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# What has changed in our endovascular practice at abdominal aortic aneurysms?

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#### ABSTRACT

**Objectives:** We aimed to investigate whether there was a change in the perioperative features and outcomes following endovascular repair.

Patients and methods: This retrospective study included 249 consecutive patients (223 males, 26 females; median age 70 years; interquartile range [IQR], 66 to 74 years) with abdominal aortic aneurysms (AAAs) who were treated using endovascular approach between January 2012 and February 2020. The patients were stratified into three tertiles based on the time period of the procedure (83 patients in each group) as follows: 2012-2017, 2017-2018, and 2018-2020. Trends over time were analyzed among the three patient groups.

Results: The median aneurysm diameter was 63 (IQR, 55 to 71) mm. The third tertile (2018-2020) had a significant association with lower durations of the procedure, particularly compared to the first tertile (2012-2017). The median duration of the intensive care unit stay (median 6 h, 4 h, and 4 h respectively; p<0.001) and hospital stay (median three days, two days, and two days, respectively; p<0.001) were found to be significantly shorter after the first tertile.

Conclusion: Based on these results, EVAR is a safe and feasible method of treatment in AAAs. These results support a potential link between improved outcomes, technical feasibility, and experience over time.

Keywords: Abdominal aortic aneurysm, aortic surgery, endovascular aneurysm repair, endovascular surgery, stent.

Endovascular abdominal aortic aneurysm (AAA) repair has become the standard treatment option for AAAs.<sup>[1]</sup> Trends over the years have shown the increased utilization of endovascular aneurysm repair (EVAR) over open surgery for the treatment of AAAs.<sup>[2]</sup> Short-time benefits have been well-documented in randomized-controlled trials.<sup>[3-6]</sup> However, there are some debates regarding the long-term outcomes of endovascular procedures.<sup>[7-9]</sup> Despite this controversy, EVAR is still the preferred option for treatment of AAAs. Since the registry data and observational studies also provide evidence for recent guidelines.<sup>[1,10]</sup>

There are some reports investigating the volume-outcome relationship for EVAR. [11,12] The main conclusion of these studies is that the high-volume center is associated with lower mortality and better outcomes. Therefore, it is obvious that experienced centers and surgeons are the key important issue for better outcomes. Gaining experience is related not only with high-volume, but also with technical skills changing over years.

In the present study, we aimed to investigate our clinical and technical outcomes of EVAR procedures in patients with AAAs.

# PATIENTS AND METHODS

This retrospective study included 249 consecutive patients (223 males, 26 females; median age 70 years; interquartile range [IQR], 66 to 74 years) with AAAs who were treated using EVAR in the Department of Cardiovascular Surgery at Turkey Yuksek Ihtisas Hospital and Ankara City Hospital between January 2012 and February 2020. All patients were treated by experienced vascular surgeons. The patients were stratified into three tertiles based on the time period

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of procedure (83 patients in each group). The time periods were designed by an equal number of patients, rather than the standard time periods as follows: 2012-2017, 2017-2018, and 2018-2020. A written informed consent was obtained from each patient. The study protocol was approved by the Ankara City Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Demographic variables, periprocedural parameters such as type of anesthesia, duration of operation, duration of radiation exposure, amount of contrast agent used, length of intensive care unit (ICU) and hospital stay, and outcomes of the procedures and mortality for the three groups were recorded for analysis.

# Devices used in this period

The stent-grafts used in our centers have changed throughout the study period. At the earliest time of the study, the unibody stent-graft Endologix AFX®, (Endologix Inc., Irvine, CA, USA) were more common to be implanted, whereas, at the recent times, all the stent-grafts were modular types mainly Medtronic Endurant™ II (Medtronic, Minneapolis, MN, USA) and Lifetech Ankura™ AAA stent graft (Lifetech Scientific Corp., Shenzen, China).

Briefly, unibody stent-graft consists of a main bifurcated unibody and aortic extension. It mainly provides anatomic fixation at the level of aortic bifurcation. One-sided femoral exploration is sufficient for deployment. On the other hand, the deployment technique of both modular devices is remarkably similar. Bilateral femoral exploration is a standard for both stent-grafts. Contralateral limb cannulation is a limiting step for fluoroscopy durations for both stent-grafts. The main difference between the modular types is the covered graft material, which is Dacron® of the Medtronic

Table 1     Baseline characteristics by tertiles													
			Tertile 2017 (n=83)	)			Tertile 018 (n=83)						
	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	p
Age (year)			70	65-74			69	66-74			70	65-77	0.614
Sex Male	72	86.7			74	89.2			77	92.8			0.442
Diabetes	19	22.9			22	26.5			25	30.1			0.573
Hypertension	58	69.9			50	60.2			62	74.7			0.125
Hyperlipidemia	26	31.3			32	38.6			15	18.1			0.013
COPD	31	37.3			21	25.3			31	37.3			0.164
Renal disease	11	13.3			6	7.2			9	10.8			0.442
PAH	7	8.4			10	12.0			5	6.0			0.388
CAD	48	57.8			35	42.2			30	36.1			0.015
CABG	25	30.1			13	15.7			14	16.9			0.039
CHF	7	8.4			3	3.6			4	4.8			0.374
Smoking	27	32.5			41	49.4			35	42.2			0.086
Malignancy	9	10.8			3	3.6			2	2.4			0.039
Abdominal surgery	12	14.5			7	8.4			2	2.4			0.020
ASA score >2	51	61.4			32	38.6			39	47.0			0.012
EF			55	50-59			55	45-57			55	50-60	0.243
Diameter (mm)			60	55-67			63	55-75			61	56-71	0.201
Ruptured AAA	3	3.6			6	7.2	1 1		10	12.0		A.D.C. C	0.121

IQR: Interquartile range; COPD: Chronic obstructive pulmonary disease; PAH: Peripheral arterial disease; CAD: Coronary artery disease; CABG: Coronary artery bypass grafting; CHF: Congestive heart failure; ASA: American Society of Anesthesiologists; EF: Ejection fraction; AAA: Abdominal aortic aneurysm.

Endurant™ II (Medtronic, Minneapolis, MN, USA) and expanded polytetrafluoroethylene (e-PTFE) of the Lifetech Ankura™ AAA stent graft (Lifetech Scientific Corp., Shenzen, China).

# Statistical analysis

Statistical analysis was performed using the SPSS 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 whether they were normally distributed. Descriptive data were presented in median and IQR for the non-normally distributed and ordinal variables. The Kruskal-Wallis test was conducted to compare variables among the tertiles. A pair-wise comparison, using an adjusted alpha ( $\alpha$ )-level of 0.017, was performed using the Mann-Whitney U test. A p value of 0.05 was considered statistically significant.

#### RESULTS

Of a total of 249 patients included in the study, there were 83 patients in each tertile. Baseline demographic and clinical characteristics are shown in Table 1. Comorbidities such as coronary artery disease, malignancy, and history of abdominal surgery were more common among the patients in the earliest tertile of the patients (p=0.015, p=0.039, and p=0.020,

respectively). In addition, patients with the American Society of Anesthesiologists (ASA) Class >2 were more frequent in the earliest period (p=0.012). The other demographics, ejection fraction values, and preoperative aneurysm diameters were similar among the groups (Table 1).

Regarding the technical details, duration of operation and duration of fluoroscopy were significantly shorter at the later period of experience (p<0.001 for both). Also, the amount of contrast agents used decreased after the second tertile (60 mL, 70 mL, and 50 mL, respectively; p<0.001). Additionally, modular parts used in the procedure (particularly iliac extensions) and need for ballooning were more common at the third tertile (p=0.003 and p<0.001, respectively) (Table 2).

The median length of ICU stay was 6 h, 4 h, and 4 h, respectively (p<0.001). The median length of stay in the hospital was three days, two days, and two days, respectively (p<0.001). The decrease for ICU and hospital stays was significant by the second tertile (p<0.001 and p=0.008, respectively).

Mortality at 30 days was 1.6% (4/249) for the whole patient cohort. The rate of in-hospital mortality was similar among three groups (p=0.169), whereas both the follow-up time and late mortality decreased in the later period (p<0.001) (Table 3).

Table 2     Technical details of procedures														
	1 <sup>st</sup> Tertile 2012-2017 (n=83)					2 <sup>nd</sup> Tertile 2017-2018 (n=83)				3 <sup>rd</sup> Tertile 2018-2020 (n=83)				
	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	Þ	
General anesthesia	56	67.5			68	81.9			72	86.7			0.007	
Type of stent-graft Unibody Modular	59 24	71.1 28.9			9 74	10.8 89.2			0 83	0 100			<0.001	
Duration of operation (min)			120	120-150			150	120-180			120	90-150	<0.001	
Duration of fluoroscopy (min)			18	14-20			16	10-25			12	9-18	<0.001	
Amount of contrast agent (mL)			60	60-80			70	60-100			50	40-60	<0.001	
Aortic extension	0	0			4	4.8			2	2.4			0.131	
Iliac extension	17	20.7			13	15.7			31	37.3			0.003	
Balloon usage	7	8.5			19	22.9			50	60.2			< 0.001	
IQR: Interquartile range.														

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Table 3 Outcomes and postoperative results													
			st Tertile -2017 (n=83	)	2 <sup>nd</sup> Tertile 2017-2018 (n=83)								
	n	%	Median	IQR	n	%	Median	IQR	n	%	Median	IQR	Þ
In-hospital mortality	1	1.2			3	3.6			0	0			0.169
Endoleak	11	13.3			18	21.7			8	9.6			0.081
Type IA	0	0			2	2.4			1	1.2			
Type IB	1	1.2			3	3.6			2	2.4			0.070
Type II	4	4.8			11	13.3			3	3.6			0.068
Type III	6	7.2			1	1.2			2	2.4			
Follow-up period													
(months)			44	31-56			25	18-29			13	12-14	< 0.001
Late mortality	28	33.7			9	10.8			1	1.2			< 0.001
Re-intervention	10	12			7	8.4			6	7.2			0.536
IQR: Interquartile range.													

# **DISCUSSION**

This study documents an evaluation of trend during the years of gaining experience on EVAR procedure. The introduction of EVAR has provided an opportunity for surgeons to treat non-operable patients and patients with comorbidities at the beginning. The satisfactory outcomes and the long-time durability of these procedures have enabled this treatment modality for almost all infra-renal AAAs. In recent years, the endovascular approach for AAAs has reached up to 75 to 80% in our clinic. [13] As shown in this study and previous studies, patients with more comorbidities (such as coronary artery disease, coronary artery bypass grafting history, malignancy, and previous abdominal operation) and increased ASA scores were treated endovascularly in earlier periods of our experience.<sup>[14]</sup> The decreased rates of these comorbidities in later periods may have contributed to the increased utilization of endovascular procedures in almost all patients, even those with no comorbidities.[13]

The shorter periods of procedure and fluoroscopy and decreased amounts of contrast agents used coincided with the last period. We observed a trend with a stabilized decrease in these parameters in each time period; however, the significant decrease was seen only in the latest period. This can be attributed to the type of the stent-graft used. In the earlier periods, we used more commonly the unibody stent-graft (71%) which provided only one-sided femoral exploration and shorter fluoroscopy

and procedure time. At the second tertile, modular stent-grafts gained popularity in our clinic (89%) and, currently, we implant only modular stent-grafts. Modular stent-grafts requires more technical procedures during deployment (such as two-sided femoral exploration, contralateral limb cannulation) which prolongs the procedure and fluoroscopy time and increases the amount of contrast agent used. An increase of these parameters (i.e., procedure duration, fluoroscopy duration, and amount of contrast agents) at the second tertile may be understandable. However, with gaining experience with a large volume of patients, we provided a plateau phase during the first and second tertiles and a decrease in the third tertile with increased experience. This decrease significantly manifested even with more use of iliac extensions and balloons which are technically time-consuming. The increased use of iliac extensions and balloons can be attributed to the increased complexity of aneurysms (angulated and elongated) over time, as the instruction-for-use criteria of the endograft types and technical experience have extended day by day. Recently, the median fluoroscopy duration of our procedures is only 12 min (IQR, 9 to 18 min), which appears to be very convenient. There are some reports documenting techniques for contralateral limb cannulation and these reports particularly aim to decrease fluoroscopy times. [15-17] In these reports, about 12 to 15 min of contralateral limb cannulation has been documented, indicating longer fluoroscopy times for whole procedure. Therefore, a 12-min

total fluoroscopy time is quite considerable for our experienced team.

The ICU and hospital stays following the endovascular procedure was significantly shorter as of the beginning of second tertile, corresponding to 2017. The patients with less comorbidities may have contributed to this finding, as the EVAR procedure gained popularity for a greater population of AAAs.

The decrease at the mid-term mortality at the latest period is quite understandable, since the follow-up period was longer for the earlier periods (44 months, 25 months, and 13 months, respectively). Overall long-term mortality rate was 15.3% (2-38/249) over a median period of 26 months. However, supporting evidence of decreasing mid-term mortality over time was published by Varkevisser et al.<sup>[18]</sup> who documented that four-year survival tended to improve in recent years, due to technical improvements and increased experience.

Nonetheless, there are some limitations. Firstly, the groups were non-heterogenous regarding stent-grafts used and comorbidities. Secondly, mid-term mortality should be assessed with comparable follow-up periods for each group.

In conclusion, technical success of the procedure and perioperative outcomes have improved in more recent years. We believe that the relative perioperative outcome benefits of EVAR such as shorter ICU and hospital stay have increased over time.

## Declaration of conflicting interests

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

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