

Funnel technique for wide infrarenal aneurysm neck with Lifetech Ankura™ Stent Graft System

Geniş infrarenal anevrizma boynunda Lifetech Ankura™ Stent Graft System ile huni tekniği

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ABSTRACT

Background: In this study, we present our mid-term results in patients undergoing treatment with the funnel technique and describe technical issues for this bailout technique in extra-wide infrarenal necks.

Methods: Between January 2018 and June 2020, a total of seven male, symptomatic patients (median: 74.5 years; range, 64 to 84 years) who had comorbidities and were in the American Society for Anesthesiologists Class IV and treated by the funnel technique in an endovascular fashion were included. Pre- and post-procedural data of the patients, early mortality and technical success rates were evaluated.

Results: There was no early mortality. Technical success rate was 100%. There was no type I or III endoleaks at the completion angiography. All patients were discharged without any problem on the second or third day of the procedure. The median follow-up was 13 (range, 6 to 28) months. The aneurysm sac shrinkage was achieved in all patients over six months of follow up. During the follow-up period, no proximal endoleak or infrarenal aortic neck diameter enlargement was found.

Conclusion: Based on our limited experience, the funnel technique may be considered more than a bailout procedure under special circumstances.

Keywords: Abdominal aortic aneurysm, endovascular procedures, hostile neck.

ÖZ

Amaç: Bu çalışmada huni tekniği ile tedavi edilen hastaların orta dönem sonuçları sunuldu ve ekstra geniş infrarenal boyunlarda bu kurtarma tekniğinin teknik hususları tanımlandı.

Çalışma planı: Ocak 2018 - Haziran 2020 tarihleri arasında eşlik eden hastalıkları olan ve Amerikan Anesteziyoloji Derneği Sınıf IV olan ve endovasküler olarak huni tekniği ile tedavi edilen toplam yedi erkek semptomatik hasta (medyan yaş: 74.5 yıl; dağılım, 64-84 yıl) çalışmaya alındı. Hastaların işlem öncesi ve sonrası verileri, erken mortalite ve teknik başarı oranları değerlendirildi.

Bulgular: Erken mortalite görülmedi. Teknik başarı oranı %100 idi. İşlem sonrası anjiyografide tip I veya tip III kaçak yoktu. İşlemin ikinci veya üçüncü gününde tüm hastalar sorunsuz olarak taburcu edildi. Medyan takip süresi 13 (dağılım, 6-28) ay idi. Altı ayın üzerinde takibi olan hastalarda anevrizma kesesinde küçülme sağlandı. Takip süresi boyunca proksimal kaçak veya infrarenal aort boynu çapı genişlemesi saptanmadı.

Sonuç: Sınırlı deneyimize göre, huni tekniği, özel koşullar altında bir kurtarma işleminden daha fazlası olarak düşünülebilir.

Anahtar sözcükler: Abdominal aort anevrizması, endovasküler işlemler, zor boyun.

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Endovascular aortic aneurysm repair (EVAR) has become the preferential treatment of choice in anatomically suitable aortic pathologies, offering a less invasive method with reduced perioperative mortality and morbidity.^[1] On the other hand, its main demerit is almost always anatomic considerations where open surgery remains versatile. Hostile neck anatomy is the major consideration in patient selection and determining the strategy. Manufacturers' efforts to improve new commercials and the increased endovascular experience for comorbid patients who are ineligible for open surgery attenuate these limitations. To do this, the chimney technique, custom-made fenestrated/branched endografts, and off-label use of combinations are on trial. Hostile necks can be treated in several ways according to patients' status, aneurysm morphology, and suprarenal aorta. Large aortic neck diameter may be treated with standard EVAR endografts under instructions for use criteria; however, a wide or extra-wide (x-large; ≥ 32 mm) infrarenal neck diameter is above the limit due to the insufficient oversizing.

Adequate sealing at the proximal and distal zones are the most important factors predicting successful early and late outcomes of endovascular procedures. Different techniques such as the covered cuff pre-deployment, funnel technique, and endo-wedge technique were studied to overcome hostile aortic neck with the development of standard endografts.^[2,3] Moreover, endo-anchors first described by de Vries *et al.*^[4] in 2011 acting as a screw may be an alternative way solely or to support these techniques with a higher cost. The Kilt technique described by Szaniewski *et al.*,^[2] the pre-deployment cuff works by straightening and stabilizing the landing zone where the funnel technique takes place, if there is a wide aortic infrarenal neck and no opportunity of chimney EVAR (ChEVAR), fenestrated EVAR (fEVAR) or open surgery.^[2,5-9]

In the present study, we aimed to present our mid-term results in patients undergoing treatment with the funnel technique and to describe technical issues for this bailout technique in extra-wide infrarenal necks.

PATIENTS AND METHODS

This retrospective study was conducted at Ankara City Hospital, Department of Cardiovascular Surgery between January 2018 and June 2020. A total of seven male, symptomatic patients (median: 74.5 years; range, 64 to 84 years) who had comorbidities and were in American Society for Anesthesiologists (ASA) Class IV and treated by the funnel technique in an endovascular fashion were included. The preoperative anatomic specifications of the aneurysms are given in Table 1. The sizes of the thoracic endografts were 42 or 46 mm in diameter and 60 mm in length. Abdominal endografts were 32 mm to 36 mm for the main body. All commercial brands could have been used in this manner; however, we preferred thoracic or abdominal aortic endografts (Lifetech Ankura™ AAA Stent Graft and Lifetech Ankura™ TAA Stent Graft; Lifetech Scientific, Shenzhen, China) for these procedures in which all sizes and lengths for thoracic endografts were available. As all patients were in ASA Class IV and had comorbidities, open surgery was not an option. One patient who had thoracic rupture and an infrarenal aneurysm underwent cerebrospinal fluid drainage to avoid spinal cord ischemia. One patient who underwent EVAR procedure two years prior in an external center experienced thrombosis of one leg and type I endoleak due to migration, while two other symptomatic patients had lung malignancy and one had contained rupture of thoracic aortic aneurysm and large infrarenal abdominal aortic aneurysms with very short and wide neck. The other three patients had symptomatic large aneurysms with short and wide necks. A written informed consent was obtained

Table 1. The preoperative anatomic specifications of the aneurysms

Patients	Infrarenal aortic diameter (mm)	Maximum aortic aneurysm diameter (mm)	Neck length (mm)	Neck angle
1	36.3	117	20	20
2	37.3	98	12	35
3	39	72	5	10
4	39	69	28	30
5	38	82	8	25
6	38	76	10	10
7	39	80	12	15

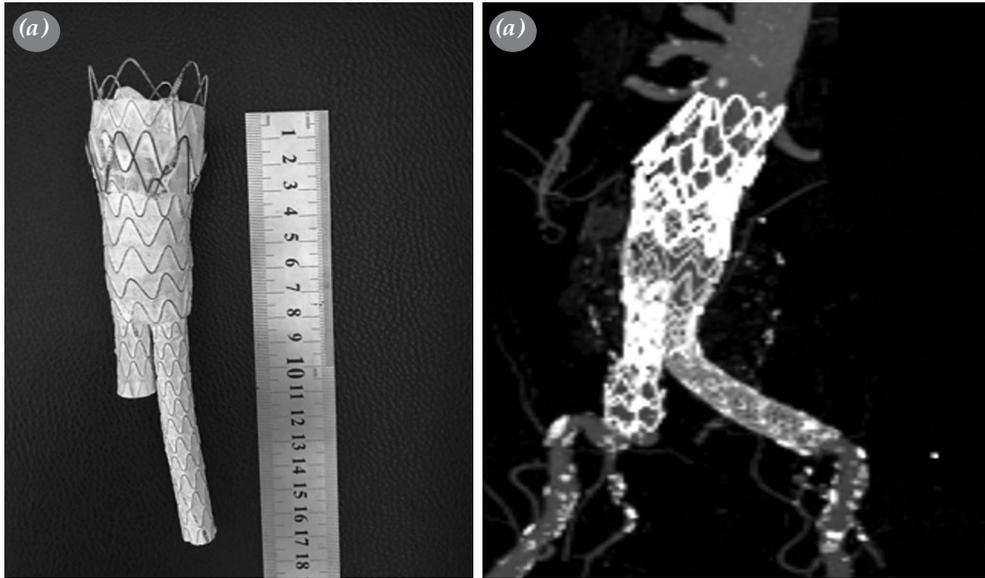


Figure 1. Demonstration of thoracic graft with 16-mm bare stent and 60-mm length deployed through the primary inserted abdominal endograft *in vitro* and *in vivo*. (a) The resultant funnel configuration. (b) At the postoperative 28th month, repeated tomography showing the intact structure of the assembled endografts with no endoleak or migration.

from each patient. The study protocol was approved by the Ankara City Hospital Ethics Committee (Date/No: 09.12.2020/E1-20-1385). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All patients were operated in the hybrid operating room with the same cardiovascular surgery team. Figure 1 and 2 demonstrates the funnel technique. The neck diameter, neck length, aneurysm length between the lowest renal artery, and aortic bifurcation were measured correctly. Minimum 10% oversizing was applied to all patients.

Two patients underwent locoregional anesthesia with sedation, as they were not suitable for general anesthesia, either, while the rest were operated under general anesthesia. For every patient, a standard EVAR procedure was initiated with heparin (5,000 IU intravenous bolus) administration and bilateral femoral access and/or a brachial way for pigtail catheterization which the latter is more practical and offers more luxury. Bifurcated endograft was first introduced from the right or left femoral access and deployed nearly 30 mm below the lowest renal artery under controlled systolic pressure (<100 mmHg) to facilitate the thoracic endograft to open sufficiently (Figure 2). Before the deployment

of thoracic endograft, if the pigtail catheter was inserted from femoral access, it was retrieved from the infrarenal segment to avoid any complications, while removing. Thoracic endograft was deployed after the insertion of the contralateral leg from the same route (Figure 2). In this way, we provided the fixation at least at the distal landing zone before the funnel.

Early mortality and technical success were assessed in this study. The success criterion for the procedure was no type I or III endoleak with proper deployment of the endograft at the completion angiography. Moreover, probable endoleaks, neck dilatation, and migration were evaluated during follow-up.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables were expressed in mean \pm standard deviation (SD) or median (min-max), while categorical variables were expressed in number and frequency. The variables were investigated using visual (histograms, probability plots) and analytical methods (Kolmogorov-Smirnov/Shapiro-Wilk test) to determine the normality of their distribution. A *p* value of <0.05 was considered statistically significant.

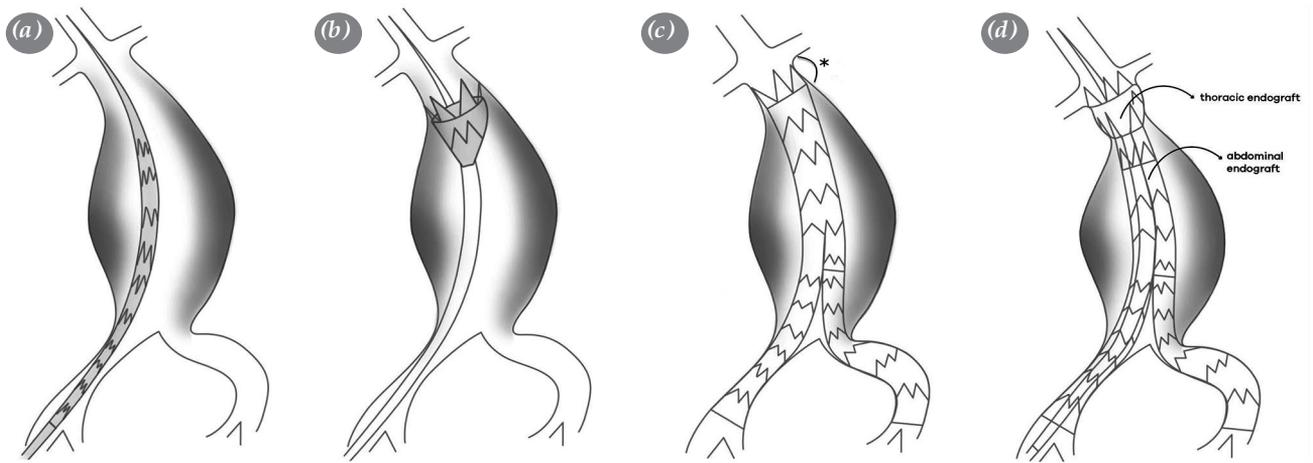


Figure 2. (a) Abdominal endograft main body introduced from the femoral artery. (b, c) This endograft was deployed approximately 3 cm below the lowest renal artery. (d) Following the contralateral limb deployment, thoracic endograft (60 mm) was introduced from the ipsilateral side and deployed inside the abdominal endograft with a 3-cm overlap.

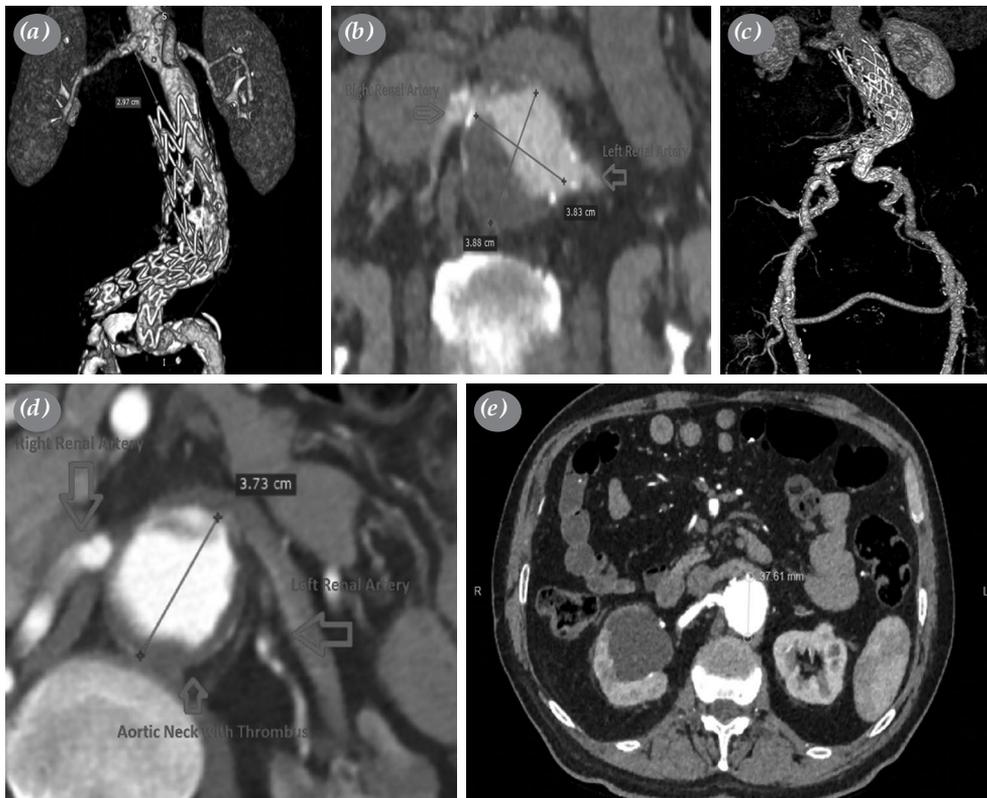


Figure 3. (a, b) shows the right leg thrombosis and approximately 28 to 29 mm of migration at the proximal landing zone with a heavy thrombus burden seriously limiting the active lumen (active lumen 1.3 cm). (c) The control computed tomography angiography images of the same patient at Month 10. (d, e) shows the same infrarenal neck diameter, redistribution of thrombus burden at Month 28 as assessed by repeated tomography.

RESULTS

There was no early mortality. Technical success was 100%. There were no Type I or III endoleaks at the completion angiography. All patients were discharged without any problem on the second or third day of the procedure. During the follow-up period, one patient died from malignancy at 14 months. Another patient who was receiving therapy for lung cancer died at 28 months of follow-up. Figures 3a and 3b show the right leg thrombosis and approximately 28 to 29 mm of migration at the proximal landing zone with a heavy thrombus burden which seriously limited the active lumen. Figure 3c demonstrates the postoperative computed tomographic angiography (CTA) scans of this patient with uni-iliac endograft and femoral-femoral crossover bypass at the first-year follow-up.

The median follow-up was 13 (range, 6 to 28) months. Aneurysmal sac shrinkage was achieved in all patients over six months of follow-up. Figure 3d, e show the same infrarenal neck diameter at 28 months of follow-up CTA, and the thrombus burden initially and 28 months later. Probably due to radial force, the thrombus became thinner and almost diminished. There was no type I endoleak or migration. None of the patients experienced neck dilatation, migration, or type IA endoleak, or thromboembolic event. There was no sac shrinkage for the last two patients who were in their postoperative six-month follow-up, as expected. The aneurysm sac was stabilized at the same diameter. There were no type II endoleaks after the procedure or during the follow-up period.

DISCUSSION

This study is one of the largest experiences of the funnel technique. Recently, Amico et al.^[10] described an elderly patient with a 36-mm proximal neck diameter who was treated with funnel technique and documented that 32 cases of funnel procedure have been reported in the literature to date. Bastiaenen et al.^[11] performed repair with thoracic stent-grafts in 11 patients. However, the majority of these patients were treated with aorta-uni-iliac endografts (n=8/11). Therefore, we can confidently mention that this series is the largest experience of funnel technique consisting of bifurcated endografts.

Hybrid assembly of standard endografts may offer an endovascular option for wide-neck aneurysms. In our study, we performed the funnel technique for these urgent patients with wide necks who were not suitable for open surgery or complex EVAR procedures due to comorbidities. A wide infrarenal

aortic neck diameter has been shown to be associated with adverse events when treated with standard EVAR procedure. Oliveira et al.^[5] reported that a proximal neck diameter of ≥ 30 mm was associated with an increased risk of neck-related adverse events and they made two recommendations as follows: infrarenal neck diameters of ≥ 30 mm should be carefully weighed among the treatment modality (fEVAR, ChEVAR, or open surgery) risks and higher risk of neck-related adverse events and close monitoring is required with CTA follow-up of these patients.

The maximum diameter of the standard EVAR endografts commercially available is 36 mm and, therefore, the diameter of our patients excludes the standard EVAR, as it is impossible to seal at the proximal landing zone. Therefore, as a bailout procedure, the funnel technique was performed basically. The utilization of available aortic stent-grafts to treat aneurysms with a challenging anatomy is attractive, as it offers option-limited patients an opportunity to undergo EVAR and the benefits of such an approach.^[6-9,12]

For these seven urgent patients, possible alternatives were fEVAR or ChEVAR techniques, which were excluded. The fenestrated custom-made graft was not available and/or was taking time to get prepared with a much more expense. The short distance to the superior mesenteric artery (SMA) and thrombus burden were the limitations for the ChEVAR technique. Instead, we preferred an easier way to seal at that x-large neck. As it was not possible with standard abdominal aortic endografts, we thought to combine a thoracic endograft placed proximally to the infrarenal segment and placement of the abdominal endograft 2 to 3 cm distal from the infrarenal orifice of the abdominal aorta.

The fEVAR is a more expensive procedure that is tailored specifically to each patient's anatomy, requiring accurate calculations, an experienced team, and time to get prepared with a higher cost. However, this approach also involves the creation of fenestrations on a back table in the hybrid room with commercially available endografts. Off-label use of devices is technically challenging and durability or long-term implications are unknown. The ChEVAR is an available technique for these patients; however, major concerns regarding these techniques are endoleaks and subsequent complications. Also, renal dysfunction following these procedures are of great concern with 4 to 8% of permanent renal deterioration for the long-term data of Cleveland Clinic.^[13] The largest collected world experience of snorkel EVAR (SnEVAR) is the PERICLES registry with 97.1%

technical success, reporting an early mortality of 4.9%, intraoperative of 7.9%, type IA endoleak and primary patency rate of 94% during 17 months of follow-up.^[14] The fluoroscopy time was 60.8 min and 162.4 mL of contrast volume was used on average. Currently, fEVAR and ChEVAR represent the two most utilized advanced endovascular techniques with comparable results. The fEVAR is a more standardized procedure, whereas the Ch/Sn EVAR may be a better alternative in symptomatic or urgent cases.

In the presence of a neck thrombus due to concerns regarding embolization to visceral arteries and the increased risk of migration or endoleak, it is a relative contraindication for endovascular procedures, as there are conflicting reports.^[15,16] In our routine practice, we quantify the thrombus burden as the percentage of neck diameter, since it provides some details about the thickness and circumferential involvement. In our experience, the presence of thrombus did not influence the technical success of EVAR. Considering the general condition of the patients, this procedure was applied, as there was no other solution due to the narrowing of the neck angle. There was no evidence of embolization after implantation and no migration or endoleak in the follow-up period. For stabilization, balloon dilatation is not recommended. As we detected the displacement of thrombus after the balloon dilatation of the thoracic endograft in one of our patients, we recommend balloon dilatation, if it is a must and should be done more gently than usual.

Neck dilatation can be described as the enlargement of ≥ 3 mm from the first postoperative scan to the last available follow-up; however, the causes of neck dilatation after EVAR have not been clearly defined yet.^[16-18] It may be a part of the ongoing aneurysmal disease or the result of endografts radial force. Neck enlargement after EVAR may develop during follow-up with an incidence of 20% at two years, regardless of endograft types, almost always causing endoleak and/or migration. Interestingly, small necks at the time of EVAR appear to be at a higher risk for subsequent dilatation than those over 25 mm.^[17] Monahan *et al.*^[18] reported that the diameter of the neck increased rapidly at early time points and, then, slowly limited to match the size of the graft and was not associated with endoleak or migration. In our study, we did not observe this situation in an average of 13 months of follow-up. However, Bastiaenen *et al.*^[11] documented two type IA endoleaks which could be attributed to neck enlargement.

Another important issue is the presence of an active fixation system for the abdominal endografts and its absence for thoracic endografts. Thoracic endografts are sealed with radial forces. Adequate overlap and positioning of the thoracic endograft is of great importance for facilitating the expansion of the thoracic endograft to a nominal diameter to achieve sealing. This is of great concern for preventing endoleak and migration.

We preferred the Lifetech Ankura™ Stent Graft System for these procedures in which all sizes and lengths for thoracic endografts are available. The main advantage of this thoracic endograft is the 60-mm length suitability for the proximal extension, considering the overlap and the sealing sections. The length of the infrarenal aorta (distance from renal artery to iliac bifurcation) is the main limiting factor for this technique. Considering that the other endografts on the market have a minimum length of 100 mm, a 60-mm endograft provides the feasibility of this technique on shorter length of infrarenal aneurysms, particularly with bifurcated endografts. Considering that the main body of the bifurcated endograft is 50 to 60 mm, the thoracic endograft provides treatment even in shorter lengths of the infrarenal aorta. On the other hand, the length of the infrarenal aorta should be at least 130 mm to deploy a 100-mm thoracic endograft extension.^[10] Bastiaenen *et al.*^[11] reported 11 cases treated with a 100-mm thoracic endograft, since most of the patients were treated with aorta-uni-iliac endografts which enables deployment of the 100-mm thoracic endograft. Although the procedure can be performed with the aortic cuff (Jotec GmbH, Hechingen, Germany) (CAF-EVAR), due to the insufficient graft size and inadequate oversizing, in x-large infrarenal aortic diameter, it may not be feasible.^[19]

The relatively small sample size is the main limitation to this study. This technique can be only used in very carefully selected patients, as this is a possible bailout procedure. Moreover, the follow-up period needs to be longer to assess the long-term durability of the technique. On the other hand, there was no comparison of the patients with the other possible techniques such as fEVAR and ChEVAR in this study.

In conclusion, x-large or wide infrarenal aortic necks with abdominal aortic aneurysms remain a challenge for every type of treatment modality. Hybrid assembly of a thoracic endograft placed through the main body of a bifurcated or uni-iliac endograft is a solution where other modalities are not available.

The funnel technique is effective and safe for a strict group of comorbid patients with a x-large neck diameter suffering from an impending aortic rupture. It is the choice of the cardiovascular surgeon whether to perform fenestrated or chimney endovascular aneurysm repair, open surgery, or funnel technique based on the patient's clinical status. According to our limited experience, the funnel technique may be considered more than a bailout procedure.

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Declaration of conflicting interests

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