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Original Article

Early and midterm outcomes of thoracic endovascular aortic repair with Lifetech Ankura™ thoracic endograft: A single tertiary center experience

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Abstract

Aim: Thoracic aortic pathologies describe a wide spectrum of potentially life-threatening diseases almost always in a comorbid aged patient cohort. Thoracic endovascular aortic repair (TEVAR) is a less invasive treatment choice, offering reduced mortality and morbidity compared to open surgery. We decided to reveal our experience over safety and efficacy data with Lifetech Ankura™ Thoracic endografts with early and midterm outcomes, retrospectivelytiology.

Material and Methods: Between January 2018 and January 2023, for a 5-year period, 203 patients who experienced TEVAR procedure with Lifetech Ankura™ Thoracic endograft were retrospectively evaluated. For the patients who required revascularization of the vessel branches originating from the aortic segments, all types of assistive techniques were performed. Intentional coverage of Left subclavian artery was also performed mostly in urgent patients.

Results: 251 endografts were implanted in 203 patients. The most frequent aortic pathologies were the thoracic aortic fusiform aneurysm (56.6%) and type B aortic dissection (25.6%), respectively. Early (30-day/in-hospital) mortality occurred in 9 patients in total (4.4%). Technical success rate was 100%, and there was no conversion to open surgery. No other major adverse event, including cerebral, cardiac, or renal complication requiring dialysis, was observed. The average intensive care unit time was 16.9±11 hours (2-160), length of stay was 5.1±3.2 days. CSF drainage was performed in 51 patients inserted before the procedure prophylactically (25.1%). All patients who survived the operation were followed for 18.6±9.3 months. In the follow up period, four patients needed extension for endoleaks and two additive petticoat procedures were performed. One patient who had TEVAR due to a malperfused type B aortic dissection in the acute phase experienced RTAD 2 weeks after the initial procedure.

Conclusion: TEVAR with LifeTech Ankura™ Thoracic Stent Graft system provides a safe, effective, and durable treatment with successful early outcomes and technical success. Wide spectrum in length and non-identical radiopaque proximal markers seem to facilitate some advanced endovascular skills. Long-term durability of the endograft should be tested.

Keywords: Aortic aneurysm, aortic dissection, endovascular aneurysm repair

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INTRODUCTION

Thoracic aortic pathologies describe a wide spectrum of potentially life-threatening diseases. This spectrum includes thoracic aortic aneurysms, Type B aortic dissections, blunt traumatic injuries (BTAI), saccular aneurysms, intramural hematomas and penetrating aortic ulcers. Despite the new surgical techniques and developments in neuromonitoring, open surgical repair in the treatment of thoracic aortic diseases has high mortality and morbidity rates. This rate is around 6-19% even in experienced aortic centers [1]. In this highly fragile patient population, especially in the advanced age group, the presence of existing comorbidities adversely affects the outcome of a technically successful surgical procedure [2].

Thoracic endovascular aortic repair (TEVAR) is a less invasive innovative treatment choice, offering reduced mortality and morbidity compared to open surgery [2]. Based on successful early results, all current guidelines have changed the primary treatment option to TEVAR in this patient group [1]. There are many TEVAR endograft brands with different characteristics. Today, three brands are serving in our country: Medtronic (Medtronic, Santa Rosa, CA, USA), MicroPort (MicroPort, Shanghai, China) and Lifetech (Lifetech, Shenzhen, China).

Etiological factors such as the type of aortic pathology, anatomical variations, connective tissue diseases and patient-specific comorbidities are the main variables that affect the results of endovascular interventions. Different brands of endografts differ from each other with their structural features, radiopaque markers, attachment sites, radial forces and materials. We decided to retrospectively review our experience with Lifetech Ankura™ Thoracic endograft, the safety and efficacy data of TEVAR procedures with this graft, as well as the early and mid-term outcomes for all thoracic aortic pathologies.

MATERIAL AND METHODS

The study protocol was approved by the Ankara City Hospital Clinical Research Ethics Committee (date/no: 15.12.2021 / E1-21-2224). 203 patients who underwent TEVAR procedure with Lifetech Ankura™ Thoracic endograft between January 2018 and January 2023 were evaluated retrospectively. TEVAR procedures with other brands of endografts were excluded from the study.

Preoperative patient data were reviewed. Thoracic aortic pathologies such as fusiform aneurysm, ruptured fusiform aneurysm, subacute-chronic type B dissection, complicated acute type B dissection, saccular aneurysm, BTAI (grade 2,3,4), intramural hematoma and penetrating aortic ulcer were determined. Comorbidities were distinguished as hypertension (HT), diabetes mellitus, hypercholesterolemia, coronary artery disease, chronic renal failure, chronic obstructive pulmonary disease (COPD), previous cerebrovascular event (CVE), and peripheral vascular disease. All patients were classified by the American Society of Anesthesiologists (ASA) physical status score.

To evaluate the "behavior" of the Lifetech Ankura™ Thoracic endograft in different situations, all procedures requiring advanced skill, emergency and elective cases that were performed in localizations from zone 1 to zone 6 were included in this study. Patients who experienced open repair for ascending aorta and arch with combined TEVAR procedures were excluded because this procedure was almost always performed with median sternotomy.

Life-Tech Ankura™ TAA stent graft (Lifetech Scientific, Shenzhen, China): This endograft has expanded polytetrafluoroethylene (e-PTFE) dual membrane material for biocompatibility and durability with a self-expanding nitinol endoskeleton (Figure 1).

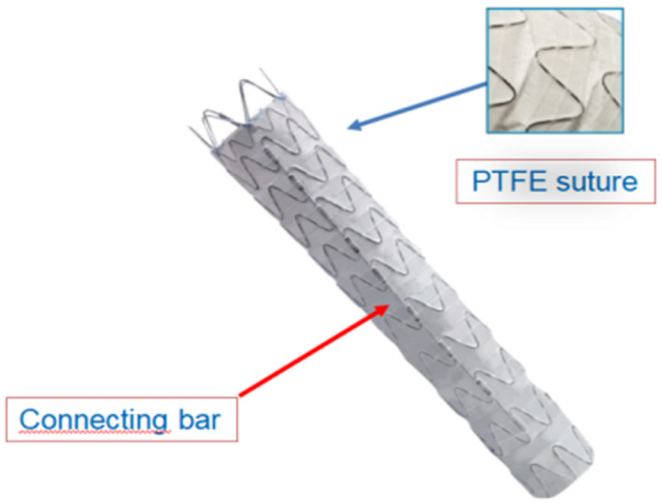


Figure 1. Lifetech Ankura™ thoracic endograft

On the proximal side there is a mini wave pattern in the first line for better apposition to the vessel wall. The graft material has no pinholes or sutures on the main body material avoiding pinhole leakage for graft integrity and durability. It has a connecting bar on the great aortic curvature side positioned under radiopaque marker "8", avoiding shortening and providing axial support.

Computed tomography (CT) was taken preoperatively for all patients. Measurements were made from 3D reconstructions of CT images using the 3D vascular imaging system (RadiAnt DICOM viewer v2021.2(64 bit)). When choosing the graft, up to 10% oversize was planned for BTAI and type B aortic dissections, and 10-20% for thoracic aortic aneurysms.

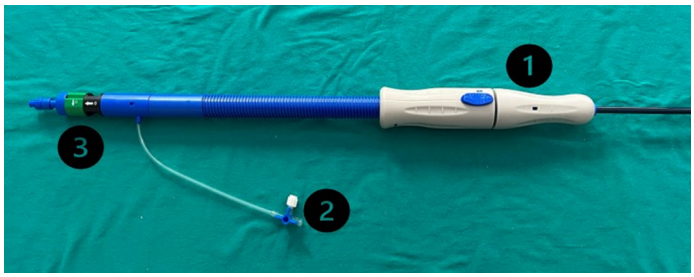


Figure 2. 1-Front handle, 2-Hemostatic valve, 3-Proximal releaser (black) and safe buckle (green)

Surgical Technique

All procedures were performed by the same cardiovascular surgery team in the angiography catheter laboratory. The patients were mostly given general anesthesia because general anesthesia allows the procedure to be more controlled and safe. Local anesthesia was preferred in the patient group where general anesthesia would be high risk. All assisted TEVAR techniques were used in patients requiring revascularization of vascular branches originating from the aortic segments: carotid-subclavian bypass (CSB), chimney (Ch-TEVAR), in-situ needle fenestration (I-TEVAR), and SMFSG [4]. The right or left femoral artery was surgically prepared. For pigtail catheterization, a 7F sheath was placed in the contralateral femoral artery or the left brachial artery. After administration of 70 units/kg systemic Heparin, the pigtail catheter was advanced into the proximal aorta. During the endograft deployment, the systolic arterial blood pressure was lowered to 60-70 mmHg to optimize accuracy. This was mostly achieved by medical management by the Anesthesiology team or by a rapid pacing procedure with a pacing lead advanced through the femoral vein. Sinus tachycardia was created at a rate of 150/min to provide optimal blood pressure with pacing. The procedure was terminated with complementary angiography. The procedure was considered technically successful if there was no endoleak on angiography, if the aneurysm sac was excluded from the circulation, or if the dissection re-entry point was closed.

In emergency cases, the left subclavian artery was closed consciously. The patients in this group were followed up clinically and LSA were revascularized with CSB if necessary. Perioperative drainage of cerebrospinal fluid (CSF) was performed if an aortic segment longer than 20 cm was to be covered with an endograft, if cerebrovascular or spinal collateral circulation was insufficient and left vertebral artery circulation was dominant, or if LSA was to be closed in a planned manner. CSF drainage catheter was placed by an anesthesiologist before the operation and CSF drainage was monitored for 24-72 hours after the procedure.

For Surgeon Modified Fenestrated Stent Graft (SMFSG), we specifically preferred this endograft, as there are two different shaped radiopaque markers “8” and “0” on each proximal side, facilitating the orientation and positioning [5].

After the procedure, the intensive care unit (ICU) and service hospitalization times of the patients were obtained from the hospital database. The first 30 days were considered as early, and the period after 30 days was considered as the middle follow-up period. Patients with BTAI were followed up in our intensive care unit on the 1st or 2nd day. If there was no cardiovascular problem, these patients were transferred to general intensive care units for the management and treatment of other traumatic injuries. Since the rehabilitation of their multi traumas would take a long time, these patients were excluded and the duration of hospital stay of the cohort was obtained.

All patients underwent CT controls at the 1st, 6th, and 12th months, and then annually.

Statistical Analysis

Statistical analyses were performed by using SPSS version 15 software. The variables were examined using visual (histograms, probability plots) and analytical methods (Kolmogorov-Simirnov/Shapiro-Wilk test) to identify distribution patterns. Demographic characteristics and perioperative variables (blood parameters, operative variables, etc.) were compared using the Mann-Whitney U test and the chi-square test and Fisher exact test, respectively. Continuous variables were expressed as mean±Standard deviation or median (range). Categorical variables were expressed as proportions (percentage). All outcome rates were appropriately calculated as the ratio of events within the designated population of respective cases.

RESULTS

Male patients were in the majority (79.8%) in the 203 patients examined. 168 patients (82.7%) were in ASA status 3-4. There were co-morbidities such as HT in 141 patients (69.5%) and COPD in 92 patients (45.3%). TEVAR was applied to 163 patients (80.3%) in elective and to 40 patients (19.7%) in emergency conditions (Table 1).

When 203 patients were examined, the most common aortic pathologies were thoracic aorta fusiform aneurysm (56.7%) and type B aortic dissection (25.6%), respectively (Table 2).

The procedure was performed under general anesthesia in 200 patients. Local anesthesia was applied to three patients whose clinical condition was not suitable for general anesthesia. During the procedure, blood pressure control was achieved with rapid ventricular pacing in 5 patients and with medical management in 198 patients. A total of 251 thoracic endografts were implanted in these patient cohort. One endograft was used in 162 patients (79.8%), two in 37 patients (18.2%), and three in 5 patients (2.5%). When the patients were examined according to the proximal landing zone, zone 4 TEVAR was most frequently applied with 77 patients (37.9%) (Table 3).

Table 1. Preoperative characteristics of the patients

		n=203	(%)
Sex	Male	162	79.8
	Female	41	20.2
ASA Status	2	35	17.3
	3	126	62
	4	42	20.7
Comorbidites	Hypertension	141	69.5
	Diabetes	46	22.6
	Chronic Obstructive Pulmonary Disease	92	45.3
	Hypercholesterolemia	76	37.4
	Coronary Artery Disase	70	34.5
	Chronic Renal Failure	26	12.8
	Previous Cerebrovascular Event	11	5.4
	Periferal Vascular Disease	16	7.9
Timing	Elective Cases	163	80.3
	Emergency Cases	40	19.7

Table 2. Pathology of the aortic disease

	n (203)	%
Thoracic aortic fusiform aneurysm	101	49.7
Ruptured Thoracic aortic fusiform aneurysm	14	6.9
Type B Aortic dissection (Subacute-Chronic phase)	40	19.7
Complicated Type B Aortic dissection (Acute phase)	12	5.9
Thoracic aortic Saccular aneurysm	12	5.9
Blunt Thoracic Aortic Trauma (Grade 3-4)	14	6.9
Blunt Thoracic Aortic Trauma (Grade 2)	5	2.5
Intramural heamatoma and penetrating aortic ulcer	5	2.5

Table 3. Distribution of patients by proximal landing zone

	n	%
Zone 1	4	2.0
Zone 2	64	31.5
Zone 3	54	26.6
Zone 4	77	37.9
Zone 5	4	2.0

Early mortality was observed in 9 patients (4.4%). Only two of these patients were in an elective manner for a thoracic fusiform aneurysm. One patient with ischemic cardiomyopathy died due to low cardiac output syndrome, and the other patient died because of visceral malperfusion. For elective cases early mortality was 1.2%, for emergent cases it was 17.5%. Other early mortalities were the 2 patients for grade 3 BTAI with no aorta-related mortality, 3 patients for complicated acute type B dissection, and 2 patients for the ruptured thoracic aneurysm. Both deaths after BTAI were from non-procedural causes. One patient died due to sepsis on the 10th day after the procedure, and the other died due to head trauma on the 12th day after the procedure.

Technical success was achieved in all TEVAR cases (100.00%). There was no conversion to open surgery. 35 SMFSG, 4 Ch-TEVAR, 1 I-TEVAR and 8 CSB were performed for revascularization of vascular branches. Mostly LSA, LCCA, and celiac truncus were revascularized. LSA thrombosis was observed in only one patient at the first month follow-up. The patient was not intervened because she was asymptomatic (100% early procedure success).

Upon the development of CVE in two emergency patients whose LSA was closed, emergency CSB was performed and CVE resolved without sequelae.

The femoral incisional hematoma was detected in 17 patients (8.4%) and wound infection was detected in 2 patients (1%). No pseudoaneurysm was observed. The hematoma was removed by minor surgery in 2 patients and by applying weight in 15 patients.

The mean ICU time was 16.9±11 hours (2-160). In 51 (25.1%) patients, a prophylactic CSF drainage catheter was placed before the procedure. These patients remained in the ICU for approximately 48 hours. No complications were observed in patients who underwent CSF drainage, except for mild hematoma at the procedure site.

Subclavian steal syndrome was seen in 2 patients and left arm ischemia in 1 patient, who underwent emergency TEVAR after the closure of the LSA. CSB was applied to these 3 patients.

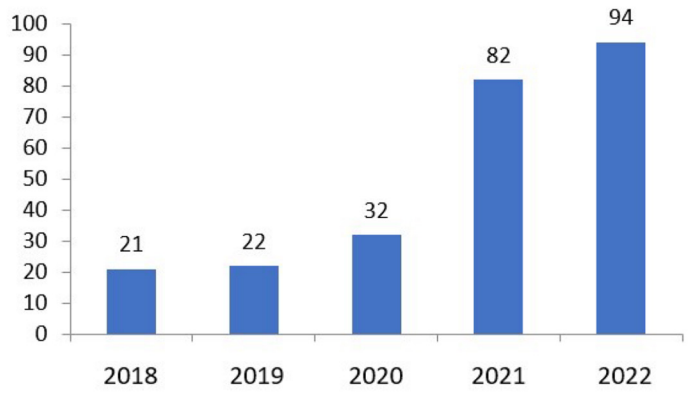
Patients with BTAI had a long hospital stay of 90-100 days. We excluded these 19 patients because their hospital stay was not due to the TEVAR procedure. The mean length of stay for the remaining patient cohort was 5.1±3.2 days.

All discharged patients were followed up for 18.6±9.3 months. There were no complications that required re-intervention in the early period.

A total of 4 patients who completed the first year control had type I, 1 patient had type II and 1 patient had type III endoleak. All were treated endovascularly. A type Ia endoleak was observed in one Ch-TEVAR patient. Two patients had PETTICOAT procedure with bare stent to abdominal visceral segment in the follow up period. One patient who underwent SMFSG for LSA had LSA occlusion at the first month follow-up. Since this patient was asymptomatic, no intervention was performed and her follow-up continues. Two "bird beak" patterns were detected, no complications were observed in the follow-up of these patients and no re-intervention was performed.

Two weeks after the procedure, retrograde type A aortic dissection developed in a type B aortic dissection case with a 38 mm proximal aortic diameter who underwent TEVAR in the acute stage due to the development of malperfusion. Although this patient was operated under emergency conditions, he died on the second postoperative day.

The distribution of TEVAR transactions by years is shown in Graphic 1.



Graphic 1. The distribution of TEVAR transactions by years

DISCUSSION

In a nonrandomized study published by Bavaria et al. in 2007, TEVAR and open surgical repair options were compared in thoracic aortic pathologies. Early mortality rates were 2.8% and 11.7%, respectively. Spinal cord injury (SCI) was seen in 3% after TEVAR and in 14% after open surgery. While 1% pulmonary complications were observed in the TEVAR group, this rate was 13% in the other group [6]. We did not evaluate the results of open surgery in our review, but we did not observe SCI and pulmonary complications after TEVAR.

The overall mortality of all TEVAR cases in our patient cohort was 4.4%. We did not observe SCI in this group. The results of TEVAR are dependent on the anatomy of the aneurysm, secure landing areas, and other morphological features. In patients who do not meet the criteria specified in the instructions for use, technical success can be achieved by applying assisted TEVAR techniques. There is no need to group the outcomes as elective or urgent as this result is quite successful in such a patient cohort. As expected, different aortic pathologies had different mortality rates. However, as there are urgent and elective cases in our patient cohort, this kind of a classification will create some confusions. It seems that acute phase complicated Type B aortic dissections have the highest mortality risk. There was no statistical significance between the etiologies maybe because of the small patient subsets.

In the Bolton Relay Thoracic Aortic Endovascular Pivotal study in which 120 patients were enrolled, early mortality was reported as 5.3% [7]. In 2016, a meta-analysis of 673 patients who underwent TEVAR for thoracic aortic aneurysm was published by Biancari et al. Here, the technical success rate of the procedure was 91.0%, and the 30-day and 3-year survival rates were 96.0% and 74.0%, respectively. Paraplegia occurred in 3.2% of patients and was permanent in 1.4% of patients. The CVE rate was 2.7%. In the follow-ups, 7.3% type I, 2.0% type II and 1.2% type III endoleaks were detected. The rate of freedom from re-intervention was 90.3% at the end of the follow-up [8]. Type I, II and III endoleaks developed in 6 patients in our series. All of these patients were treated with endovascular methods. Freedom from re-intervention rate was 96.5% at the end of our follow-up period.

The VALOR study included results from 195 patients who underwent TEVAR using a Medtronic Talent Thoracic stent graft. Aneurysm-related mortality in this cohort was 3.1% at 1 year and 3.9% at 5 years. Type I endoleaks occurred in 4.6%, additional endovascular procedures were performed in 14.4% of patients at 5-year follow-up. In the first year follow-up, stent graft migration was recorded at a rate of 0.6% [9]. 160 patients with higher cardiovascular risk factors were enrolled in the VALOR II study. In this cohort, 3.1% mortality, 0.6% paraplegia, 1.9% paraparesis, and 2.5% CVE were observed in the early period [10]. Although our patient population consisted of frail patients with ASA status 3-4 with a rate of 82.7%, cardiac and cerebrovascular complications were not observed in any of our patients during early follow-up. Complications such as meningitis and hematoma at the procedure site were reported at a rate of 1.5% in the patient group who underwent CSF drainage [10]. In our experience, we had only one complication in the form of a localized hematoma. In our study, the fact that all procedures were performed by an experienced team, and CSF drainage in the perioperative period were the main factors reducing the complication rate.

Involvement of LSA appears to be 20-40% of cases for sufficient proximal sealing [11]. Since LSA closure causes 0-6% neuroischemic morbidity, current guidelines recommend revascularization of LSA [12]. With the SMFSG method, which we applied for the first time in 2020, we achieved LSA patency in 29 patients in total. We also applied SMFSG to the celiac trunk to provide a safe distal landing zone in three cases [4]. SMFSG on Lifetech Ankura™ endograft is a safe, effective, fast and economical technique that does not require special materials.

Our previous experience with endovascular treatment of BTAI showed the involvement of LSA at the injury site as 65.8% [13]. While there are ideas about deliberate closure of the LSA in such emergencies, we have revascularized the LSA as recommended by current guidelines.

Stent induced new entry (SINE) is an important issue. Our clinical principle is deploying tapered or double tapered endografts, caring the distal sealing sites oversize and waiting for all type B aortic dissections until the subacute phase if there is no malperfusion. Retrograde type A dissection (RTAD) is the most feared complication of TEVAR and has been reported with a rate of 1-2% [14]. Patients with an ascending aortic diameter greater than 36 mm are at risk for RTAD. In our experience, one patient (0.5%) with an ASA score of 4 and an ascending aortic diameter

of 38 mm, who underwent emergency TEVAR for type B aortic dissection, developed RTAD two weeks after the procedure, the patient could not survive the open surgical operation and was lost in the second postoperative day.

The main limitations are that it is a retrospectively designed single-center experience and not comparable with other endograft brands or surgical techniques. The follow-up period includes only the early and mid-term.

In all thoracic aortic pathologies, Lifetech Ankura™ thoracic endograft provides early results like similar products of other brands. It provides an advantage in the application of assistive TEVAR techniques, especially in SMFSG. The wide spectrum of the thoracic endograft length also facilitates some other techniques like a funnel in wide infrarenal aortic necks with 60 mm in length [15]. Long-term follow-up of these patients will be more decisive in terms of the durability of the endografts and the success of the procedure.

Ethics Committee Approval: The study protocol was approved by the Ankara City Hospital Clinical Research Ethics Committee (date/no: 15.12.2021 / E1-21-2224).

Patient Consent for Publication: Individual informed consent was waived due to retrospective design.

Data Sharing Statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Contributions: All authors contributed equally to the article.

Conflict of Interest: The authors declared no conflicts of interest with respect to the authorship and/or publication of this article.

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