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Original Article

Early and midterm outcomes of EVAR with 34 and 36 mm large endograft sizes: A single tertiary center study

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Abstract

Aim: Endovascular aneurysm repair (EVAR) has become a preferred method for accessing anatomically suitable abdominal aortic aneurysms in recent years. Advances in techniques and materials have led to the management of more challenging cases. Anatomical difficulties in the structure of the aneurysm neck can adversely affect the success of the procedure. In this study, we aimed to evaluate early and midterm outcomes in patients with wide-necked infrarenal abdominal aortic aneurysms treated with 34 mm or 36 mm EVAR endografts.

Material and Methods: We evaluated infrarenal abdominal aortic aneurysms treated with 34 mm or 36 mm long EVAR allografts between January 2019 and January 2023 at Ankara Bilkent City Hospital Cardiovascular Surgery Clinic. We included and assessed patients with a neck diameter of 28 mm or greater using follow-up computed tomography angiography (CTA). We evaluated early and midterm morbidity and mortality as well as endovascular complications such as endoleak or migration.

Results: A total of 58 patients with wide-neck infrarenal abdominal aortic aneurysms underwent 34 mm or 36 mm EVAR endograft deployment. There was no early mortality. The mean follow-up period was 21.7±6.4 months. Eight patients were found to have endoleaks—four had type 2 endoleaks, two had type 1b endoleaks, one had type 3 endoleak and one had type 1a endoleak. Except for type 2 endoleaks, all patients underwent endovascular reintervention.

Conclusion: Our study demonstrated the successful application of 34 mm or 36 mm long endografts to patients with abdominal aortic aneurysms with a wide neck diameter. Regarding the midterm outcomes, standard EVAR procedures with large endografts are feasible and have successful outcomes.

Keywords: Wide neck, endoleak, endovascular aneurysm repair, abdominal aortic aneurysm

INTRODUCTION

Endovascular aneurysm repair (EVAR) has become the most preferred method for treating anatomically suitable abdominal aortic aneurysms in recent years [1]. With the development of endograft technologies and the increase in experience, the number of applications of endovascular interventions has increased.

The proximity of the aneurysm to the neck significantly affects the outcome of endovascular intervention [2]. Several adverse aortic neck characteristics, including a wide infrarenal aortic neck diameter, short neck length, excessive angulation and reverse tapering, are known to be associated with complications in the proximal landing zone [3-5]. Furthermore, studies have shown that an infrarenal neck diameter greater than 28 mm is also an important factor in adverse outcomes [4,5].

Wide aortic neck definitions vary based on the authors. Although there is no consensus, wide necks greater than 28 mm tend to be

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associated with more type 1a endoleaks and late interventions [6]. However, some studies claim no differences when patients are sorted as >25 mm infrarenal aortic neck diameter or below [7]. AbuRahma et al. reported that patients with a larger aortic neck diameter of 31 mm had greater type 1a endoleak and late intervention or mortality rates [8]. Additional characteristics, such as short necks and larger aneurysm diameters, may also explain the greater morbidity rates found in patients with wider proximal necks after standard EVAR procedures.

The present study aimed to investigate the early and midterm effects of 34 mm or 36 mm long endografts on wide-necked abdominal aortic aneurysms (AAAs) after EVAR. The frequency of endovascular complications was noted and the literature was reviewed.

MATERIAL AND METHODS

Study Design and Sample Selection

This study was initiated after receiving the approval of the Ankara Bilkent City Hospital Clinical Research Ethics Committee (Number: E1-21-1721, Date: 14-04-2021) Written consent was obtained from the patients after being informed. Between January 2019 and January 2023, EVAR procedures performed at our single tertiary center were retrospectively scanned from the hospital database and patient records. A total of 58 patients who underwent the EVAR procedure for infrarenal neck diameters measuring 28 mm or larger constituted the patient cohort. Patients who underwent complex EVAR, such as the parallel graft chimney technique, surgeon-modified fenestration or emergency surgery, were excluded from the study.

Data Collection and Measurements

All patients underwent preoperative high-resolution multislice computed tomography angiography (CTA). To plan the procedure and determine the appropriate device size, we utilized a three-dimensional vascular imaging tool (RadiAnt DiCOM viewer v2021.2 (64-bit)). Demographic data, comorbidities, and measurements from preoperative CTAs were recorded. All patients who survived the follow-up period were evaluated using our surveillance program with colored Doppler ultrasound (CDUS) and CTAs [9].

The aneurysm neck was evaluated using Diameters A and B, neck length, thrombus, calcification, and angulation. The aortic diameter just below the renal arteries was measured as the 'diameter A', and the aortic diameter just above the aneurysm sac was measured as the 'diameter B'. Oversizing was performed over the largest diameter. The presence of endoleaks and the need for additional procedures were also added to the postoperative CTA data. The defined diameters are demonstrated on the same patient images in Figure 1 and Figure 2.

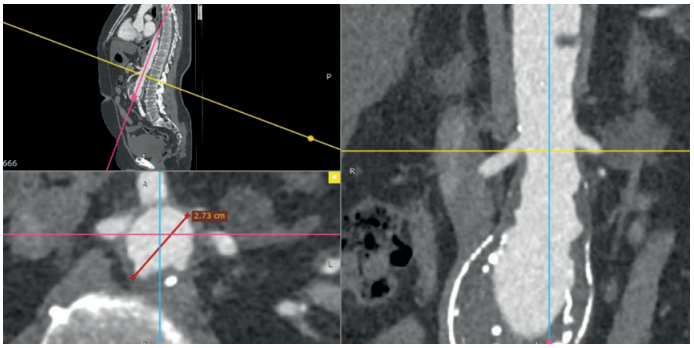

Figure 1. Demonstration of Diameter A measurements on the CTAs

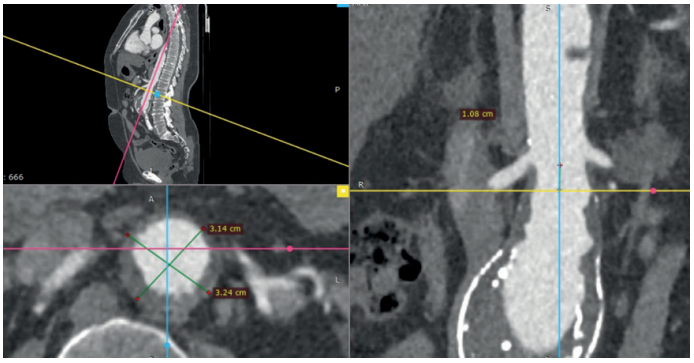

Figure 2. Demonstration of Diameter B measurements on the CTAs

Procedural Details

All patients were evaluated based on the American Society of Anesthesiologists (ASA) classification and the endovascular procedure was performed as previously described in our study [10]. Graft selection was performed by oversizing approximately 20% of the aortic neck diameter. EVAR was performed with contrast media or, in patients with renal insufficiency, with CO_2-guided imaging using the 34 mm Lifetech AnkuraTM AAA Stent Graft System (Lifetech, Shenzen, China) or the 36 mm Medtronic Endurant II abdominal endograft (Santa Monica, CA). All EVAR procedures were performed by the same Cardiovascular Surgeon Team in the hybrid operating room. Additionally, in patients requiring additional procedures during intraoperative complementary angiography beyond the standard procedure, interventions involving aortic cuffs and balloons were applied. Following the procedure, patients were admitted to the intensive care unit.

Technical success was defined as the absence of type 1a or 3 endoleaks on completion angiography. Early mortality was in-hospital (30 days) mortality. Successful sac shrinkage or positive sac remodeling was defined as a decrease of more than 5 mm at the maximum diameter of the aneurysm sac.

Study Endpoints

The patients were evaluated with colored Doppler ultrasound (CDUS) and all patients had postoperative one-year CTA data. The primary endpoints were early and midterm mortality

or morbidities such as the presence of endoleaks or graft migration. Positive remodeling, defined as >3 mm of decrease in the sac diameter, was evaluated. The secondary endpoints were the presence of graft thrombosis or the need for late-stage reoperation. The patients were monitored through first, sixth, and 12th-month CDUS and CTA follow-ups.

Statistical Analysis

The data were analyzed using the IBM SPSS 25.0 (Armonk, NY: IBM Corp.) and MedCalc 15.8 (MedCalc Software bvba, Ostend, Belgium) statistical package software. Descriptive statistical methods (frequency, percentage, mean, standard deviation, median, min–max) were used to evaluate the study data. The normality of the distribution of the data was assessed using the Shapiro–Wilk test, skewness–kurtosis test, and graphical methods (histogram, Q–Q plot, stem and leaf, boxplot). A paired samples t test was used to compare quantitative data that were normally distributed within groups (preoperative-control). The statistical significance level was set at $p<0.05$.

RESULTS

There was no early mortality. The procedure for all patients was successfully completed with 100% technical success. There was no early or late conversion to open surgery. The mean age of these patients was 68.6±7.3 years (ranging from 58 to 80 years). All patients in this group were male and were classified as ASA class 3 or 4. Further details regarding the demographics and comorbidities of these patients and measurements of neck and aneurysm diameters are presented in Table 1. The mean infrarenal aortic neck diameter was 29.6±1.3 mm (25-32 mm).

In three patients, proximal extension was placed below the renal arteries for Type 1a endoleak detected via completion angiography. All these proximal extensions were 36 mm long aortic cuffs and a ballooning procedure was also performed after deployment.

The predefined and postprocedure parameters of Diameters A and B are presented in Table 2. The mean postoperative maximum aneurysm diameter was 65.1±16.4 mm (ranging from 36 to 95 mm). There was a decrease in the aneurysm sac diameter, with no significant difference. Successful sac shrinkage (>5 mm) was managed for 34.5% of the patients (20 patients) during the midterm follow-up period of 21.7±6.4 months.

Table 1. Demographics, comorbidities, and preoperative measurements

		n Mean±SD	% Median (Min-Max)
Gender*	**Female**	0	0.0
	Male	58	100
Age**		68.6±7.4	Range (58–80)
Comorbidities*	**DM**	14	24.1
	HT	38	65.5
	HL	26	44.8
	CKD	4	6.9
	CAD	30	51.7
	Malignity	2	3.5
	PVD	12	20.7
	COPD	18	31
Mean maximum Aneurysm diameter (mm)**		67.6±15.7	Range (55–113)
Follow-up (month)**		21.7±6.4	Range (12–39)

*: n/%, **: Mean±SD/Median (Min-Max), DM: diabetes mellitus, HT: hypertension, HL: hyperlipidemia, CKD: Chronic Kidney Disease, CAD: coronary artery disease, PVD: peripheral vascular disease,COPD: chronic obstructive pulmonary disease

Table 2. Comparison of preoperative and postoperative control measurements

	Preoperative	Postoperative	P value*
Mean maximum aneurysm diameter (mm)	67.6±15.7	65.1±16.4	0.275
Diameter A (mm)	28.3±3.6	29.1±4.0	0.377
Diameter B (mm)	29.9±3.9	33.4±2.6	<0.001

*: Paired Samples t Test (Mean±SD)

The diameter B increased postoperatively, with a significant change ($p<0.001$). According to postoperative follow-up CTAs, endoleaks were detected in eight patients (13.8%). Two patients had type 1b endoleaks (3.45%) due to native iliac artery dilatation, four patients had type 2 endoleaks (6.9%), one patient had type 3 endoleaks (1.7%), and one patient had type 1a endoleak (1.7%). Patients with type 2 endoleaks were under the control of sac diameter measurements at six months. The rest of the patients were endovascularly treated. There was no conversion to open surgery. Additionally, no graft migration was observed. Given that there was only one proximal fixation failure after the procedure, only Kaplan–Meier freedom from adverse events is given in Figure 3.

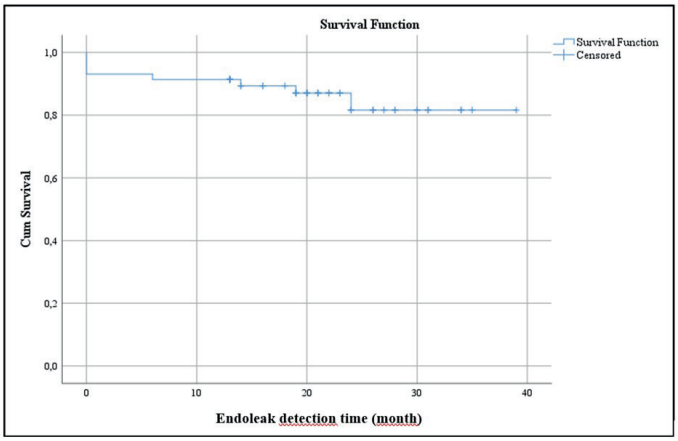

Figure 3. Kaplan Meier analysis of freedom from adverse events

DISCUSSION

EVAR is considered a viable option for patients with infrarenal abdominal aortic aneurysms (iAAAs) characterized by wide aortic necks, particularly those deemed to be at high risk for open surgical repair [11]. Notably, the definition of a wide neck can vary in the literature. It typically spans from 25 mm or greater to 30 mm or greater [6-8] and wide necks were reported to have adverse outcomes after EVAR. In our current study, large endografts deployed to wide infrarenal aortic necks >25 mm had comparable and successful results. We found that EVAR with 34 mm and 36 mm long endografts was feasible, safe, and effective.

The outcomes of EVAR are intricately linked to the morphological characteristics of the preoperative anatomy. Factors such as the length, diameter, angulation, and the presence of thrombus or calcification in the proximal infrarenal aortic neck play crucial roles in achieving effective sealing [12]. In accordance with Chaikof's classification, a proximal neck diameter exceeding 28 mm is recognized as one of the factors associated with unfavorable EVAR outcomes [13].

Preoperative neck diameter is one of the risk factors contributing to aortic neck degeneration, particularly during EVAR procedures performed with self-expandable grafts. Furthermore, it has been reported that having more than two undesirable features in difficult aneurysm necks increases the risk of developing type 1a endoleak by 45.5% [14,15]. The presence of a wide neck alone cannot be considered the sole cause of complications. Previous reports have suggested that neck enlargement occurs through two mechanisms [16-18]. The first component is attributed to the radial force exerted by the endografts against the aortic wall, while the second component is the ongoing dilation of the aortic wall resulting from the progression of aneurysmal disease [16,17].

The results of this study were consistent with the literature, which showed a significant increase in diameter B values. Studies in the literature recommend an oversizing ratio of between 15% and 20% to minimize adverse effects associated with wide-necked anatomies [19]. It has been noted that narrow-necked aneurysms are more prone to expansion after EVAR and can expand to the maximum endograft size. However, this change did not significantly alter the complication rate.[20] In our series, 30% of the patients had reverse tapered proximal aortic necks. While there was a marked change in diameter A, this change did not reach statistical significance. This may be attributed to the follow-up period or small patient cohort. However, there was a significant difference in diameter B (from 29.2±3.9 mm to 33.4±2.6 mm) ($p<0.001$). The diameter B was closer to the diseased segment of the aorta. We believe that, potentially, later in the follow-up period, the diameter A may also increase to a significant difference. However, this enlargement was up to the endograft-oversized diameter and was not associated with endoleak or migration.

Adequate oversizing has proved to reduce the likelihood of proximal endoleak up to 24 months of follow-up when appropriately performed. There may be a greater risk of failure during follow-up when the infrarenal neck is short and wider [19]. In our study, grafts were seated on wide necks with an increase in size of approximately 15–20%, aiming to reduce the rates of proximal endoleak and graft migration. The type 1a endoleak rate was 1.72%, which was comparable and successful.

In a large multicenter study with an average follow-up period of 31 months for patients with wide-necked AAAs, there was a greater risk of an increase in aneurysm sac diameter [4]. In our current study, 50% of our patients experienced positive remodeling for sac regression (>3 mm), and for the remainder of the patients, there was no significant change in maximum aneurysm diameter.

Studies in the literature suggest that the likelihood of adverse outcomes leading to failure is higher with longer-term follow-up. Due to our relatively short follow-up, we did not observe these adverse outcomes. Our study demonstrated the feasibility, safety, and effective use of 34 mm and 36 mm long EVAR endografts with approximately 15-20% oversizing, resulting in low and acceptable complication rates.

Limitations

This study had a retrospective nature, with a relatively short follow-up duration, particularly given the limited number of patients from a single center. There were no comparisons of endografts with different characteristics, endograft materials or radial forces.

CONCLUSION

As a result, the continuation of close follow-up for patients who underwent EVAR due to a wide-necked AAA is important for assessing potential adverse outcomes, the development of complications, and the need for reintervention. This study demonstrated the feasibility and safety of EVAR for infrarenal wide-necked AAA patients with large (34 mm and 36 mm) endografts. However, long-term close monitoring can be more instructive in identifying potential complications that may lead to the development and guidance of interventions.

Ethics Committee Approval: Ankara Bilkent City Hospital Clinical Research Ethics Committee (Number: E1-21-1721, Date: 14-04-2021)

Patient Consent for Publication: Not necessary for this manuscript.

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