent-grafts (44x210mm and 46x210mm), showing patent bypass grafts to both carotids and left subclavian artery with good stent-graft apposition and complete exclusion of aneurysm. Right common iliac artery had to be stented due to 60% stenosis to permit passage of device

Figure 3: TEVAR for traumatic aortic injury in a 23 year old polytrauma patient

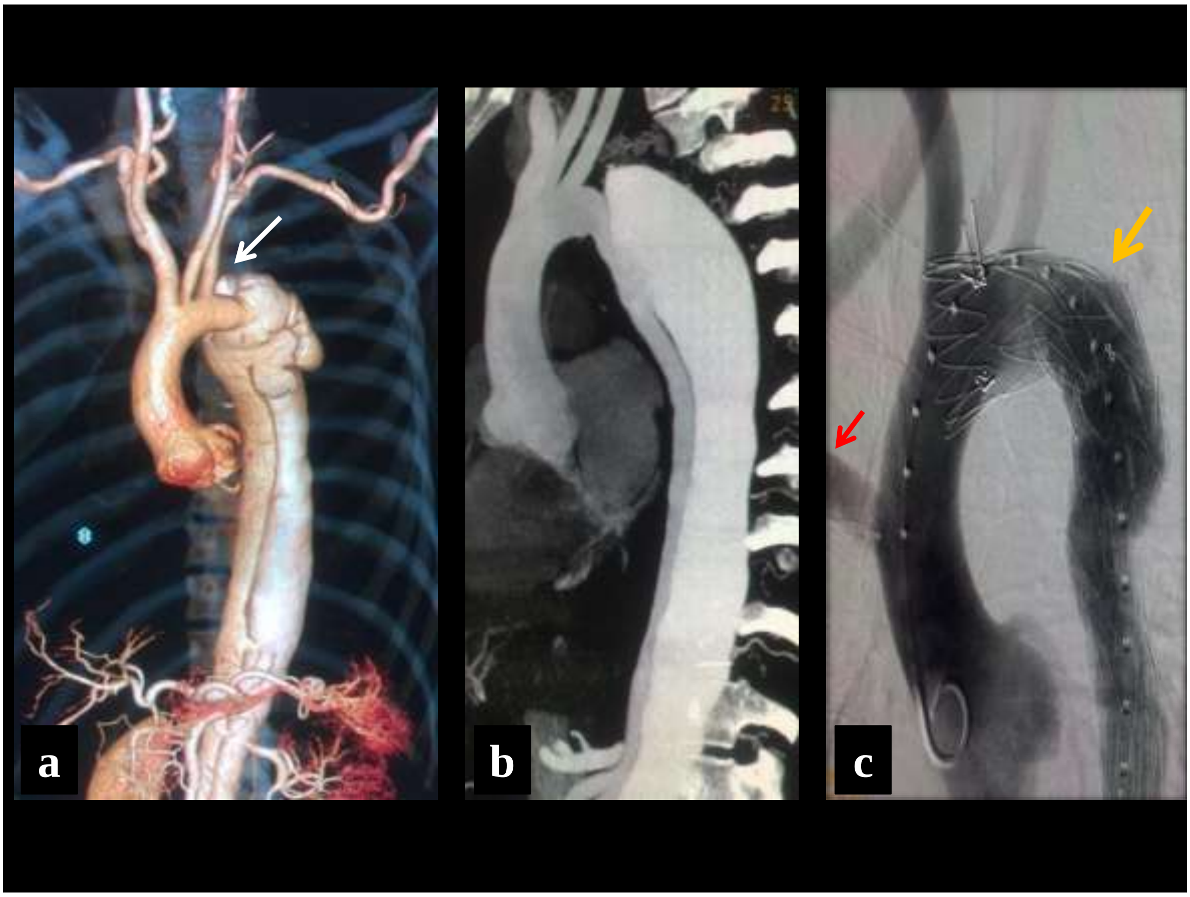


A: CT-angiogram, multiplanar reconstructed image , revealing a pseudoaneurysm at the aortic isthmus in a patient who recently sustained a major road-trafffic accident

B: Digital subtraction angiogram with aortic injection through marker pigtail catheter prior to stent graft deployment confirming the traumatic aortic lesion

C: Digital subtraction angiogram at the completion of deployment of 24x112mm Medtronic Valiant thoracic aortic stent-graft into Zone 2 showing complete exclusion of pseudoaneurysm with retrograde left subclavian artery flow

Figure 4: Hybrid repair in a case of chronic type B aortic dissection

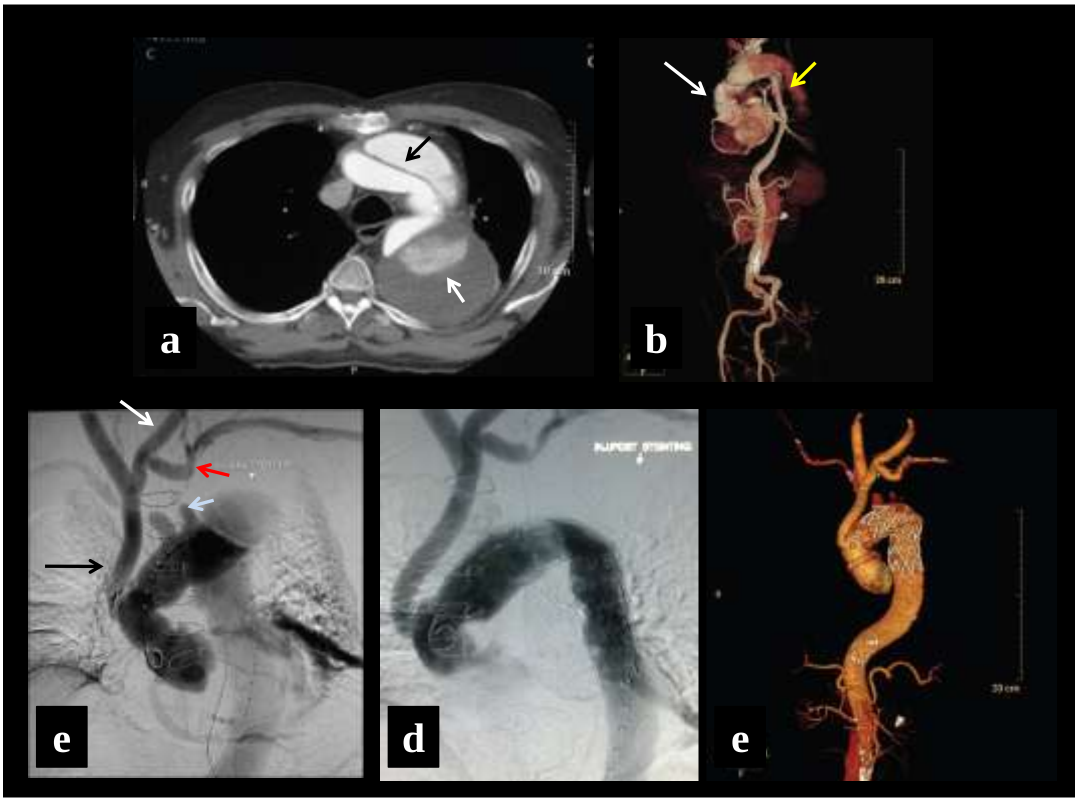


A: CT-angiogram, volume rendered 3-dimentional image, showing Stanford B aortic dissection arising just distal to left subclvian artery (white arrow)

B: CT-angiogram, multiplanar reconstructed image, large entry tear in post-subclavian descending thoracic aorta with enlarged flow lumen and compressed true lumen

C: Digital subtraction angriogram taken at the completion of staged repair (left carotid debranching with ascending aorto-left carotid bypass (red arrow) and endorepair with Medtronic Valaint thoracic 24 x 152mm stent-graft showing non-opacification of false lumen and opened up true lumen

Figure 5: Staged Hybrid repair for progressive dissection with aneurismal degeneration 4 years following supracoronary replacemnent of ascending aorta for Type A dissection



A: Preoperative axial contrast CT chest showing intimomedial flap in the aortic arch (black arrow) and partially thrombosed aneurysmal false lumen (white arrow).

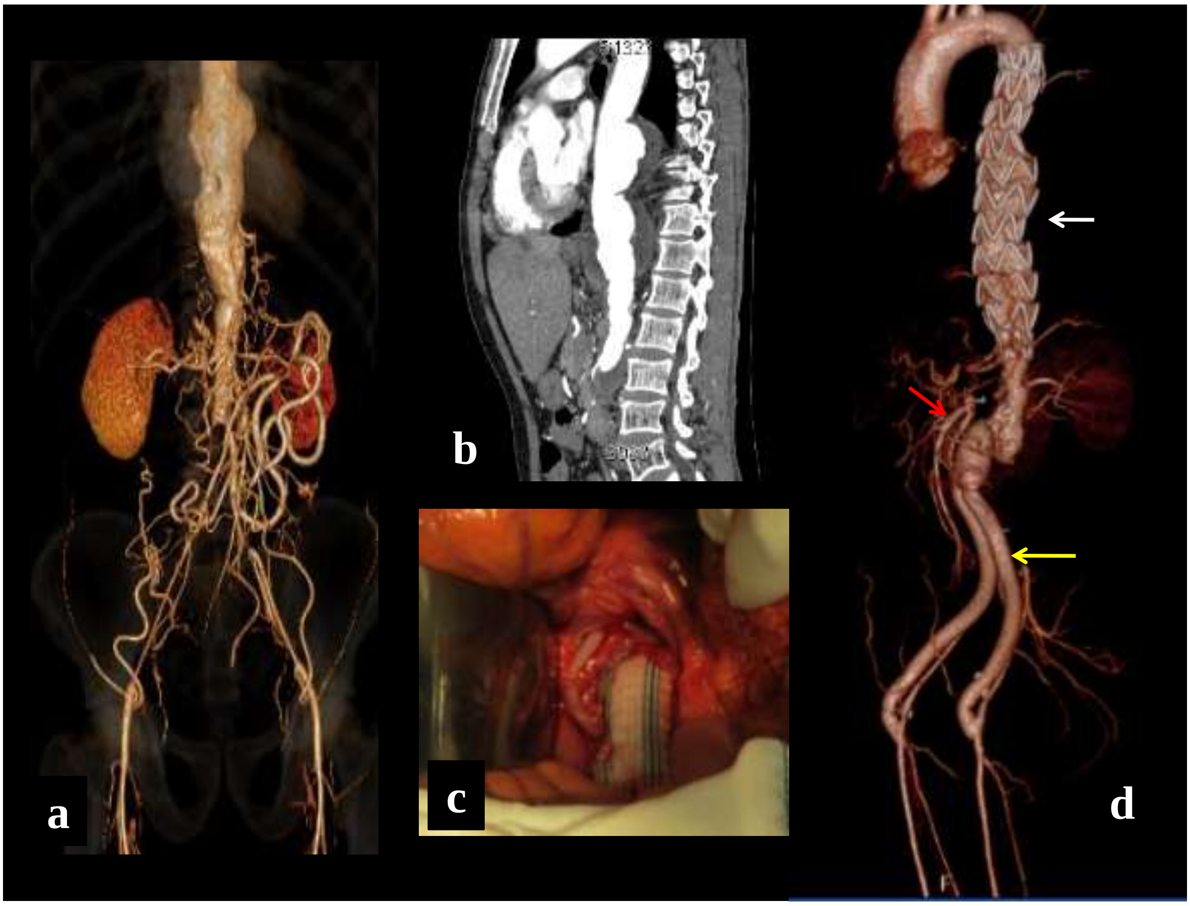
B: CT angiogram, volume-rendered 3D image showing residual aortic arch and DTA dissection with aneurysmal degeneration (yellow arrow) following prior graft replacement of ascending aorta (white arrow)for type A aortic dissection.

C: Digital subtraction angiogram prior to stent graft deployment showing patent grafts from ascending aorta with 10mm graft to right CCA (black arrow), piggybacking an 8mm graft to left CCA (white arrow), and another 8mm graft to left SCA (red arrow). Native stumps of the debranched arch vessels are seen (blue arrow).

D: Check angiogramafter stent graft deployment

E: CT angiogram, volume-rendered 3D image at 1 year follow-up showing patent bypass grafts, significantly remodelled aorta, and near-totalthrombosis of false lumen

Figure 6: Synchronous repair of type I Thoraco-abdominal aortic aneurysm with concomitant aorto-iliac and mesenteric occlusive disease

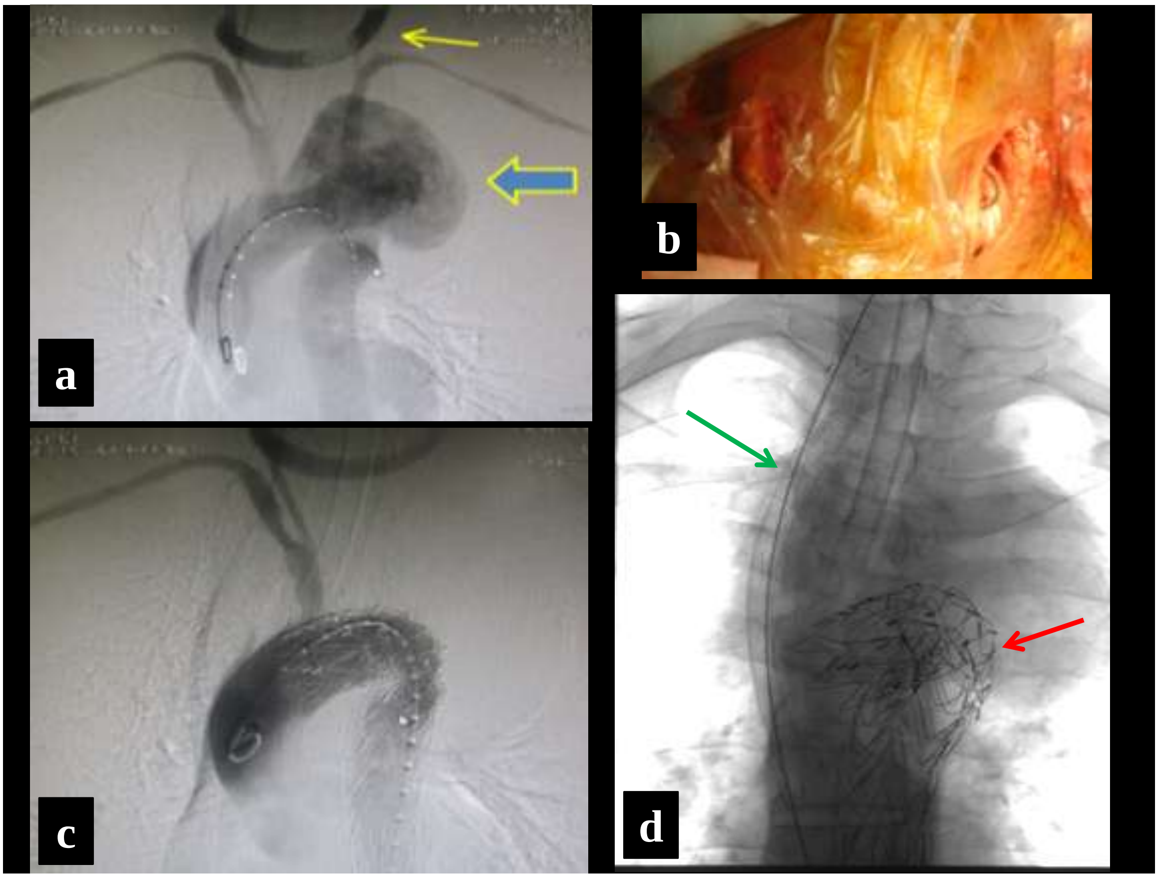


A: CT angiogram, volume rendered three dimensional image showing occlusion of ostio-proximal segments of celiac truck and SMA, with total occlusion of infra-renal aorta extending to both common iliac arteries. Extensive mesenteric collateral arcades noted with a large arc of Riolan fed by inferior mesenteric artery with 70% ostial stenosis

B: CT, multi-planar reconstruction image showing type I extent thoraco-abdominal aortic aneurysm of maximum diameter 6.6cm

C: Per-operative photograph showing completed retrograde SMA bypass grafting using reversed saphenous vein from main body of polyester graft used for aorto-bifemoral bypass D: CT angiogram,volumerendered three dimensional image at 6-month follow-up showing well apposed stent-graft (white arrow) in the thoraco-abdominal aorta and patent aorto-bifemoral (yellow arrow) and mesenteric bypass (red arrow) grafts.

Figure 7: Emergent hybrid repair of ruptured aortic arch aneurysm with aorto-esophageal fistula



A: Digital subtraction angiogram through marker pigtail catheter demonstrating large 8.5cm aneurysm in the distal aortic arch (blue arrow). Patent carotid-carotid bypass graft is also visualised

B: Intra-operative photograph after completion of carotid-carotid bypass with 8mm polyester graft (necklace procedure)

C: Digital subtraction angiogram at completion of stent-graft deployement showing excluded aneurysm with normal flow through innominate artery (procedure required a additional stent-graft to tackle Type III endoleak

D: Post-procedure fluoroscopy image showing 36x167mm and 34x167mm Medtronic Valiant Thoracic aortic stent-grafts (red arrow) and esophageal cover stent (green arrow) in situ. Patient was kept nil orally and enteral feeding administered through feeding jejunostomy

LESSONS LEARNT

1. Meticulous pre-operative planning with a multi-disciplinary approach is fundamental in the successful execution of endovascular/hybrid repair; so much that failing to plan is equivalent to planning to failure

2. Obligatory proximal sealing zone of 3cm ideally with horizontal lie in the arch is an important measure to abate long-term adverse outcomes like migration, proximal endoleak and retrograde aortic dissection for both degenerative aneurysm pf arch as well as Stanford B aortic dissection

3. Intentional coverage of left subclavian artery is safe and well tolerated, although in specific situations a proactive bypass is mandatory to avoid devastating posterior circulation, spinal cord or upper limb ischemia

4. Deployment of covered portion of stent-graft into common innominate-left carotid artery ostium is a potential cause of type IA endoleak due to diastolic flow reversal into the arch. Hence, Zone 0 depolyment after total arch debranching is mandatory for hybrid repair of bovine aortic arch

5. Stent-grafts with proximal bare-springs are better avoided in case of acute aortic dissections in view of the real hazard of retrograde aortic dissection

6. Staging of hybrid repairs by 1 or 2 days is preferable to limit physiological insult to the patient and allow for sufficient wound stabilisation, hemostasis and system recovery

7. Close clinical with CT surveillance at stipulated intervals is mandatory for the early identification of endo-graft related complications and so decide timely re-intervention, if needed

8. Patients in the subset of ruptured thoracic aortic pathologies have immensely benefitted with tremendous survival benefit and excellent quality of life.

ANNEXURES

TAC APPROVAL CERTIFICATE

Technical Advisory Committee (Clinical Studies)
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2014/211 **Date:14.03.2014**

Project title: Short and Mid-term results of state-of-the-art endovascular and hybrid techniques for treatment of Thoracic aortic pathologies

Principal Investigator:	
Name: Dr. Sidharth Viswanathan Address: Senior resident (MCh Vascular Surgery), SCTIMST, TRIVANDRUM-695011	Degree: M.S
Co-Principal Investigator(s)	
Name: Prof. Unnikrishnan M. Address: Professor, Senior grade (Dept of CVTS), SCTIMST, TRIVANDRUM-695011	Degree: M.S, MCh
Co- Investigator(s)	
Name: Prof. Kapilamoorthy Address: Professor and Head (Dept of IS&IR), SCTIMST, TRIVANDRUM-695011	Degree: M.D.

Members who participated in the TAC meeting on 6/03/2014
Dr. Sanjeev V Thomas (Chairman)

Dr. Biju Soman

Dr. Bejoy Thomas

Dr. Easwer. H.V

Dr. Rathore Chaturbhuj Gopalsingh

Dr. K. Shivakumar (Member Secretary)

Risk Classification of the project (Minimum/ Moderate/ High): Minimum

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

Recommendations of TAC:
Recommended for consideration of IEC in the light of the responses received from the investigator.

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).

1

IEC APPROVAL CERTIFICATE

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान
तिरुवनन्तपुरम - 695 011, केरल, भारत

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
THIRUVANANTHAPURAM - 695 011, INDIA
(An Institute of National importance under Govt. of India)

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013)

SCT/IEC/ 666/AUGUST -2014 — 25-09-2014

Dr. Sidharth Viswanathan
Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Sidharth Viswananthan,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "SHORT AND MID-TERM RESULTS OF STATE-OF-THE-ART ENDOVASCULAR AND HYBRID TECHNIQUES FOR TREATMENT OF THORACIC AORTIC PATHOLOGIES" (IEC/666) on 16th August, 2014.

The following documents were reviewed:

1. *Covering letter addressed to the Chairman dated 2.6.2014.*
2. *IEC Application form.*
3. *TAC Approval Letter.*
4. *Declaration form.*
5. *Application form for TAC.*
6. *Study proposal.*
7. *Appendix I – copy of investigators response to questions from TAC.*
8. *Consent form (English and Malayalam).*
9. *Observation chart.*
10. *Curriculum vitae of Investigators.*
11. *Covering letter addressed to the Chairperson, IEC, dated 20.09.2014.*
12. *IEC recommendation letter dated 5.09.2014.*

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तार : चित्रमेट
Grams : Chitramet
फोन
Phone : 2443152
फाक्स
Fax : (91)471-2446433 2550728
ई-मेइल
E-mail : sct. @sctimst.ac.in
वेबसाइट
Website : www.sctimst.ac.in

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Mala Ramanathan
Member Secretary, IEC

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OBSERVATION SHEET

BIODATA:

S.NO:

Name of the patient:
Age:
Sex:
Hospital number:
Contact Details:
Diagnosis:
Date of Procedure:

RISK FACTORS AND CO-MORBIDITIES: (Tick if present)

□ Hypertension □ Diabetes mellitus □ Smoking history □ Dyslipidemia
□ Coronary artery disease □ Chronic obstructive pulmonary disease □ Renal dysfunction
□ Cerebrovascular disease
□ Peripheral arterial disease
□ H/o previous aortic repair: ______________________________________

PROCEDURAL DETAILS:

Timing: □ Elective □ Emergency: (indication)______________________
Diameter of aneurysm/aortic dissection:
Stent-graft used and size:
Coverage of Lt subclavian artery: (Yes/No)
Access vessel (Native CFA/conduit placement):
Zone of deployement:

Hybrid repair: (Yes/No) –

- Hemiarch debranching
  - Carotido-carotid bypass □
  - Ascending – left carotid bypass □
- Total arch debranching
  - Ascending – bicarotid bypass □
  - Pan supra-aortic bypass □

Anaesthesia employed:

GA □

LA with awake sedation □

PERI-OPERATIVE DETAILS (30- day):

Mortality □ Stroke □ Paraplegia/paraparesis □

Renal failure (requiring dialysis) □ Transient renal dysfunction □

Myocardial infarction □

Respiratory failure □

Visceral ischemia □

Endoleak □ (if yes, type:_____)

Access related complications: _________________________

Wound infection:

Length of hospital stay: ________

FOLLOW-UP DATA:

Length of follow-up:

Survival (in months):

Cause of death:

Follow-up CT findings:

- Endoleak:
- Stent-migration:
- Sac/false lumen size:
- False lumen patency:
  - Complete thrombosis □
  - Partial thrombosis □
  - Patent □

Re-interventions:

Signature of the investigator :

MASTER CHART

S No	Name	Age	Sex	H No	Diagnosis	Maximum aortic	HTN	DM	Smoki	DLP	CAD	COPD	Renal	CVD	PAD	Prior	Date of procedure	Intact vs Rupture	Hybrid (Y/N)	Stage I procedur	Interval	LSA Coverage
1	SHMH	32	M	270798	cTBAD	4	1	0	0	0	0	0	0	0	0	0	06-09-2007	1	Y	Ao-Lt CCA	0	Yes
2	SR	73	M	228663	DTAA type C	6.4	1	0	1	1	1	0	0	0	0	0	20-02-2008	1	N	NA	NA	No
3	CTK	80	M	294481	TAAA type 5	7.7	1	0	1	0	1	0	0	0	0	0	07-05-2009	1	N	NA	NA	No
4	SCKR	56	M	294787	Arch aneurysm	5	0	0	0	0	0	0	0	0	0	0	09-05-2009	1	Y	Ao-Lt CCA	4	Yes
5	KC	79	M	299633	Arch + DTAA	7.5	0	0	1	0	0	0	0	0	1	0	16-09-2009	1	Y	C-C	2	Yes
6	SI	77	M	318713	Arch aneurysm	7	1	0	1	1	1	1	0	0	0	0	29-10-2010	2	Y	Ao-BiCCA	0	Yes
7	TKY	51	M	324003	TAAA type 5	7	1	0	1	0	0	0	0	0	0	0	22-02-2011	2	N	NA	NA	No
8	KNK	69	M	324111	DTAA type C	7	1	0	1	1	0	1	0	0	0	0	04-03-2011	1	N	NA	NA	No
9	R	70	M	331024	cTBAD	4	1	0	1	0	0	0	0	0	0	0	24-08-2011	1	N	NA	NA	No
10	SK	61	M	333499	Arch aneurysm	5	1	1	1	1	0	0	0	0	0	0	25-10-2011	1	Y	Ao-Lt CCA	1	Yes
11	GPK	79	M	322044	DTAA type B	6.5	1	0	1	1	0	0	0	0	0	0	17-12-2011	1	N	NA	NA	No
12	JR	20	M	302656	BAI	-	0	0	0	0	0	0	0	0	0	0	16-12-2011	2	N	NA	NA	Yes
13	VVS	71	M	335708	Arch + DTAA	7.2	1	0	1	1	0	1	0	0	1	0	20-01-2012	1	Y	Ao-BiCCA	5	No
14	RS	64	M	330134	DTAA	3	1	1	1	1	1	0	0	0	0	0	03-04-2012	1	N	NA	NA	No
15	JA	53	M	342980	TAAA type 5	8	1	0	1	0	0	1	0	0	0	0	12-04-2012	2	N	NA	NA	No
16	SM	70	M	342492	Arch + DTAA	11	1	1	1	1	0	0	1	0	0	0	17-04-2012	1	Y	Ao-BiCCA	1	No
17	SS	56	M	340959	Arch + DTAA	4.3	1	0	1	0	0	0	0	0	0	0	18-04-2012	1	Y	Ao-Lt CCA	5	Yes
18	RMM	44	M	346186	cTBAD	7.3	0	0	0	0	0	0	0	0	0	0	03-07-2012	1	Y	Ao-Lt CCA	4	Yes
19	MK	49	M	294243	Post surgical	6.9	1	0	1	0	0	0	0	0	0	OSR	21-09-2012	1	N	NA	NA	No
20	VTT	39	M	9804452	Post surgical	1.7	1	0	0	0	0	0	0	0	0	DTA	11-10-2012	1	N	NA	NA	No
21	MHS	70	M	353108	TAAA type 5	6	1	0	1	1	0	1	1	0	0	0	08-12-2012	2	N	NA	NA	No
22	RP	67	M	283141	Post surgical	7.3	1	0	1	1	0	0	0	0	0	Supr	26-11-2012	1	Y	Ao-BiCCA	5	No
23	SN	56	M	355239	DTAA type B	7.3	1	0	0	0	0	0	0	0	0	0	27-12-2012	2	N	NA	NA	No
24	SNP	66	M	337884	DTAA type C	5.2	1	0	1	1	0	0	0	0	0	0	10-01-2013	1	N	NA	NA	No
25	SE	64	M	194829	TAAA type 5	6.5	1	0	1	0	0	0	0	0	1	bypa	19-01-2013	2	N	NA	NA	No
26	KMKS	55	M	356104	Arch aneurysm	8.5	0	0	1	0	0	0	0	0	0	0	21-01-2013	2	Y	C-C	0	Yes
27	PA	49	M	357176	aTBAD	-	1	0	0	0	0	0	0	0	0	0	11-02-2013	1	Y	C-C	0	Yes
28	MG	51	M	357512	cTBAD	8.9	1	0	0	0	0	0	0	0	0	0	20-02-2013	1	N	NA	NA	No
29	A	23	M	358915	BAI	-	0	0	0	0	0	0	0	0	0	0	16-03-2013	2	N	NA	NA	Yes
30	CMC	78	M	310447	DTAA type B	6	1	0	1	1	0	0	0	1	0	0	25-02-2013	1	N	NA	NA	No
31	KPA	70	M	358449	DTAA type B	8.5	1	1	1	1	1	1	1	0	0	0	19-03-2013	1	N	NA	NA	No
32	VN	73	M	8909774	Arch aneurysm	4.4	1	1	0	1	1	0	0	0	0	0	26-04-2013	1	Y	C-C	2	Yes
33	PV	44	M	353104	cTBAD	5.5	1	0	1	0	0	0	0	0	0	0	07-05-2013	1	N	NA	NA	No
34	BP	40	F	349932	cTBAD	5	1	0	0	0	0	0	0	0	0	0	14-05-2013	1	Y	BiCCA + Lt S	1	No
35	AJH	56	M	359922	TAAA type 5	5.7	0	0	1	0	0	0	0	0	0	0	24-05-2013	1	N	NA	NA	No
36	RVK	69	M	359324	Arch aneurysm	4.1	0	0	1	1	0	0	0	0	0	0	29-05-2013	1	Y	C-C	1	Yes
37	SP	38	F	359841	cTBAD	5	0	0	0	0	0	0	0	0	0	0	10-07-2013	1	Y	Ao-Lt CCA	2	Yes
38	G	72	M	343202	Arch aneurysm	5.4	1	0	1	1	0	0	0	0	0	0	21-05-2013	1	Y	Ao-Lt CCA	-	Yes
39	GSK	70	M	361474	Arch aneurysm	5	1	1	0	1	0	0	1	0	0	0	15-06-2013	1	Y	C-C	1	Yes
40	RCV	56	M	363040	BAI	3	0	0	0	0	0	0	0	0	0	0	26-06-2013	2	Y	Ao-Lt CCA	0	Yes
41	VN	55	M	364501	aTBAD	-	1	0	1	0	0	0	0	0	0	0	12-07-2013	2	Y	C-C	0	Yes
42	UK	49	F	360982	cTBAD	5.5	1	0	0	0	0	0	0	0	0	0	18-06-2013	1	Y	Ao-Lt CCA	0	Yes
43	PSM	47	M	368929	DTAA type A	6.5	0	0	1	0	0	0	0	0	0	0	18-10-2013	2	N	NA	NA	No
44	ARK	69	M	366050	DTAA type A	5	1	1	1	1	0	0	0	0	0	0	19-08-2013	2	N	NA	NA	No
45	MP	72	M	366558	DTAA type A	5.2	1	0	1	1	0	0	1	0	0	0	05-09-2013	1	Y	C-C	1	Yes
46	DVP	87	M	366190	TAAA type 5	6.6	1	0	1	1	0	0	1	1	0	0	06-09-2013	2	N	NA	NA	No
47	MM	62	M	365829	TAAA type 5	4.7	1	0	1	1	1	0	1	0	1	0	12-09-2013	1	N	NA	NA	No
48	GUB	71	M	360577	Arch aneurysm	3.6	1	0	1	1	1	0	0	0	0	0	25-10-2013	1	Y	C-C	1	Yes
49	MP	69	F	368179	cTAAD	7	1	0	0	0	0	0	0	0	0	0	09-10-2013	1	Y	Ao-BiCCA	0	Yes
50	BG	40	M	366588	cTBAD	4.5	1	0	0	0	0	0	1	0	0	0	08-11-2013	1	Y	Ao-Lt CCA	1	Yes
51	MKM	60	M	366674	TAAA type 1	6.6	1	0	1	0	0	0	0	0	1	0	01-11-2013	1	N	NA	-	No
52	VAK	68	M	370327	cTBAD	4	0	0	1	0	0	1	0	0	0	0	26-11-2013	1	Y	C-C	0	Yes
53	EB	50	F	370705	aTBAD	-	1	0	0	0	0	0	0	0	0	0	25-11-2013	2	N	NA	NA	No
54	BM	37	F	282371	Post surgical	5.5	1	0	0	0	0	0	0	0	0	Bent	20-12-2013	1	Y	Ao-BiCCA	1	No
55	BB	28	F	373208	aTAAD	-	1	0	0	0	0	0	0	0	0	0	10-01-2014	2	Y	Ao-BiCCA	0	Yes
56	LV	42	M	367521	cTBAD	4.5	1	0	1	0	0	0	1	0	0	0	09-01-2014	1	N	NA	NA	No
57	R	59	M	374601	BAI	4	0	0	0	0	0	0	0	0	0	0	10-02-2014	2	Y	C-C	0	Yes
58	JS	65	M	376256	DTAA type A	8.7	1	0	1	1	1	0	0	0	0	0	09-04-2014	1	N	NA	NA	Yes
59	SP	69	F	376526	DTAA type A	6	1	1	0	1	0	0	0	0	0	0	09-05-2014	1	N	NA	NA	Yes
60	MT	65	M	374958	DTAA type A	4.2	1	0	1	0	0	0	0	1	0	0	22-05-2014	1	N	NA	NA	No
61	IKA	72	M	379950	DTAA type C	6	1	0	1	1	0	0	0	0	0	0	10-06-2014	1	N	NA	NA	No
62	SD	60	M	380193	DTAA type C	6.2	1	0	1	0	0	0	0	0	0	0	11-06-2014	1	N	NA	NA	No
63	MEM	72	M	379919	cTBAD	4.5	1	0	1	1	1	1	0	0	0	0	12-06-2014	1	N	NA	NA	No
64	GN	75	M	381054	Arch aneurysm	5.5	0	0	1	1	0	0	0	0	0	0	10-07-2014	1	Y	C-C	0	Yes
65	RS	62	F	380099	cTBAD	4	0	0	0	0	0	0	0	0	0	0	20-08-2014	1	N	NA	NA	No
66	GG	72	M	308644	TAAA type 1	8.7	1	0	1	1	0	1	0	0	0	AAA	22-08-2014	1	Y	C-S	0	No
67	GP	38	M	383785	DTAA type B	6	1	0	1	0	0	0	1	0	0	0	25-08-2014	2	N	NA	NA	No
68	PD	71	M	377238	TAAA type 5	6	0	0	1	1	0	0	0	0	0	0	27-08-2014	1	N	NA	NA	No

Stent Graft Model	Size (dia in mm)	Length of hospital stay	Technical Success	30-day mortality	Cause of death (if	Neurological	Cardiac compli	Respiratory compli	Renal compli	Viceral ischemia	Wound compli	Endoleak type	Follow-up durationn	Late endoleak	FL status (1-CT, 2-PT,	Re-interventi	L de
Gore TAG (31 mmx 150mm)	30	7	Y	N	-	0	0	0	0	0	0	0	84	No	1	-	
Medtronic VALIANT THORACIC	38, 44	7	Y	N	-	0	0	0	1	0	0	0	78	No	NA	-	
Medtronic VALIANT THORACIC	40	6	Y	N	-	0	0	0	0	0	0	0	30	No	NA	-	2
Medtronic VALIANT THORACIC	39	5	Y	N	-	0	0	0	0	0	0	0	64	No	NA	-	
Medtronic VALIANT THORACIC	40, 44	-	Y	Y	Respirato	0	0	2	0	0	0	0	-	-	-	-	
Medtronic VALIANT THORACIC	34	28	Y	N	-	0	0	2	0	0	0	0	36	No	NA	-	3 y
Medtronic VALIANT THORACIC	40	12	Y	N	-	0	0	0	0	0	0	0	6	No	NA	Esophage	6 m
Medtronic VALIANT THORACIC	42	6	Y	N	-	0	0	0	1	0	0	1	42	No	NA	-	
Medtronic VALIANT THORACIC	26, 30	4	Y	N	-	0	0	0	1	0	0	0	37	No	1	-	
Gore TAG (34mmx150mm)	34	6	Y	N	-	0	0	0	0	0	0	0	36	No	NA	-	
Medtronic VALIANT THORACIC	44	6	Y	N	-	0	0	0	0	0	0	0	34	No	NA	-	
Cook Zenith TX2	32	15	Y	N	-	0	0	0	0	0	0	0	33	2	NA	-	
Medtronic VALIANT THORACIC	44, 46	18	Y	N	-	0	0	2	0	0	0	0	32	No	NA	-	
Medtronic VALIANT THORACIC	30	4	Y	N	-	0	0	0	0	0	1	0	28	No	NA	-	
Medtronic VALIANT THORACIC	36	7	Y	N	-	0	0	0	1	0	0	0	28	No	NA	-	
Medtronic VALIANT THORACIC	36, 42	-	Y	Y	MODS	2	0	2	2	0	0	0	-	-	-	-	
Medtronic VALIANT THORACIC	42	14	Y	N	-	0	0	2	0	0	0	0	28	No	NA	-	
Medtronic VALIANT THORACIC	24	11	Y	N	-	0	0	0	0	0	0	0	26	No	2	-	
Medtronic VALIANT THORACIC	30	5	Y	N	-	0	0	0	0	0	0	0	24	No	NA	-	
Medtronic VALIANT THORACIC	24	5	Y	N	-	0	0	0	0	0	0	0	24	No	NA	-	
Medtronic VALIANT THORACIC	38	-	Y	Y	Acute on	2	0	2	2	0	1	0	-	-	-	-	
Medtronic VALIANT THORACIC	36	21	Y	N	-	0	0	2	1	0	3	0	15	No	2	-	15n
Medtronic VALIANT THORACIC	36	8	Y	N	-	0	0	0	0	0	0	0	21	No	NA	-	
nic VALIANT THORACIC (34mmx2	34	5	Y	N	-	0	0	0	0	0	0	0	21	No	NA	-	
nic VALIANT THORACIC (32mmx2	32	9	Y	N	-	0	1	0	0	0	0	0	20	No	NA	-	
Medtronic VALIANT THORACIC	36, 34	25	Y	N	-	0	0	2	0	0	0	3	3	No	NA	-	3 m
nic VALIANT THORACIC (34mmx1	34	12	Y	N	-	0	0	0	0	0	0	0	19	No	1	-	
nith TX2 DISSECTION SET (32mm	32	6	Y	N	-	0	0	0	0	0	0	0	19	No	NA	-	
nic VALIANT THORACIC (24mmx1	24	20	Y	N	-	0	0	0	0	0	0	0	18	No	NA	-	
Medtronic VALIANT THORACIC	38	6	Y	N	-	0	0	0	0	0	0	0	19	No	NA	-	
Medtronic VALIANT THORACIC	46	8	Y	N	-	0	0	2	1	0	0	0	18	No	NA	-	
Medtronic VALIANT THORACIC	34	7	Y	N	-	0	0	0	0	0	0	0	3	No	NA	-	3 m
Medtronic VALIANT THORACIC	34	5	Y	N	-	0	0	0	0	0	0	0	15	No	2	-	
Medtronic VALIANT THORACIC	34	10	Y	N	-	0	0	2	1	0	0	2	15	No	2	-	
nic VALIANT THORACIC (42mmx2	42	5	Y	N	-	0	0	0	1	0	0	0	15	No	NA	-	
nic VALIANT THORACIC (40mmx1	40	10	Y	N	-	0	0	0	0	0	0	0	15	No	NA	-	
nic VALIANT THORACIC (36mmx1	36	11	Y	N	-	0	0	0	0	0	0	0	14	No	2	-	
nic VALIANT THORACIC (44mmx1	44	8	Y	N	-	1	0	0	0	0	0	1	28	No	NA	-	
Medtronic VALIANT THORACIC	36	9	Y	N	-	0	0	0	1	0	0	0	15	No	NA	-	
Medtronic VALIANT THORACIC	34	15	Y	N	-	0	0	0	0	0	1	0	15	No	NA	-	
Medtronic VALIANT THORACIC	38	20	Y	N	-	0	0	0	0	0	0	0	14	No	2	-	
Medtronic VALIANT THORACIC	34	10	Y	N	-	0	0	0	0	0	0	0	15	No	2	-	
Medtronic VALIANT THORACIC	34	8	Y	N	-	0	0	0	0	0	0	0	12	No	NA	-	
Medtronic VALIANT THORACIC	32	8	Y	N	-	0	0	0	0	0	0	0	4	No	NA	-	4 m
Medtronic VALIANT THORACIC	36	7	Y	N	-	0	0	0	1	0	0	0	13	No	NA	-	
Medtronic VALIANT THORACIC	36	12	Y	N	-	0	0	0	1	0	0	0	12	No	NA	-	1
Cook Zenith TX2 (30mmx80mm)	30	7	Y	N	-	0	0	0	1	0	0	0	9	No	NA	-	9 m
Medtronic VALIANT THORACIC	38	10	Y	N	-	0	0	0	0	0	0	0	12	No	NA	-	
Medtronic VALIANT THORACIC	34	14	Y	N	-	0	0	0	0	0	1	0	11	No	2	-	
Medtronic VALIANT THORACIC	40	-	N	Y	Viceral	0	0	0	1	1	0	0	-	-	NA	-	
Medtronic VALIANT THORACIC	36	18	Y	N	-	0	0	0	1	0	0	0	6	No	NA	-	7 m
nic VALIANT THORACIC (28mmx1	28	7	Y	N	-	0	0	0	0	0	0	0	10	No	2	-	
nic VALIANT THORACIC (32mmx1	32	12	Y	N	-	0	0	0	0	0	0	0	10	Retrograde	2	-	
nic VALIANT THORACIC (32mmx2	32	16	Y	N	-	0	0	0	0	0	2	0	9	No	2	-	
nic VALIANT THORACIC (34mmx1	34	18	Y	N	-	0	0	0	0	0	0	0	8	No	3	-	
nic VALIANT THORACIC (32mmx1	32	3	Y	N	-	0	0	0	0	0	0	0	8	No	2	-	
Medtronic VALIANT THORACIC	38	-	Y	Y	Cerebral	1	0	2	0	0	0	0	-	No	NA	-	
Medtronic VALIANT THORACIC	34, 38	5	Y	N	-	0	0	0	0	0	1	0	5	No	NA	-	
Medtronic VALIANT THORACIC	34	4	Y	N	-	0	0	0	0	0	0	0	4	No	NA	-	
Cook Zenith TX2	30	3	Y	N	-	0	0	0	0	0	0	0	4	No	NA	-	
Medtronic VALIANT THORACIC	40	3	Y	N	-	0	0	0	0	0	0	0	3	No	NA	-	
Medtronic VALIANT THORACIC	42, 44	4	Y	N	-	0	0	0	0	0	0	0	3	No	NA	-	
Medtronic VALIANT THORACIC	38	4	Y	N	-	0	0	0	0	0	0	0	3	No	2	-	
Medtronic VALIANT THORACIC	38, 42	10	N	N	-	0	0	0	1	0	0	0	2	IA	NA	Extension	
Cook Zenith TX2 (28mmx80mm)	28	4	Y	N	-	0	0	0	0	0	0	0	1	No	2	-	
Medtronic VALIANT THORACIC	40, 42	14	Y	N	-	0	1	2	1	0	2	0	1	No	NA	-	
Medtronic VALIANT THORACIC	36	16	Y	N	-	0	0	2	1	0	3	0	1	No	NA	-	
Medtronic VALIANT THORACIC	34	6	N	N	-	0	0	0	0	0	0	IB	1	IB	NA	-	

LIST OF ABBREVIATIONS

TEVAR	–	Thoracic EndoVascular Aortic Repair
DTA	–	Descending Thoracic Aorta
CFA	–	Common Femoral Artery
CCA	–	Common Carotid Artery
LSA	–	Left Subclavian Artery
CSF	–	CerebroSpinal Fluid
GA	–	General Anaesthesia
LA	–	Local Anaesthesia
BAI	–	Blunt Aortic Injury
TBAD	–	Type B Aortic Dissection
DTAA	–	Descending Thoracic Aortic Aneurysm
TAAA	–	Thoraco-Abdominal Aortic Aneurysm
COPD	–	Chronic Obstructive Pulmonary Disease
CAD	–	Coronary Artery Disease
PAD	–	Peripheral Artery Disease
CVD	–	CerebroVascular Disease
FL	–	False Lumen
TL	–	True Lumen
CIN	–	Constrast Induced Nephropathy