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Original Article

# The early- and mid-term results of our endovascular aneurysm repairs in thoracic aortic pathologies

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**Abstract**

**Aim:** Endovascular therapy can be an alternative option to open surgical treatment in high-risk patients with dissecting or pure aneurysmal dilation of aorta. Endovascular therapy is associated with less complication rates, as well as shorter hospital stay and favourable blood products need perioperatively when compared to those in open surgical treatment. Our study aims to present a single center experience by evaluating the early and midterm follow-up results of thoracic endovascular aortic repairs (TEVAR).

**Material and Methods:** Nineteen patients who underwent TEVAR procedure between March 2005 and March 2011 were evaluated retrospectively. Pre- and postoperative blood samples and computerized tomography angiograpy (CTA) results were compared. The type of stent graft used, need for blood product, postprocedural complications were evaluated.

**Results:** The patients' mean length of hospital stay was 12,8±6.5 days. The mean age was 56.1±8.7 years. Two patients (10.5%) were urgently taken to operation; one of these (5.2%) was exitus on the postoperative day 7. None of the patients developed thrombo-embolic or neurological complication. Three patients (15.7%) developed endoleaks in their early-term follow-up whereas none had endoleaks in their mid-term follow-up. There was a statistically significant difference between the preoperative and postoperative hemoglobin and hematocrit values of the patients ($p<0.05$).

**Conclusion:** Endovascular aneurysm repair in thoracic aortic pathologies can be an alternative to surgery in suitable cases. However, we are of the opinion that the experience of surgical team to perform this procedure with this subject will be useful in reducing the complication rates.

**Keywords**: Thoracic; aorta; endovascular; TEVAR.

## INTRODUCTION

A number of open surgical techniques are defined for patients with aortic aneurysm (AA), and these techniques are associated with high morbidity and mortality rates, especially in patients with severe comorbidities. While surgical resection of dissected thoracic aorta continues to be relevant in complicated cases, open surgery may show high mortality and morbidity despite the developing surgical techniques and perioperative patient treatments (1). Endovascular aneurysm repair has been widely adopted in both AAs and aortic dissections (AD) regardless of location (thoracic or abdominal), and has been put into practice as an alternative treatment option since it is a less invasive intervention than the conventional open surgery repair (2,3). In comparison of standard surgery with thoracic endovascular aortic repair (TEVAR), TEVAR has some advantages such as less blood loss and transfusion requirement, shorter procedural time, shorter length of intensive care unit and hospital stay, lower complication rates and shorter recovery times (4). Moreover, aorto-enteric fistula, pseudoaneurysm in the anastomosis site, intraabdominal adhesions and ileus, which are encountered in surgical series, have not been reported in follow-up results after TEVAR (5).

However, in many studies in which mid-term results regarding TEVAR have been published, it has been mentioned about various problems and complications such as endoleak, stent-graft migration, aneurysm rupture, post-procedural neurological sequelae, impairments in stent structure and limb ischemia (6,7).

The aim of this study is to report the early- and mid-term results of TEVAR carried out in our department on patients with AA and AD in the thoracic region.

## MATERIAL and METHODS

This study was conducted using retrospective data

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registry of 19 consecutive patients who underwent TEVAR between March 2005 and March 2011. The patients were evaluated retrospectively in terms of postoperative early- and mid-term complications. Postoperative early-term complications were defined as complications occurred within 6 months after the procedure whereas mid-term complications were accepted as those were seen 6 months to 1 year postoperatively. Informed consent form was obtained voluntarily from all the patients before the procedure. The procedures were carried out in company with an interventional radiologist in the angiography laboratory. A council decision was made in terms of TEVAR for patients with an aneurysm larger than the diameter of 5.5 cm. Since the aneurysms of five patients were located in the Zone 2, carotid-subclavian bypass was performed on these patients as a separate surgical session before the intervention. The proximal landing zones and complication rates in all the patients are shown in Table 1. The demographic data of the patients are given in Table 2.

**Table 1. Proximal landing zone and associated complication and re-intervention rates**

| Zone | Number of patient (n) | Percentage (%) | Complication (n) | Complication percentage (%) | Re-intervention (n) | Re-intervention percentage (%) | Mortality (n) |
|---|---|---|---|---|---|---|---|
| 2 | 5 | 26 | 2 | 10.5 | 1 | 5.2 | 1 |
| 3 | 7 | 37 | - | - | - | - | - |
| 4 | 7 | 37 | 1 | 5.2 | - | - | - |

**Table 2. The demographic data of the patients included in the study**

| | Mean/ Number* | Standard Deviation/Percentage* |
|---|---|---|
| Mean Age (years) | 56.1 | 8.7 |
| Mean Preoperative Systolic Blood Pressure (mmHg) | 142 | 9.9 |
| Mean Preoperative Diastolic Blood Pressure (mmHg) | 75.5 | 5.8 |
| Male Gender (n) | 17* | 89.4* |
| Diabetes mellitus (n) | 1* | 5.2* |
| Chronic Renal Failure | 1* | 5.2* |
| COPD history (n) | 1* | 5.2* |
| Smoking (n) | 16* | 84.2* |

**Preoperative Preparation**

Routine blood tests were sent from all the patients during their admission to the hospital. Along with the current tests of the patients, 3-mm-slice thoracoabdominopelvic computerized tomography angiographies (CTA) with 3-dimensional reconstruction were gathered to evaluate whether or not the dissection is extending to the abdominal aorta, and if so, from which lumen the major organ is fed, especially in the patients with Type B dissection. With these results, the patients were re-evaluated in the cardiovascular surgery and interventional radiology council for surgery or endovascular treatment, and the suitable stent graft was selected for patients who were decided to undergo endovascular treatment. Since the left subclavian artery would preferably be closed with stent-graft if the aneurysm of the patients also included the proximal part of the left subclavian artery, the elective patients with such pathology first underwent carotid-subclavian bypass, whereas in emergency cases, this procedure was performed after TEVAR procedure in the case of clinical necessity. As the need for open surgery could arise, the patients were prepared for this procedure prior to operation. Anxiolytic treatment was given to the patients a night before the operation (Alprazolam 0.5 mg). Cerebrospinal fluid (CSF) drainage catheter was placed according to the prediction of high paraplegia risk in all patients except emergent cases. High paraplegia risk was determined according to the possible extension of the graft between the T9-T12 levels of aorta from which arises arteria radicularis anterior magna (Adamkiewicz artery) of medulla spinalis. Electrocardiography, saturation pulse oximetry (SPO2), invasive artery monitoring from the right radial region were carried out on the patients. SPO2 of the patients was monitored from the upper left limb. The operation was performed under general anesthesia.

**Surgical Procedure**

The femoral artery access was the standart method in all of the cases. The femoral artery was exposed through a femoral incision from the side with suitable iliac anatomy. The Back-up Meier guide-wire was advanced up to the ascending aorta through the catheter by femoral arteriotomy. The location of the graft was precised upon the scopic evaluations. The catheter was pulled out and the graft was placed through an introducer sheat of appropriate diameter. While the graft was being placed, a Pigtail catheter either placed from a percutaneous axillary or percutaneous contralateral femoral access determined the output site of the left subclavian artery. If necessary, dilatation was carried out with balloon after the procedure. Direct subtraction angiography (DSA) imaging was performed to evaluate endoleak or stent graft patency. Either Medtronic Talent Valiant or Medtronic Talent Captivia or Gore TAG endovascular stent-grafts were used on our patients.

**Postoperative Care**

The patients were transferred to the intensive care unit to follow up mostly in extubated status. If the intubated

patients do not pose a risk for extubation, they were extubated as soon as their muscular strength came back to a sufficient level. The patients without problems were decided to be followed up in the ward on the postoperative day 1. Aggressive intravenous and oral antihypertensive medication were planned for the patients. The intravenous antihypertensive treatments were only given in the intensive care unit. The patients were transferred to the ward scheduled for oral antihypertensive treatment. The target systolic arterial blood pressure of the patients was determined to be 120 mmHg. During the first 24 hours following the operation, the patients were hydrated with 2000cc fluid daily in addition to oral intake. N-acetylcysteine medication was initiated to avoid the contrast nephropathy. The TEVAR patients were closely followed up in the early postoperative period especially for lower limb plegia. CSF drainage was performed on the patients to obtain a CSF pressure of 9-12 cmH2O. The CSF drainage catheter was removed within 48-96 hours postoperatively. In the patients with zone 2 localized aneurysm who underwent carotid-subclavian bypass procedure and in whom the left subclavian artery was closed with TEVAR graft, close ischemia follow-up was performed with physical examination and arterial doppler ultrasonography for the left upper limb during hospitalization. Low molecular-weight heparin (LMWH) and acetylsalicylic acid (ASA) treatment were initiated for the patients during the hospitalization period. The outpatient ischemia follow-ups of these patients were continued on the 1st week, 15th day and 1st month following the discharge. The LMWH + ASA treatment was continued in the patients for the first 15 days, LMWH was then discontinued and switched to dual antiplatelet treatment for 1 year (Clopidogrel + ASA). At the end of a year, only ASA treatment was given.

**Statistical Analysis**

The statistical analyses were made in the SPSS Software version 11.5 (SPSS Inc., Chicago, Illinois, USA) and MedCalc version 11.2.1.0 (MedCalc Software, Mariakerke, Belgium) statistical software. The continuous variables were expressed as mean ± standard deviation (SD) and the categoric variables were expressed as numbers and percentage (%). Normality distribution for continuous variables was evaluated using Kolmogorov-Smirnov test. The Paired-Samples T-Test and Wilcoxon test were used in the comparisons depending on whether the data were normally distributed or not. Categoric variables were compared using Chi-squared test. A probability value of $p<0.05$ was accepted as a statistically significant difference.

## RESULTS

2 of the patients (10.5%) had traumatic rupture. Two patients (10.5%) were followed up with type B dissection, 1 patient (5.2%) was followed up with penetrating ulcer accompanied by chronic rupture, and the remaining patients (n=14) (73.7%) were followed up with thoracic aortic aneurysm. The mean aneurysm diameter of the patients was 55.5±18 mm and the mean age was 56.1±8.7 years (ranging between 39-80 years).

TEVAR was perfomed in emergency conditions in two patients (10.5%). Both had aortic rupture at the thoracic segment. One rupture was due to intra-vehicle traffic accident while the other resulted from fall from the height.

Our patients' mean length of hospital stay was 12.8±6.5 days. The mean length of intensive care stay was 20.6±9.7 hours while the mean duration of intubation was 1.2±0.9 hours.

There was a significant difference between the preoperative and postoperative hemoglobin and hematocrit values of our patients ($p=0.03$ for hemoglobin, $p=0.02$ for hematocrit).

There was no statistically significant difference between the preoperative and postoperative creatinine, blood-urea nitrogen values ($p>0.05$).

None of the patients developed neurological or thromboembolic complications.

Endoleak complication was observed in a total of 3 TEVAR patients (15.7%) during the follow-ups. Two patients (10.5%) had Type I endoleak. One of the patients was treated by adding an extension graft to the distal end 6 months after the procedure. The probable reason of the endoleak was graft migration. Control CTA in the follow-ups revealed no endoleak. Balloon dilatation was performed to Type I endoleak in the second patient. No endoleak was detected after the procedure and the aneurysm sac of that patient was remained to be thrombosed during the follow-ups. However, in another patient with Zone 4 proximal landing zone (5.2%), Type II endoleak was observed, but this was observed to have disappeared during the further follow-ups. None of the eighteen patients had a newly developed endoleak during the mid-term follow-ups.

In 5 of our patients (26%), the stent-grafts were placed in "Zone 2" proximal landing zone. There were 7 patients (37%) with stent grafts placed in Zone 3. The stent-grafts of seven patients (37%) were located in Zone 4.

Five patients (26%) who had "Zone 2" landing zone underwent carotid-subclavian bypass operation before the procedure to avoid ischemic complications due to cclusion of left subclavian artery. The median time to TEVAR procedure from carotid-subclavian bypass was 5 days (2-8 days).

None of the patients developed acute or chronic renal failure in the early or late period. Only one patient (5.2%), who was scheduled for the procedure in emergency conditions, had chronic renal failure.

In our study, our mean patient follow-up time was 17.3±16.6 months and only number of 30-day mortality was 1 (5,2%). That patient with chronic renal failure had implantation in "Zone 2" under emergency conditions.

We used a total of 26 units of erythrocyte suspension and 24 units of fresh frozen plasma for our interventions.

## DISCUSSION

Endovascular aneurysm repair (EVAR) is a treatment modality that has been successfully used since 1990s. The idea of placing endograft in aneurysm sac through the main femoral arteries was introduced in the late 1970s and the first successful procedure was reported by Parodi et al. in 1991 in high-risk patients with abdominal aortic aneurysm (2). In the same period, EVAR was also tried in thoracic aortic aneurysms and again in 1991, it was successfully put into practise by Volodos et al. (3) in patients with thoracoabdominal aneurysm.

EVAR in aortic dissections was performed in a later period because of the need for interpretation of the early-term results in aneurysms and waiting for the completion of surgeon's learning curve. The first EVAR practise in AD's was simultaneously performed by Dake et al. (8,9) from the Stanford University and by Nienaber et al. from the Eppendorf University.

This treatment method, which has been used since 1990s in the world, started to be used in our country in 2000s and gradually became widespread. The efficacy of this method is still being investigated in several randomized clinical trials. The early- and mid-term results have been reported by the records such as UK Endovascular Aneurysm Repair (EVAR trial 1&2), Dutch Randomised Endovascular Aneurysm Management (DREAM), European Collaborators on Stent Graft Techniques for Abdominal Aortic Aneurysm Repair (EUROSTAR), Comparision of surveillance vs Aortic Endograftingfor Small Aneurysm Repair(CAESAR), Positive Impact of endoVascular Options for Treating Aneurysm earLy (PIVOTAL) (10). The results obtained from these studies have been reported by many authors as review studies (11,12). The general conclusion in the studies is that endovascular aneurysm repair in high-risk patients is associated with lower peroperative mortality and morbidity rates compared to surgical treatment. However, patient selection and determination of eligibility criteria are the limiting factors for endovascular treatments.

Endovascular interventions have become good alternatives to the conventional surgical therapies as the experiences in the endovascular procedures have improved. Endovascular interventions were reported as the first-line therapies after precise multidisciplinary assessment on the anatomy, pathology, comorbidity and predicted durability especially in the high-risk individuals according to the recent guidelines (13,14).

Many complications have been encountered in such a procedure that has been discussed so much in terms of its benefits and periodic results. Definitive diagnosis of endoleak and the resulting increase in the internal pressure, which are the major complications and their treatment planning still, raise question marks in minds. In a study by Veith et al. (15), it has been reported that the endoleak terminology needs new definitions since not all endoleaks can be detected. Pearce et al. (16) reported that intravascular ultrasound might be useful to be able to diagnose endoleak in EVAR and TEVAR, instead of CTA with too much radiation burden and invasiveness. By obtaining similar results, Badri et al. (17) also reported that color Doppler ultrasound was highly sensitive in determining the type of endoleak and also additional procedure whether or not is required. Although the use of ultrasound seems to be valuable in the aforementioned studies, more and extensive cohort studies are needed to fully understand the efficacy of this examination. We carried out all the controls of our patient group with CTA examination, which is more invasive than ultrasound. None of our patients showed opaque nephrotoxicity during the controls. Rayt et al. (18) conducted another interesting study for endoleak complication. In this study, it was demonstrated that conservative treatment did not increase the risk of aneurysm rupture in 362 patients with Type II endoleak. Veith et al. (15) have indicated that the incidence rate of Type I endoleak is between 0%-10% in all endovascular aneurysm repairs, whereas this rate is 10% to 25% in Type II endoleak. In our series, this rate was found to be 10.5% for Type I endoleak and 5.2% for Type II endoleak.

There are many studies on the neurological complications, the other complications of TEVAR procedure. In a study by Cheung et al. (19), it was reported that somatosensory evoked potential monitoring, continuous neurological evaluation, increased systemic arterial pressure and cerebrospinal fluid drainage might be useful to avoid this complication and to be able to take precautions in the early period. Again Mc. Garvey et al. (20) reported a new spinal cord protection model by increasing the blood pressure with vasopressor treatment and cerebrospinal fluid drainage after TEVAR. According to the European Society of Cardiology (ESC) 2014 Guidelines on the diagnosis and treatment of aortic diseases, CSF drainage was recommended as Class IIa in the high-risk patients (13). Consistent with this guideline, in the clinical practice guidelines of the European Society for Vascular Surgery (ESVS) on management of descending thoracic aorta prophylactic CSF drainage with the strength of Class IIa was recommended if the graft length would be 200 mm in TEVAR or there was previous history of abdominal aortic aneurysm repair which were both defined as high-risk (14). In our study, we also performed cerebrospinal fluid drainage through the CSF drainage catheter prior to TEVAR procedure. None of our patients developed paraplegia or associated neurological complication.

Carotid-subclavian bypass is a controversial issue in TEVAR interventions. Weigang et al. (21) recommended prophylactic carotisubclavian bypass or subclavian transposition to avoid ischemic complications if the left subclavian artery occlusion was inevitable. Caronno et al. (22) carried out TEVAR without performing caroticosubclavian bypass in their 11-patient experience and they found no ischemia or neurological sequel finding during the follow-up. Prophylactic carotid-subclavian bypass was the choice of treatment in our patient group if the left subclavian artery occlusion will be carried out.

The mortality rates are another issue that the researchers dwell on. Geisbüsch et al. (23) reported that renal failure, age>75 years and emergency procedures were independent risk factors in a study they conducted to determine the risk factors for mortality after TEVAR. Czerny et al. (24) investigated the effect of gender on mortality and reported that it was not a risk factor for mortality. Chung et al. (25) defined preoperative leukocytosis and aneurysm diameter as independent risk factors for late mortality.

Wang et al. (26) reported the TEVAR results in patients with impaired renal function, and indicated that especially the prognosis of emergency patients with a creatinine value of >2 mg/dL was poor. Huddle et al. (27) in this regard conducted another study. In this study, a pre-operative creatinine value of>1.5 mg/dL was reported to be a significant risk predictor for mortality. Dillavou et al. (28) also reported that increased preoperative creatinine levels were a predictive value for mortality or morbidity endpoints. Although the risk factor was not assessed in our study, a patient with chronic renal failure was exitus on the postoperative week 1. We think that this patient, the only mortality in our study, can be evaluated to be significant in terms of our mortality endpoint.

In the study of Arnaoutakis et al. (29) comparing open thoracic aortic surgery with TEVAR, it was indicated that TEVAR did not reduce the hospital costs but was associated with a reduction in mortality, length of intensive care and hospital stay. Patel et al. [30] reported that TEVAR shortened the length of hospital stay in non-traumatic ruptured aortic aneurysms in a cohort in which open surgery was highly risky. Again, in a study of Patel et al. (31), they compared TEVAR with open descending aortic surgery in patients aged >75 years, and reported that the duration of hospitalization was shorter in the TEVAR patients.

However, there are many limitations of this study. First, the patient cohort is too small to make specific considerations on this procedure. Moreover, this study was carried out in a single center in which procedures had recently been performed. This needed a learning curve that could be noted by increased blood product need postoperatively and longer mean hospital stay duration.

## CONCLUSION

In conclusion, TEVAR, which is superior to open surgery in eligible cases in terms of morbidity and mortality, is an alternative procedure to surgery that requires a certain learning curve. With the widespread use of technology and the diversity of procedures, it will possible to obtain more precise information about the reliability of the procedure from the long-term results of studies done with large populations.

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