

A multi-center study for instructions for use-compatible elective endovascular abdominal aneurysm repair via Lifetech Ankura™ abdominal aortic aneurysm stent graft

Naim Boran Tümer¹, Eyüp Serhat Çalık², Alper Sami Kunt³, Murat Kurtoğlu⁴, Bekir Bogaçhan Akkaya¹, Mehmet Karahan¹, Ertekin Utku Ünal¹, Hakkı Zafer Işcan¹

¹Department of Cardiovascular Surgery, University of Health Sciences, Ankara City Hospital, Ankara, Turkey

²Department of Cardiovascular Surgery, Atatürk University Medical Faculty, Erzurum, Turkey

³Department of Cardiovascular Surgery, University of Health Sciences, Kayseri City Hospital, Kayseri, Turkey

⁴Department of Cardiovascular Surgery, Ankara Güven Hospital, Ankara, Turkey

ABSTRACT

Objectives: In this study, we present our early and postoperative first-year results of instructions for use-compatible elective endovascular abdominal aneurysm repair via the Lifetech Ankura™ abdominal aortic aneurysm (AAA) stent graft and evaluate the efficacy, conformability, and durability of the endograft.

Patients and methods: Between January 2018 and December 2019, a total of 100 consecutive patients (95 males, 5 females; mean age 71.5±9.3 years; range, 56 to 92 years) with an elective infrarenal AAA treated using the Lifetech Ankura™ stent graft in four centers were retrospectively analyzed. All the patients were compatible with the instructions for use. All the patients underwent angiography, first-month computed tomography, and postoperative one-year follow-up.

Results: There was no early mortality or conversion to open surgery. Technical success was 100%. The mean procedural time was 126 min including anesthesia, and the mean fluoroscopy time was 12.4±2.96 min (range 10.3-14.5). The type of anesthesia was general anesthesia in 90% patients. The mean amount of the opaque material used was 45.0±9.8 mL. The mean length of stay in the intensive care unit and hospital was 2.3±0.9 and 3.2±1.9 days, respectively. There were two type Ib endoleaks for native iliac artery dilatation and five type 2 endoleaks with no sac enlargement in the first postoperative year.

Conclusion: For the instructions for use-compatible patients, the Lifetech Ankura™ AAA stent graft yields successful results, and also is effective for the early period and durable for the first postoperative year.

Keywords: Endograft, elective infrarenal abdominal aortic aneurysms, instructions for use.

The possibility of treating elderly with comorbidities carrying high mortality and morbidity for open aortic surgery was the beginning of a minimally invasive endovascular surgery. After the early results of randomized-controlled trials were obtained, endovascular popularity was spread out all over the world and despite similar long-term results with secondary interventions for the endovascular side and ongoing debates, endovascular solutions are still the leading treatment modalities for infrarenal abdominal aortic aneurysms (iAAAs).^[1-5]

Currently, there are many endografts commercially available around the world, all having their own specialties and European Conformity (CE, since 2011) or United States Food and Drug Administration (FDA) trademark markings. Of note, the CE trademark has nothing to do with efficacy and it is only the passport for availability and marketing in the European countries. In recent years, there is a dramatic improvement in the field of endovascular technology. The Ankura™ abdominal aortic aneurysm (AAA) stent graft which was developed by the

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Correspondence: Naim Boran Tümer, MD. SBÜ Ankara Şehir Hastanesi Kalp ve Damar Cerrahisi Kliniği, 06800 Çankaya, Ankara, Türkiye.
e-mail: naimborantumer@hotmail.com

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Lifetech Scientific (Lifetech Scientific (Shenzhen) Co. Ltd., Shenzhen, China, since 2004), is one of these manufacturers instructed in China and has been in the European market since 2011 with a CE passport, as well as in Turkey since 2016 as endovascular tools. According to the economic issues about the marketing in our country, commercially available endografts are changeable and have gradually decreased for today.

According to randomized-controlled trials, endovascular iAAA treatment carries an early mortality advantage with erosion in the mid-term and the same long-term results with open surgery. The use of the endovascular solutions with the instructions for use (IFU) gives the most satisfactory early- and long-term results.^[1-7]

In the current study, we present our early and postoperative first-year results of IFU-compatible elective endovascular abdominal aneurysm repair via the Lifetech Ankura™ AAA stent graft and evaluate the efficacy, conformability, and durability of the endograft.

PATIENTS AND METHODS

In this multi-center, randomized study, a total of 100 consecutive patients (95 males, 5 females; mean age 71.5±9.3 years; range, 56 to 92 years) with an elective iAAA treated using the Lifetech Ankura™ stent graft in four centers where over 10 endovascular procedures are performed annually were retrospectively analyzed between January 2018 and December 2019. All the patients were compatible with the IFU and underwent angiography, first-month computed tomography (CT), and postoperative one-year follow-up. The IFU criteria were considered valid, unless the patient was excluded from the study. Urgent cases and those receiving procedures with concomitant surgery were also excluded. A written informed consent was obtained from each patient. The study protocol was approved by the Ankara City Hospital Ethics Committee (E1-20-422). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Baseline demographic and clinical characteristics of the patients, perioperative data, type of anesthesia, operation time, the volume of contrast agent used, total fluoroscopy time, laboratory tests including complete blood count and creatinine, length of stay in the hospital and in the intensive care unit (ICU), endoleak at the completion angiography, and procedure-related complications were recorded. For

the first year, all morbidity, mortality, outpatient visits, and readmissions were noted. The primary endpoints were the technical success without type 1 or 3 endoleak in completion angiography, operative, early, and postoperative first year mortality and morbidities, and aneurysm-related mortality.

IFU and pre-procedural measurements

All patients underwent multi-slice CT angiography (CTA) preoperatively. The patients with minimum 15 mm infrarenal aortic neck length and aortic angulation under 60 degrees with proper infrarenal and iliac diameters and compatible access diameters for the delivery system was selected. Table 1 shows the IFU criteria for the use of the Lifetech Ankura™ AAA stent graft.

The Lifetech Ankura™ AAA stent graft system is indicated for the endovascular repair of patients with AAAs. It is preloaded into the delivery system to advance the stent graft via the femoral artery to the target site. The graft material is an expanded polytetrafluoroethylene (ePTFE) film supported by a nitinol stent. The ePTFE dual membrane provides low permeability and biocompatibility. Self-expanding nitinol stent offers a stable radial force and smaller waves on the main body by improving the flexibility. The diameters of the available proximal aortic section of the bifurcated stent graft range from 20 to 34 mm and the covered length of the bifurcated stent graft are 120 and 140 mm. There is a bare stent with six anchors at the proximal end to fix the stent graft in place inside the aorta above the renal arteries. The anchors are 3.5 mm in size and have 30 to 45 degrees to the outer side of the bare stents. There are seven improved radiopaque markers to aid the visualization and to facilitate accurate placement. Proximal “8-shaped” and “O-shaped” markers are corresponding with the contralateral limb and ipsilateral limb of the stent, respectively. The contralateral limb has three markers as follows: “e-shaped”, “O-shaped”, and “v-shaped”, making it easier to distinguish bilateral limbs and guiding the cuff release. The ipsilateral limb has two

Table 1. Anatomical criteria according to the IFU of the Lifetech Ankura™ AAA stent graft

Proximal aneurysm neck diameter	18-32 mm
Infrarenal neck length	>15 mm
Neck angulation	<60 degrees
Iliac diameter	8-22 mm
Distal fixation length	>15 mm

IFU: Instructions for use; AAA: Abdominal aortic aneurysm.

v-shaped markers. The Cuff stent graft provides more options for patients' clinical needs with the lengths ranging from 60 to 120 mm, and the diameters range from 10 to 20 mm. The flared configuration of the designed cuff stent graft avoids endoleak, and spiral woven connecting bar provides more flexibility. The radiopaque "v-shaped" markers at the proximal and distal end of the cuff stent graft increase the visibility during positioning. The connecting bar of the cuff prevents stent graft shortening in tortuous vessels. The delivery system consists of the tapered tip, hydrophilic coating sheath, sheath front grip, trigger, slider grip, screw gear, proximal releaser, and hemostatic valve. The delivery system has a tip capture mechanism for precise deployment. The main body delivery system consists of a 21 to 23F and iliac extensions are 18F in size. The iliac extensions are available in tapered, reverse tapered, and tube manner with 14 to 22 mm in diameter.

Procedural technique

All the procedures were performed under general or locoregional anesthesia. Bilateral femoral exploration and after the administration of heparin, cannulation with a standard femoral introducer sheath was done. Over the stiff guidewire, the system deployment was initiated firstly main body, with caution to the proximal "8" and "O" opaque markers after renal artery visualization. Contralateral leg cannulation and appropriately sized extensions were deployed. With the completion angiogram, if there was no type 1 or 3 endoleak, the procedure was terminated.

After the procedure, follow-up was performed with CTA at the end of the postoperative first month and the first year as a part of the standardized protocol.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk test) to determine the normality of their distribution. Normally distributed continuous variables were expressed in mean \pm standard deviation (SD) or median (min-max) values if not normally distributed. Categorical variables were expressed in number and percentage. The Wilcoxon test was used to analyze the preoperative and follow-up diameters of the aneurysm sac. A *p* value of <0.05 was considered statistically significant.

RESULTS

The mean diameter of the iAAA was 62.3 ± 6.8 (range, 52 to 71) cm. The most common comorbidity was hypertension in 68% of patients. Eight patients were symptomatic. The baseline demographic and clinical data of the patients are given in Table 2.

There was no early mortality or conversion to open surgery. Technical success was 100%. type of anesthesia was general anesthesia in 90% patients, while only 10 patients with the American Society of Anesthesiologists (ASA) Class IV underwent locoregional anesthesia. For high-risk patients, we gave every effort to perform the procedure under locoregional anesthesia and sedation. The mean procedural time was 126 min including anesthesia, and the mean fluoroscopy time was 12.4 min. The mean amount of the opaque material used was 45.0 ± 9.8 mL. The mean length of stay in the ICU and hospital was 2.3 ± 0.9 h and 3.2 ± 1.9 days, respectively. The patient turnover was very effective. Peri- and postoperative data are given in Table 3.

In the postoperative first-year multi-slice CT findings, there was no migration, no kink or fracture, and no limb occlusion. Only five patients (5%) experienced type 2 endoleak and two had type 1b endoleak due to native iliac artery dilatation. These two type 1b endoleaks were treated by limb extension. These patients had an iliac extension to the external iliac artery. None of the remaining patients with type 2 endoleak underwent an intervention and all were followed for the expansion of the aneurysm sac.

Table 2. Baseline demographic and clinical data of the patients

Variable	n	%	Mean \pm SD
Gender			
Male	95	95	
Diabetes mellitus	16	16	
Hypertension	68	68	
Chronic obstructive pulmonary disease	39	39	
Coronary artery disease	51	51	
Coronary artery bypass grafting	29	29	
Peripheral artery disease	8	8	
Hyperlipidemia	26	26	
Smoking	43	43	
Ejection fraction (%)			48.2 \pm 8.7
Aneurysm diameter (cm)			62.3 \pm 6.8
ASA I-II	70	70	
ASA III-IV	30	30	
Symptomatic	8	8	
Malignancy	7	7	
Previous abdominal surgery	14	14	

SD: Standard deviation; ASA: American Society of Anesthesiologists.

Table 3. Peri- and postoperative data

Variable	Mean
Procedure time (min)	126
Fluoroscopy time (min)	12.4
Amount of opaque material (mL)	45
Type 2 endoleaks	5
Intensive care unit period (h)	2.3
Length of stay (day)	3.2

The freedom from secondary interventions at one year was 98%. All-cause mortality was 2% at one year mainly from cardiac and neurological causes. Endoleak-free survival at one year was 93%. On postoperative CTA at one year following endovascular aneurysm repair (EVAR), the mean AAA diameter decreased from 64.5±17.4 mm to 63.2±15.3 mm; however, the difference was not statistically significant ($p=0.799$).

DISCUSSION

The anatomical inclusion criteria of the different commercially available endografts are comparable. In particular, short and angulated necks, thrombus, and calcification at the implantation sites, tortuous iliac arteries are related to adverse outcomes. Kansal et al.^[7] reviewed 1,060 consecutive EVARs and suggested that IFU adherence of EVARs later requiring open surgical conversion was markedly low. Adherence to device-specific IFU was reported as markedly lower among EVARs requiring open surgical conversion than uncomplicated cases (43.8% vs. 79%, respectively; $p<0.01$).^[7] Additionally, potential long-term complications of endovascular procedures may be expected to be lower for IFU patients. The IFU criteria for different endografts may differ from each other and, therefore, it may not be reasonable to compare these results.

It may be outdated due to the first- and second-generation endografts; however, in the randomized-controlled trials, the long-term results are comparable with open surgical repair with a higher reintervention rate and aneurysm-related mortality rate on the endovascular side.^[1-4] Therefore, it is a major challenge to decrease reintervention rates after EVAR. Besides, the improvements in novel stent endografts, the most crucial point is to perform the endovascular power under the IFU. That is the reason why we identified the IFU-compatible patients first.

There are many endovascular procedures performed outside the IFU criteria; however, EVAR

has still advantageous over open surgery, as these patients should be also considered as challenging patients for open surgery. The introduction of novel stent endografts may be a step forward in treating these patients via standard ways endovascularly. Endovascular therapy is also satisfactory for the patients, as it offers a minimal invasive opportunity without open surgical stress and aortic cross-clamp.

In this study, the technical and clinical success rate of the Lifetech Ankura™ AAA stent graft and the first-year secondary intervention rate was comparable with other grafts.^[8-11] In particular, there was no limb occlusion and migration. This may be due to the high radial force, graft material, and active fixation system of the endograft. Nitinol endoskeleton of the graft is thicker than other commercially available grafts, when examined manually. That is the reason for the thickness of the delivery system diameter and the loss of flexibility as a disadvantage; however, this may be also an advantage depending on the anatomy of the aneurysm. In the European Collaborators on Stent/Graft Techniques for Aortic Aneurysm Repair (EUROSTAR) registry data, the AneuRx™ (Medtronic Inc., CA, USA) and Talent™ (Medtronic Inc., CA, USA) stent grafts had the highest rates of migration, endoleak (type 1 or 3), and conversion.^[12] The Zenith™ (Cook Medical, IN, USA) stent graft, despite having the highest rate of aneurysm sac shrinkage and lowest rate of migration, had the highest rates of limb occlusion.^[12] Malina et al.^[13] also showed that barbs and hooks increased the fixation 10-fold, whereas radial force had no impact. The migration rate appears to be lowest for stent grafts which offer proximal active fixation. The radial force of the endografts differs according to the composition of the materials and the variety of the nitinol stents. In our study, we found no migration in any of the patients.

In the present study, the AAA-related mortality and reintervention rates during this first year were acceptable and comparable with other endografts.^[8-11] There were no access site problems. The delivery system for the main body has 21 to 23F diameter and the contralateral limbs have 18F. There were no graft-related deployment or handling problems. Furthermore, the majority of the aneurysms in this study did not significantly change in size, and the rate change of shrinking aneurysms was 1.2 mm in the first year. The absolute and relative ratio of sac regression was calculated only for 12 months. According to Jetty et al.,^[14] most of the sac regression was achieved

within two years. Variability in sac regression was influenced by non-anatomical variables including age, sex, original AAA diameter, and specific endograft device, even after controlling for the presence or absence of an endoleak. The sac shrinkage may be defined as the loss of pressure of the aneurysm sac and the success of the procedure. According to our results, the sac shrinkage was as expected.

The main limitation of our study includes variability in the experience of the centers, although only centers performing over 10 cases were included in the study. In addition, there was no randomization and control group, as only the Lifetech Ankura™ AAA stent graft was used for elective iAAAs, which were suitable for IFU criteria. Therefore, no head-to-head comparison with other grafts was able to be done.

In conclusion, the competitive pressure composed by another commercial in the endovascular field, the advantageous sides of the Lifetech Ankura™ AAA stent graft are the presence of bare stent with safety anchors for fixation, dual membrane e-PTFE material with no sutures on the main body for biocompatibility, and avoiding leakage. The satisfactory radial force may be the key to no limb occlusion. Based on these findings, we can suggest that the Lifetech Ankura™ AAA stent graft is successful and durable during the first year after EVAR. Nonetheless, further large-scale, long-term, prospective, randomized-controlled studies are needed to establish a definite conclusion.

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REFERENCES

- Greenhalgh RM, Brown LC, Kwong GP, Powell JT, Thompson SG. EVAR trial participants. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. *Lancet* 2004;364:843-8.
- Patel R, Sweeting MJ, Powell JT, Greenhalgh RM; EVAR trial investigators. Endovascular versus open repair of abdominal aortic aneurysm in 15-years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. *Lancet* 2016;388:2366-74.
- van Schaik TG, de Bruin J, van Sambeek M, Verhagen H, Prinssen M, Grobbee R, et al. Very long-term follow-up (12-15 Years) of the Dutch Randomized Endovascular Aneurysm Repair Management (DREAM) Trial. *J Vasc Surg* 2016;63:S143.
- Powell JT, Sweeting MJ, Ulug P, Blankensteijn JD, Lederle FA, Becquemin JP, et al. Meta-analysis of individual-patient data from EVAR-1, DREAM, OVER and ACE trials comparing outcomes of endovascular or open repair for abdominal aortic aneurysm over 5 years. *Br J Surg* 2017;104:166-78.
- İşcan HZ, Ünal EU, Sarıcaoğlu MC, Aytekin B, Soran Türkcan B, Akkaya B, et al. Our clinical approach to the last five-year elective infrarenal abdominal aortic aneurysm: Short-term results. *Turk J Vasc Surg* 2018;27:1-7.
- Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. *J Vasc Surg* 2018;67:2-77.
- Kansal V, Nagpal S, Jetty P. Editor's Choice - Late Open Surgical Conversion after Endovascular Abdominal Aortic Aneurysm Repair. *Eur J Vasc Endovasc Surg* 2018;55:163-9.
- van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, Harris PL, Buth J, Laheij RJ; EUROSTAR collaborators. Risk-adjusted outcome analysis of endovascular abdominal aortic aneurysm repair in a large population: how do stent-grafts compare? *J Endovasc Ther* 2005;12:417-29.
- van Keulen JW, de Vries JP, Dekker H, Gonçalves FB, Moll FL, Verhagen HJ, et al. One-year multicenter results of 100 abdominal aortic aneurysm patients treated with the Endurant stent graft. *J Vasc Surg* 2011;54:609-15.
- Espinosa G, Ribeiro M, Riguetti C, Caramalho MF, Mendes WD, Santos SR. Six-year experience with talent stent-graft repair of abdominal aortic aneurysms. *J Endovasc Ther* 2005;12:35-45.
- Teijink JAW, Power AH, Böckler D, Peeters P, van Sterkenburg S, Bouwman LH, et al. Editor's Choice - Five Year Outcomes of the Endurant Stent Graft for Endovascular Abdominal Aortic Aneurysm Repair in the ENGAGE Registry. *Eur J Vasc Endovasc Surg* 2019;58:175-81.
- Buth J, van Marrewijk CJ, Harris PL, Hop WC, Rimbau V, Laheij RJ; EUROSTAR Collaborators. Outcome of endovascular abdominal aortic aneurysm repair in patients with conditions considered unfit for an open procedure: a report on the EUROSTAR experience. *J Vasc Surg* 2002;35:211-21.
- Malina M, Lindblad B, Ivancev K, Lindh M, Malina J, Brunkwall J. Endovascular AAA exclusion: will stents with hooks and barbs prevent stent-graft migration? *J Endovasc Surg* 1998;5:310-7.
- Jetty P, Husereau D, Kansal V, Zhang T, Nagpal S. Variability in aneurysm sac regression after endovascular aneurysm repair based on a comprehensive registry of patients in Eastern Ontario. *J Vasc Surg* 2019;70:1469-78.