

Short Term Outcome of Endovascular Intervention in Patients with Aortic Diseases

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Abstract

Background: Open surgical repair (OSR) for thoracic aortic aneurysms (TAAs) is associated with a high perioperative morbidity and mortality, depending on the extent of repair. Also, as a result of the high mortality rates associated with OSR; stable patients with uncomplicated type B aortic dissection (AD) frequently obtain medical treatment.

Objectives To evaluate the efficacy and predictors of outcomes of early thoracic endovascular aortic repair in patients with uncomplicated type B aortic dissection and patients with thoracic aortic aneurysms.

Methods: A total of 50 patients from Benha University Hospital and National Heart Institute with uncomplicated type B AD and descending thoracic aortic aneurysm who underwent endovascular aortic repair in the period between 2017 and 2020 were included in the study.

Results: Of the 50 patients, 10 patients had a descending thoracic aortic aneurysm, and 40 patients had uncomplicated type B AD, the total mortality rate was 8% throughout the follow-up period. Procedure related complications were observed in 8% of the study population, where 4 patients developed type I endoleak, which resolved spontaneously during the follow-up period. Both death and endoleak occurred in subacute and chronic cases, while using TEVAR in acute AD and aortic aneurysms showed no complications.

Conclusion: Early thoracic endovascular aortic repair, along with optimal medical therapy, in uncomplicated type B aortic dissections and thoracic aortic aneurysms is associated with better outcome.

Introduction

Aortic dissection (AD) is a potentially life-threatening condition. Data on the epidemiology of AD are scarce. In the Oxford Vascular study, the estimated incidence of AD is 6/100,000 persons per year. This incidence is higher in men and increases with age.⁽¹⁾

The prognosis is worse in women, as a result of atypical presentation and delayed diagnosis. The most common risk factor associated with AD is hypertension, mostly poorly controlled.⁽²⁾

Aortic dissection (AD) is classified according to either De Bakey (Type I, II and III) or Stanford (Type A and B) classifications. Stanford classification takes into account the extent of dissection, rather than the location of the entry tear.⁽³⁾

Because of the high mortality rates associated with surgery, stable patients with uncomplicated type B dissection usually receive non-operative treatment. Approximately, 70% of type B aortic dissections are uncomplicated and are medically treated only which carries a 50% 5-year mortality rate.^(5,6)

Open surgical repair (OSR) for TAAs is associated with a perioperative paraplegia rate of about 2% and a mortality rate of approximately 10%, depending on the extent of repair.

Approval of the first endograft device by the U.S. Food and Drug Administration (FDA) was in 2005, thoracic endovascular aortic repair (TEVAR) has become the preferred approach for management of thoracic aortic pathology and has early mortality and morbidity advantage reported when compared with OSR of the thoracic aorta.⁽⁸⁾

In patients with suitable anatomy, TEVAR is now considered the first-line therapy for isolated aneurysms of the descending thoracic aorta.⁽⁹⁾ Also, TEVAR is recommended in treatment of complicated type B aortic dissection and should be considered in uncomplicated aortic dissection.⁽¹⁰⁾

The aim of this study is to evaluate the efficacy and predictors of outcomes of early thoracic endovascular aortic repair in patients with uncomplicated type B aortic dissection and patients with thoracic aortic aneurysms through 18 months follow up

2. Patients and methods

This study included 50 patients recruited from the patients with uncomplicated thoracic type B aortic dissection and descending aortic aneurysm who had expected life-span longer than 1 year and underwent endovascular aortic repair in National Heart Institute and Benha university hospital in the period between 2017 and 2020. Patients who had Femoral, iliac, or Aortic disease hampering catheterization, patients with a dissection involving the ascending aorta, patients with a history of bleeding diathesis, sepsis or endocarditis, and patients with severe valvular or CAD needed surgical intervention were excluded. The Ethical approval for research was obtained from the Research Ethics Committee, Faculty of Medicine, Banha University. Written informed consent was obtained from all participants. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

All patients were subjected to full history and physical examination. 12 lead ECG, chest X-ray, full echocardiographic evaluation were performed for all patients. CT scan was done for all patients including the whole aorta (thoracic and abdominal) and iliac-femoral axis.

Team of TEVAR included 2 interventional cardiologists, 1 cardiac surgeon and an anesthesiologist. The procedure was done under general anesthesia and mechanical ventilation using fluoroscopy with contrast injection and intra-operative transesophageal echo (TEE) for accurate positioning. In situations involving important aortic side branches (e.g. left subclavian artery), TEVAR was often preceded by limited surgical revascularization of these branches (the 'hybrid' approach)

Clinical follow-up data was collected at one, three, six, twelve and eighteen months thereafter. Clinical follow-up events included: death from all causes, Aorta related deaths, neurological deficits (stroke or TIAs), symptoms of chronic peripheral malperfusion syndrome (claudication, abdominal pain) and 2ry endovascular or surgical re-intervention. Multi-slice CT was performed at three and eighteen months after intervention, and according to the clinical situations, to detect procedure related complications e.g. presence of endoleak and its type, stent migration, and/or aneurysmal expansion of aorta

2.1. Primary outcome measures

The primary endpoints were technical success during implantation, 30-day all-cause mortality and surgical conversion.

2.2. Secondary outcome measures

The secondary endpoints were the number of procedure-related complications and secondary procedures. A complication was defined as any graft-related complication: endoleak, endotension, migration, kinking or thrombosis of the stent-graft.

3. Statistical Analysis

Analysis of the data obtained from the database was done by Statistical package for social sciences version 20 (SPSS 20) program.

Data was expressed in terms of frequency as numbers and percentages for categorical variables and as mean value \pm standard deviation (SD) or median for numerical variables.

4. Results

This prospective observational study included 50 patients whom were divided into two groups based on the nature of the aortic disease (*Table 1*).

Table (1): Distribution according to the nature of the aortic disease.

Nature of aortic disease		All patients
Number (%)		50 (100%)
Group (A)	Acute AD	18 (36%)
	Subacute AD	10 (20%)
	Chronic AD	12 (24%)
Group (B)	TAAAs	10 (20%)

Group A: Included 40 patients who had uncomplicated Type B-AD (uTBAD), 30 patients underwent absolute TEVAR and 10 patients needed a Hybrid technique. Patients presenting with acute AD were 18 patients, while patients presenting with subacute AD were 10 patients and those presenting with chronic AD were 12 patients.

Group B: Included 10 patients who had thoracic descending aortic aneurysm who underwent absolute TEVAR.

In our study population, male gender predominated (88% males versus 12% females), with mean age (56.9 ± 8.2). Smoking and elevated blood pressure were the predominant risk factors. 44 patients were hypertensives (88%) and the same number for smoking. Only 10 patients were diabetics (20%), while 32 patients had dyslipidemia (64%) and 16 patients had CAD (32%) (fig 1)

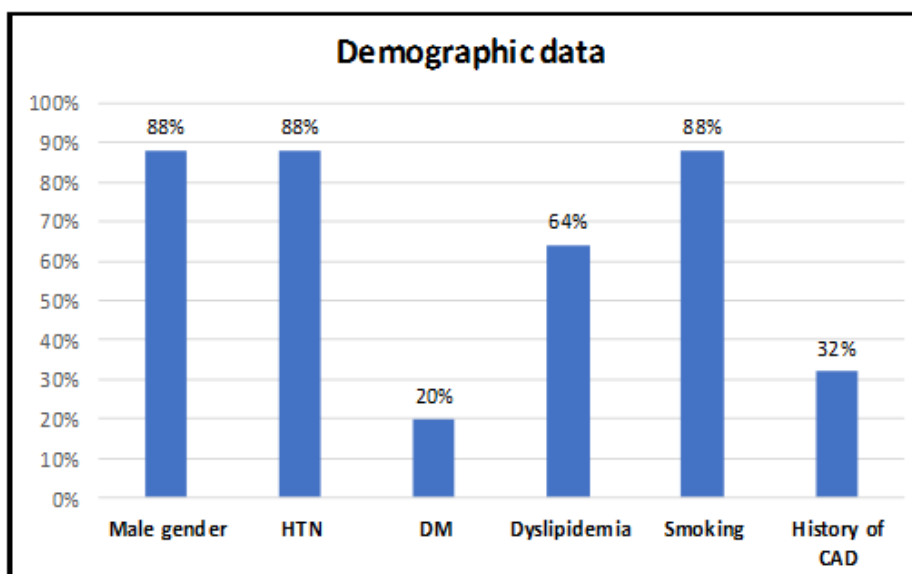


Fig (1): Distribution of the study cases according to history of hypertension, diabetes, dyslipidemia, CAD and smoking.

The outcomes after 18 months follow up

The median follow-up time was 18 months. None of the patients were lost during follow-up. 4 cases of type I endoleak (8%) were reported at 12 and 24 weeks, respectively, after the initial procedure, two of them had chronic AD, other two case had subacute AD. Both improved spontaneously during the first 12 months of follow up.

The mortality rate was (8%). 4 cases died during the first month of follow up period; all of them had chronic AD. The main causes of death were sepsis and acute kidney injury (Table 2 & fig 2,3). Complications reported mainly in patients who underwent hybrid technique (p-value 0.01). 4 out of the 10 cases that underwent hybrid technique died (all had chronic AD) and 2 cases developed type I endoleak (had subacute AD) (fig 4). None of neither thoracic aortic aneurysm cases nor acute cases of aortic dissection died or developed endoleak after the procedure.

Table (2): In-hospital and 18 months outcome of the whole study population.

In-hospital and 18 months outcome	All patients
Number (%)	50 (100%)

Outcome

● Stroke / TIA	0 (0%)
● Spinal cord ischemia	0 (0%)
● Death	4 (8%)
● Endoleak	4 (8%)
Re-intervention	0 (0%)

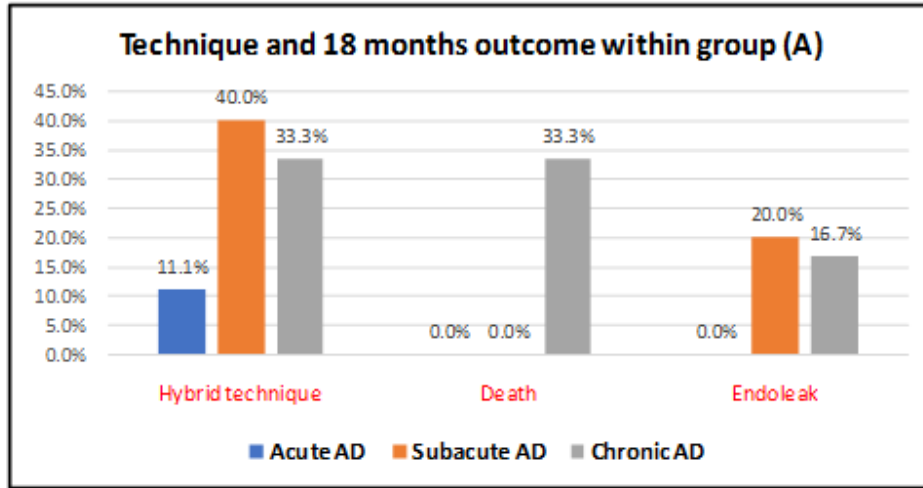


Figure (2): Technique & 18 months outcome within group (A)

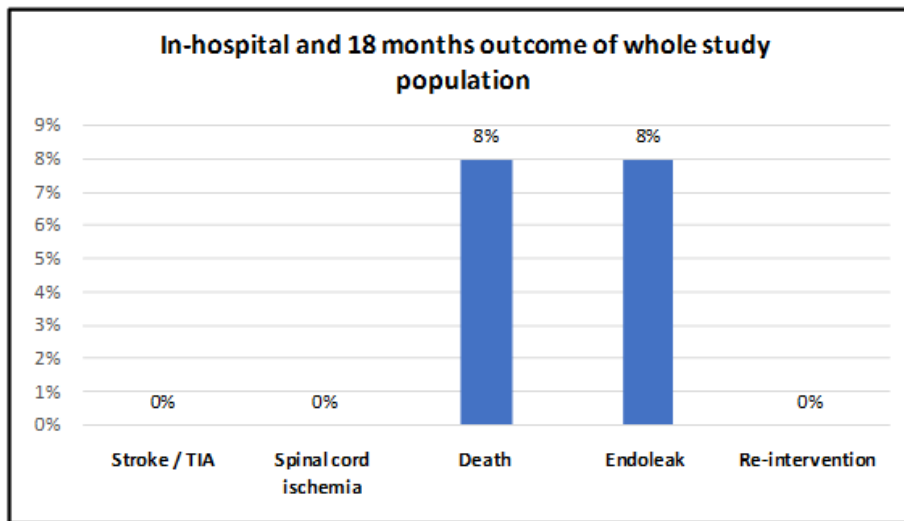


Figure (3): In-hospital & 18 months outcome of the whole study population

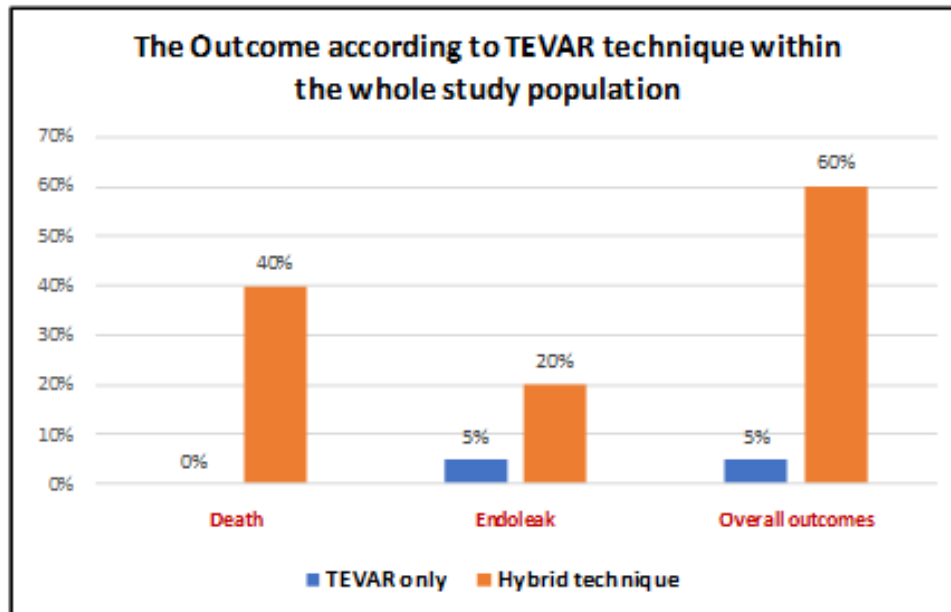


Figure (4):The outcome according to TEAR technique in the whole study population.

None of our patients developed stroke/TIA, spinal cord ischemia or graft-related complications (e.g. endoleak, migration, thrombosis and kinking). Also none of them underwent TEVAR re-intervention during the 18 months of follow up.

5. Discussion

Thoracic endovascular aortic repair (TEVAR) as a management option for type B aortic dissection patients is considered life saving in the setting of complications such as malperfusion syndrome or contained rupture⁽¹¹⁾, although its role in uncomplicated cases is not well known. Traditionally, stable patients are managed with medical treatment with annual survival $\geq 80\%$, however long-term outcomes are sobering because of aneurismal expansion and a 30% cumulative mortality at 5 years⁽¹²⁾. Consistently, false lumen perfusion is considered a signal of adverse outcome, whereas complete thrombosis of the false lumen may evoke remodeling and improve outcomes.⁽¹³⁾

The role of TEVAR as a treatment option of uncomplicated type B aortic dissection has remained a controversial debate. Although short-term results of conventional medical therapy have been acceptable, suboptimal long-term results have frankly been disappointing, with about (20%) of patients developing late complications requiring intervention and (30% - 40%) cumulative mortality risk at 5 years. The development of late aortic complications and compromised long-term survival have encouraged investigators to achieve a more effective therapeutic approach and evaluate the potential role of TEVAR in this patient population.⁽¹⁴⁾

- **TEVAR in aortic aneurysm**

In our study, All 10 cases underwent absolute TEVAR (Hybrid technique was not used in all cases). None of our patients were lost during follow-up. None of descending thoracic aortic aneurysm patients died or developed graft related complications (i.e. endoleak, thrombosis, endotension, migration, and kinking). None of our patients developed stroke or TIA, and no TEVAR re-intervention for graft related complications (i.e. re-endografting or conversion to open repair) was done during the 18 months of follow up in all sample cases.

- **our results were similar to that of several studies**

Patel et al. in VALOR trial, reported a superior 30-day and 1-year outcomes of TEVAR in patients considered low or moderate risk for OSR compared with surgical repair of descending thoracic aneurysms⁽²²⁾.

In VALOR II trial, Fairman RM et al. reported that TEVAR was an effective and safe treatment for patients with descending thoracic aortic aneurysms of degenerative etiology at the 1-year follow up⁽²³⁾.

In contrast to our results, the **MOTHER** (Aortic Pathology Determines Midterm Outcome After Endovascular Repair of the Thoracic Aorta: Report From the Medtronic Thoracic Endovascular Registry) Database, which included 670 patients with thoracic

aortic aneurysms, demonstrated that patients with TAA had a higher rate of elective adverse outcomes than patients with chronic type B aortic dissection (a higher incidence of stroke in patients with aneurysms).⁽²⁵⁾

In our study, all group B patients were males. **Jackson et al.**, in a study (using data of VALOR study) found that no gender-based differences were seen in all-cause mortality or in aneurysm-related death, although female patients had higher rates of periprocedural complications at the 1-year follow-up.⁽²⁴⁾

TEVAR in Aortic dissection:

Our study included 40 patients who had uncomplicated Type B-AD (uTBAD), 30 patients underwent absolute TEVAR and 10 patients needed a Hybrid technique. Patients presenting with acute AD were 18 patients, while patients presenting with subacute AD were 10 patients and those presenting with chronic AD were 12 patients.

In the present study, the primary technical success rate was excellent, with no primary conversion to surgery and the 30-day mortality was 10%. The median follow-up time was 18 months. None of the patients were lost during follow-up.

Findings were similar to that of several studies: in the **ADSORB trial**, which evaluated TEVAR + BMT vs. BMT alone in patients with acute type B AD, Hughes GC. demonstrated a zero neurological complications and aorta related mortality rates in both groups but aortic remodeling after one year was in favor of TEVAR.⁽¹⁷⁾ **Nienaber et al.** also reported in **INSTEAD XL Trial**, a study of survivors of type B aortic dissection, that TEVAR in addition to BMT was associated with delayed disease progression and improved 5-year aorta-specific survival.⁽¹⁸⁾

Siwen Wang, et al. in a study compared TEVAR in addition to BMT vs. BMT alone in patients with acute uncomplicated type B AD, found also a better long-term survival rate and favorable aortic remodeling

In our study, 4 cases developed type I endoleak, 2 of them had chronic AD and the other 2 cases had subacute AD. 4 cases died during the first month follow up; all of them had chronic AD. this means the complications were more evident in the non acute cases of AD

Benjamin P, et al. in the **MOTHER**, reported that lower elective mortality was observed in patients with chronic dissections. In the midterm, the all-cause mortality rate was 4.9 and 3.2 deaths per 100 patient-years for acute type B aortic dissection, and chronic type B aortic dissection, respectively. The rates of aortic-related death were 1.2 and 0.4 deaths per 100 patient-years for acute type B aortic dissection, and chronic type B aortic dissection, respectively.⁽²⁵⁾

In our study None of our patients developed stroke/TIA, spinal cord ischemia or graft-related complications (e.g. endoleak, migration, thrombosis and kinking). Also none of them underwent TEVAR re-intervention during the 18 months of follow up.

Nienaber et al. also reported in **INSTEAD XL Trial**, a study of survivors of type B aortic dissection, that TEVAR in addition to BMT was associated with delayed disease progression and improved 5-year aorta-specific survival.⁽¹⁸⁾ **Oikonomou et al.** also, reported also that early TEVAR enhances false lumen thrombosis, provokes remodeling of the aortic wall and should be considered preventively in selected patients with suitable anatomy.⁽¹⁹⁾ **Bell et al.** reported low rates of reintervention after TEVAR and a low risk of complications, particularly neurological complications. They therefore encouraged the use of endovascular approach for certain aortic arch and descending aortic pathologies, particularly in elderly patients.⁽²¹⁾

In contrast to our study: **Booher AM, et al.** reported in the international registry of acute aortic dissections (IRAD) that placement of an endograft in the acute setting increased the risk for retrograde type A dissection, distal malperfusion, stroke and paraplegia.⁽¹⁵⁾

Luebke T, et al., demonstrated that TEVAR may not be the treatment of choice in all patients with uncomplicated type B AD because of the intrinsic periprocedural and stent graft induced complications.⁽¹⁶⁾

6. Conclusion

According to our study, early TEVAR in acute cases with uTBAD and thoracic aortic aneurysms along with optimal medical therapy has a favorable outcome. Also, we noticed that complications were more common when TEVAR was accompanied by hybrid technique, so more caution should be taken when we use TEVAR in these circumstances.

7. Recommendation

Optimal treatment strategy for uncomplicated type B AD and thoracic aortic aneurysm requires further investigations and randomized clinical trials (with large number of patients and extended follow up) that will focus on the prognostic factors of early and late complications and the timing of intervention.

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