EVAR in Hostile Aortic Neck; indications outside the IFU’s

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ABSTRACT

Aim: The aim of this study was to evaluate the outcome of unselected, real-world patients with ‘‘off-label’’ proximal necks treated with endovascular repair (EVAR). Patients and Methods: This is a retrospective study of 9 patients with AAA who underwent endovascular repair over a period of 18 months from January 2013 and were followed up for one year. All patients had an aortic neck that had challenging anatomy either short (less than 10 mm) (n=4) or severely angulated (more than 60°) (n=5). None of them had more than 50% of the neck circumference lined by mural thrombus. None of the patients had a conical neck. The follow-up protocol included physical examination, duplex-ultrasound scan (DUS), and CT at 30 days. Results: During the study period, 9 patients underwent standard EVAR. They were 7 men and 2 women with an age range of 56 to 74 with a mean of 65 years. All of them had one or more comorbidities such as: Diabetes (n=3), hypertension (n=5), coronary artery disease (CAD)(n=4), COPD (n=2) and previous laparotomy (n=1). The device that was used is the Endurant II® (Medtronic, Santa Rosa, CA, USA). Immediate technical success was achieved in all cases. One patient had acute myocardial infarction and one had temporary renal dysfunction within 30 days. At 1-year follow-up, 1 patient suffered a type Ia endoleak which required a proximal aortic extension, and 1 had an acute iliac limb occlusion, treated by surgical thromboendarterectomy. Conclusion: This study presents some limitations; it is a non-randomized retrospective study with a small number of patients. Also, a longer follow-up would be needed to confirm the durability of EVAR in patients with hostile aortic necks. We do confirm the notion that this minimally invasive procedure can be performed safely and effectively in patients with challenging neck anatomy. Keywords: EVAR, AAA, endoleak

INTRODUCTION

The link between aortic neck anatomy and the development of complications, such as type Ia endoleak and endograft migration, has been evident since the inception of EVAR in the early 1990s. 2-4 A short infrarenal neck length and excessive aortic neck angulation can compromise the proximal fixation and sealing of the EVAR device, both in the immediate and the long term. Neck diameter is also important whether absolute (in cylindrical necks) or relative (i.e. conical necks). The presence of mural thrombus in the proximal neck and the amount of calcium in its wall also contribute to unfavorable neck anatomy. 5

A neck length of 15 mm is generally considered to be the minimum requirement for reliably achieving adequate infrarenal graft fixation especially for new generation devices. Neck lengths shorter than 15 mm are associated with higher rates of early and late type Ia endoleaks, with approximately 10% to 40% requiring intraoperative proximal aortic cuff deployment. Equally, severe aortic neck angulation affects proximal fixation. Conventional wisdom is that neck angulation greater than 45 to 60 degrees constitutes a relative contraindication for use of AAA endografts. 6

PATIENTS AND METHODS

This is a retrospective study of 9 patients with AAA who underwent endovascular repair over a period of 18 months from January 2013 and were followed up for one year.

All patients had an aortic neck that had challenging anatomy either short (less than 10 mm)(n=4) or severely angulated (more than 60°) (n=5). None of them had more than 50% of the neck circumference lined by mural thrombus. None of the patients had a conical neck.

Preoperative Planning

CT angiography was performed using a multidetector CT scan with and without contrast
medium during the arterial and venous phases, at a thickness of 1 mm. All measurements (diameter, length, and angles) were performed using a workstation with dedicated reconstruction software and center lumen line (CLL) reconstruction. Post-analysis included three-dimensional (3D) volume rendering, preoperative simulated angiographic projections, and multiplanar reconstruction. In particular, AAA neck length was defined as the longitudinal distance between the first transverse computed tomography (CT) section directly distal to the lowermost renal artery and the first transverse CT section that showed at least a 15% larger outer aortic wall diameter, whereas infrarenal AAA neck angulation was defined as the true angle between the longitudinal axis of the proximal AAA neck and the longitudinal axis of the AAA lumen as analyzed on three-dimensional CT reconstructions.

**End Points**

The end points were 30-day and 1-year technical and clinical success. Primary technical success was defined as successful passage of the delivery system through the iliac vessels, the correct deployment of the device, the appropriate positioning of the contralateral limb, and the complete withdrawal of the delivery system in the absence of surgical conversion, mortality, type Ia, Ib, or III endoleaks, and migration (> 5 mm displacement) or stent-graft limb occlusion in the first 24 hours after surgery. The post-operative patency of renal arteries was assessed by duplex scan upon discharge.

Clinical success was defined as the absence of intraoperative, 30-day, or in-hospital mortality or any significant morbidity such as aneurysm rupture, major adverse event (MAE), minor adverse event. Acute myocardial infarction (AMI), respiratory complications requiring invasive mechanical ventilation, and renal dysfunction (RD) were considered as MAE. All other medical conditions were registered as minor. AMI was suggested by electrocardiographic changes and confirmed by the elevation of cardiac enzymes, regardless of symptoms. RD was defined as a rise in serum creatinine exceeding the baseline value by 30% and surpassing an absolute level of 2.0 mg/dL.

The follow-up protocol included physical examination, duplex-ultrasound scan (DUS), and CT at 30 days.

**RESULTS**

During the study period, 9 patients underwent standard EVAR. They were 7 men and 2 women with an age range of 56 to 74 with a mean of 65 years. All of them had one or more comorbidities that made the endovascular option more appealing than open surgical repair such as: Diabetes (n=3), hypertension (n=5), coronary artery disease (CAD) (n=4), COPD (n=2) and previous laparotomy (n=1).

An epidural anesthetic was used in 3 (33.3%) of patients, while all other cases were performed under general anesthesia. Bilateral surgical cutdown to both groins were performed in all patients.

The stent-graft device that was used is the Endurant II® (Medtronic, Santa Rosa, CA, USA). Immediate technical success was achieved in all cases.

At 30-day follow-up, no endoleaks, reintervention, stent-graft migration, or AAA-related mortality were observed. One patient had AMI and one had temporary RD. All patients completed the 1-year follow-up. No AAA-related death or AAA rupture was reported. At 1-year follow-up, 1 patient suffered a type Ia endoleak due to downward stent graft migration which required a proximal aortic extension, and 1 had an acute iliac limb occlusion, treated by surgical thromboembolectomy.

**DISCUSSION**

Some authors who evaluated first-generation devices concluded that application of endografts outside anatomically specific IFU variables had an incremental negative effect on late results, indicating that adherence to the IFU guidelines was appropriate to clinical practice when using such devices. 7

The outcomes of EVAR with the newer generations of devices, which have different profiles and more active fixation mechanisms, are still unknown beyond the IFU. 8

In our series the outcomes of the patients compare favorably with those from other series internationally.

In a German series of 177 consecutive patients with AAA's who were treated by the Endurant stent-graft the 30-day rate of type I endoleak was higher amongst the 56 patients with off-label use
compared with no type I endoleak amongst the 121 patients within the IFU (2 patients, 3.6% vs. 0 in IFU). Nevertheless, after a follow-up of 1 year, this finding did not affect the results in terms of survival or freedom from any device-related reintervention.  

Similarly, AbuRahma and colleagues concluded that late reinterventions were no more frequent in patients with a very short proximal aortic neck, despite a higher rate of early and late type I endoleak.  

In a study from the Netherlands severe neck angulation had no effect on the midterm outcomes as long as there was adequate length of the aortic neck.  

In studies mentioned above, the presence of a ‘‘hostile proximal aortic neck,’’ as defined by the manufacturer’s IFU, did not not significantly affect short- and mid-term clinical success.  

The prevalence of severe comorbidities amongst our population would call for more demand for EVAR procedures regardless of their compatibility to devices’ IFU.  

The use of branched or fenestrated endografts is clearly a suitable alternative to standard EVAR in patients with challenging necks. However, we should take into account an obvious increase in costs compared with standard grafts, and a non-negligible risk of reoperation because of branch-related complications.

**CONCLUSION**

This study presents some limitations; it is a non-randomized retrospective study with a small number of patients.

Also, a longer follow-up would be needed to confirm the durability of EVAR in patients with hostile aortic necks. We do confirm the notion that this minimally invasive procedure can be performed safely and effectively in patients with challenging neck anatomy.

**REFERENCES**

TEVAR in Uncomplicated Acute Type B Aortic Dissection

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ABSTRACT

Aim: TEVAR in uncomplicated Acute Type B Aortic Dissection can be performed safely and may reduce late false lumen expansion and mortality compared to best medical therapy (BMT) alone. Methods: This is a retrospective study in which six patients had endovascular treatment (TEVAR) for uncomplicated Acute Type B Aortic Dissection over a period of 12 months starting from January 2015 with a mean follow-up six months (range from 4 to 15 months). The initial goals for BMT were to reduce SBP to 100 - 120 mm Hg and pain relief. All of the patients had an initial CT angiogram on admission to confirm the diagnosis and to exclude rupture and malperfusion and to plan the endovascular intervention. Follow up CT scans were obtained to exclude rapid progression of the size of the false lumen. The devices used were Zeinth® TX2® (Cook Medical, Indiana, USA) in 4 patients and Relay Plus® (Bolton Medical, Werfern Group, USA) in 2 patients. Results: By the time of intervention all our patients were treated at their subacute phase (i.e. between 14 and 90 days). The left subclavian artery had to be covered in four out of six patients. None of them developed ischemic symptoms in their arms. A proximal Type I endoleak was evident on the completion angiogram in two patients which necessitated ballooning in one patient and a proximal aortic cuff in the other. The postoperative course was uneventful with no endograft related complications and no clinical evidence of spinal cord ischemia. There were no in-hospital or 30-day mortality rates. One patient (16.6%) died after six months from the intervention. Follow up CT scans done 1month, 3months and 6months after discharge revealed no increase in the maximum aortic diameter and total complete thrombosis of the false lumen in all patients. Conclusion: This study has many limitations. First being a single center retrospective study. Second, limited number of patients enrolled and also a short duration of follow-up, yet it represents an addition to case collection of proven efficacy and safety to manage those cases with type B aortic dissection. Keywords: Type B Aortic Dissection, TEVAR, False Lumen

INTRODUCTION

An intimal tear is the inciting pathology of an aortic dissection, with a cleavage plane affecting the intima and media of the arterial wall and propagating to some degree, either antegrade or retrograde.1,2

The typical type B dissection has an intimal tear that originates within few centimeters of the takeoff of the left subclavian artery, attributable to the large pressure fluctuations per unit time notoriously occurring in this area.3-5

Several imaging modalities are used in the diagnostic evaluation of aortic dissection, with computed tomographic angiography(CTA) and magnetic resonance imaging (MRI/MRA) having the highest sensitivity and specificity for diagnosis.

In spite of its higher sensitivity and specificity, MRI is more expensive with more time consumption in such acute pathology.6-11 Current consensus holds that patients with complicated Acute Type B Aortic Dissection (cATBAD) could be treated with thoracic endovascular aortic repair (TEVAR), leading to better in-hospital survival than open surgery.12-16

In an interdisciplinary expert consensus document on management of Type B Aortic Dissection the following suggestions were made to define complicated dissection as having one or more of the following:

- Malperfusion is indicative of impending organ failure (spinal, iliac, or visceral arteries) and must be recognized early. Diagnosis of static or dynamic organ malperfusion is corroborated by laboratory markers (bilirubin, amylases, lactate dehydrogenase, creatine phosphokinase and serum creatinine) and imaging data.
• Refractory Hypertension which is defined as failure of control despite full medical therapy
• Increases in periaortic hematoma and hemorrhagic pleural effusion in 2 subsequent CT examinations during medical expectant management of acute type B aortic dissection are findings suggestive of impending rupture.14

Approximately 25% of patients presenting with acute type B aortic dissection are complicated at admission by malperfusion syndrome or hemodynamic instability, resulting in a high risk of early death if untreated.12,15,16

Patients with uncomplicated Acute Type B Aortic Dissection (uATBAD) are commonly treated with conservative therapy (best medical treatment [BMT]). However, the long-term outcome of medical therapy alone is suboptimal17 with a reported 30% to 50% mortality rate at 5 years and a delayed expansion of the false lumen in 20% to 50% of patients at 4 years.18

Subgroup analysis showed that a thrombosed false lumen predicts lower event rates with ATBAD19 and favorable false lumen remodeling after TEVAR.20-22

METHODS

This is a retrospective study in which six patients had endovascular treatment (TEVAR) for uncomplicated Acute Type B Aortic Dissection over a period of 12 months starting from January 2015 with a mean follow-up six months (range from 4 to 15 months).

We used the following classification to define types of dissection according to the duration:23
Acute dissection: <15 days and Subacute dissection: 15-92 days while Chronic dissection: > 92 days.

There were four men and two women with an age range of 56-72 years and a mean of 64. The only presenting symptom was acute onset of chest pain with negative screening for acute coronary syndromes using the three consecutive sets of cardiac enzymes and frequent ECG tracings. They all had hypertension (> 140/90 mmHg) on admission but only three of them were known to be hypertensive prior to admission.

Their high blood pressure was controlled in the critical care unit. Antihypertensive medications (calcium-channel blockers, nitroglycerine, b-blockers, or a combination) were administered to all patients, and were able to control pressure to the goal value within the initial 3 days. The initial goals for BMT were to reduce SBP to 100-120 mm Hg and pain relief. For persistent chest pain, after blood pressure control, a narcotic analgesic (morphine hydrochloride) was prescribed.

There were no symptoms or signs of branch vessel malperfusion involving the lower extremities, the bowels or the kidneys, nor neurological deficit. There were no lab markers indicative of ischemic bowel, failing kidneys or skeletal muscle infarction (e.g. rising serum lactate, creatinine and/or CPK levels).

All of the patients had an initial CT angiogram on admission to confirm the diagnosis and to exclude rupture and malperfusion and to plan the endovascular intervention. Follow up CT scans were obtained to exclude rapid progression of the size of the false lumen which would’ve been indicative of impending rupture. The endografts that were used to repair these dissections were Zenith® TX2® (Cook Medical, Indiana, USA) in 4 patients and Relay Plus® (Bolton Medical, Werfern Group, USA) in 2 patients. They ranged in diameter from 24-36 mm and they ranged in length from 120-200mm. They were all introduced via a single groin cutdown mostly on the left side in five patients and in one patient we went through the right groin because of a tight iliac stenosis on the left side. A right brachial artery access was used in all patients to introduce a pigtail catheter for angiographic purposes. A transesophageal echo cardiogram (TEE) was used in all patients to confirm the presence of the guide wire in the true lumen.

Our end-points were all cause and aorta specific mortality rates, the absence of maximum aortic diameter progression and shrinking of the false lumen.

RESULTS

The initial CT angiogram revealed the site of the proximal entry tear to be within 2 cm of the takeoff of the left subclavian artery in all patients. The size of the proximal entry tear was more than 1 cm in two patients. The false lumen diameter was 22 mm or more in three patients.

By the time of intervention all our patients were treated at their subacute phase (i.e. between 14 and 90 days). The left subclavian artery had to
be covered in four out of six patients to ensure adequate seal in the proximal landing zone. None of these four patients developed ischemic symptoms in their arms in their postoperative period and consequently we did not have to do a Carotid-Subclavian bypass.

A proximal Type I endoleak was evident on the completion angiogram in two patients in whom the left subclavian artery was already covered which necessitated ballooning in one patient and a proximal aortic cuff in another patient and that was sufficient to achieve a good seal at the proximal landing zone without encroaching on the origin of the left Common Carotid Artery. The postoperative course was uneventful with no endograft related complications and no clinical evidence of spinal cord ischemia. There were no in-hospital or 30-day mortality rates. One patient (16.6%) died after six months from the intervention and although we couldn’t determine whether or not it was aorta related but it may be worth mentioning that this particular patient was known to have ischemic heart disease. Pre-discharge CT scans revealed complete thrombosis of the false lumen in four out of six patients (66.6%) with 2 patients having incomplete thrombosis of their false lumen. Incomplete thrombosis was defined as the presence of blood flow in any portion of the false lumen parallel to the stent graft, and complete thrombosis was defined as absence of blood flow in any portion of the false lumen parallel to the stent graft.

After discharge, all patients with hypertension were treated with calcium antagonists, angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, or β-blockers (either alone or in combination) to maintain the morning SBP (140 mm Hg or less).

Follow up CT scans done 1 month, 3 months and 6 months after discharge revealed no increase in the maximum aortic diameter and total complete thrombosis of the false lumen in all patients.

DISCUSSION

In our modest experience thoracic endovascular repair inpatients with uncomplicated acute type B aortic dissection (uATBAD) was safe and effective. However, the benefit of this type of treatment does not become apparent before two years. This is supported by evidence from prospective randomized studies such as the INSTEAD trial which demonstrated that endovascular repair had no advantage over best medical therapy in the first two years. However, the extended follow-up of those same patients (INSTEAD-XL) revealed higher aorta related mortality rates in the BMT only study arm. Similar outcomes after five years were suggested by Fattori et al from the IRAD (international registry of aortic dissections) database analysis which reflects “real-world” scenario.

Our results compare favorably with the 1-year results of the ADSORB trial (multicenter randomized European trial) that showed more frequent false lumen thrombosis and aortic remodeling in those patients treated medically plus TEVAR compared to those managed only medically. Although it was not intended but by the time of intervention, all our patients fell into the subacute category (14-90 days) and this may have aided in improving the outcomes as there is a growing body of evidence that prophylactic TEVAR in uATBAD cases if done in the subacute phase reduces the incidence of retrograde dissection (which could be fatal) and at the same time has no disadvantage (compared to acute cases) regarding aortic remodeling.

Regarding the coverage of the left subclavian artery (LSA); some surgeons routinely perform LSA revascularization in these patients, whereas others do so prophylactically in certain circumstances (e.g., a dominant left vertebral artery, a previous left internal mammary coronary artery bypass graft, or absent right vertebral artery) and some do it only if symptoms develop after TEVAR. We decided to adopt the latter policy, and none of our patients had adverse outcomes from left subclavian artery coverage and therefore required no intervention.

Published reports show the baseline risks of adverse outcomes in patients who have TEVAR and LSA coverage are 6% arm ischemia, 4% spinal cord ischemia, 2% vertebrobasilar ischemia, 5% anterior circulation stroke, and 6% death. We were lucky enough not to have any cases of spinal cord ischemia however should paraparesis develop it should be emergently treated by CSF drainage and blood pressure augmentation as demonstrated by a recent study.
from the cardiovascular group in Emory University in Atlanta.\textsuperscript{31}

The ideal concept is to perform stent-grafting in this subgroup of patients with uATBAD prone to developing progression of the disease and future complications. A number of studies have suggested several prognostic factors of early or late adverse events such as the patency of the false lumen in the follow-up, an initial aortic diameter $\geq 4$ cm with a patent false lumen, an initial false lumen diameter $\geq 22$ mm in the proximal descending aorta, recurrent pain or hypertension, partial false lumen thrombosis and a proximal entry tear size $> 10$ mm.\textsuperscript{32}

**CONCLUSION**

This study has many limitations. First being a single center retrospective study. Second, limited number of patients enrolled and also a short duration of follow-up, yet it represents an addition to case collection of proven efficacy and safety to manage those cases with type B aortic dissection.

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