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Elective endovascular repair of abdominal aortic aneurysms in elderly with Endologix AFX® endograft: Our short-term and one-year results

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ABSTRACT

Objectives: In this study, we aimed to evaluate the performance of Endologix AFX® endografts in elderly in the early period and in the first postoperative year.

Patients and methods: Between January 2012 and December 2017, a total of 63 consecutive patients (60 males, 3 females; mean age 68.2±7.2 years; range, 52 to 84 years) with an infrarenal abdominal aortic aneurysm (AAA) were operated using endovascular aneurysm repair (EVAR) with an Endologix AFX® endograft in an elective fashion. The patients were divided into two groups as those aged under 70 years (n=35) and over 70 years of age (n=28).

Results: The most associated comorbidities were hypertension (63.5%), coronary artery disease (57.1%), and chronic obstructive pulmonary disease (38.1%). There was no 30-day mortality and no renal or cardiac morbidity in the early postoperative period. The mean length of intensive care unit stay was 9±6.4 h and the mean length of hospital stay was 3±1.4 days, indicating no statistically significant difference between the groups.

Conclusion: Our study results suggest that the Endologix AFX® endograft can yield successful outcomes in the early and postoperative first year, irrespective of the age of the patient.

Keywords: Early mortality; elderly patients; Endologix AFX endograft; endovascular aneurysm repair.

Since Parodi[1] performed the first endovascular aneurysm repair (EVAR), lots of benefits including shorter hospital stay, minimal blood transfusion, rapid recovery time, minimal invasive nature, and successful 30-day mortality/morbidity rates have been achieved with EVAR. The evolution of endoluminal devices and anesthetic techniques have also allowed physicians to treat higher-risk patients, particularly who are unfit for conventional open repair (OR).[2,3]

The risk of death among patients with unrepaired aneurysms increases exponentially with increasing aneurysm size to an eventual rupture. Non-operative management of infrarenal abdominal aortic aneurysms (iAAAs) carries the risk of death and rupture with high mortality rates of urgent surgery for rupture.[4-6]

Age is a well-known independent risk factor for death after iAAA repair and there are many studies comparing mortality rates among EVAR and OR in octogenarians.[2,3,7,8] As the life-expectancy has increased, the prevalence of iAAAs is expected to increase. Besides, as the technology improves, different endografts with different characteristics and different advantages would be available. Recent developments in the iAAA stent-graft devices such as more flexible devices, small delivery catheters, and partial

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deployment of endografts to facilitate repositioning have made more patients eligible for EVAR.

In the present study, we aimed to evaluate the performance of Endologix AFX® endografts (Endologix, Inc., Irvine, CA, USA) in elderly in the early period and in the first postoperative year and to compare our results with the OR and medical non-operative aortic aneurysm management results in the light of literature data.

PATIENTS AND METHODS

Between January 2012 and December 2017, a total of 63 consecutive patients (60 males, 3 females; mean age 68.2±7.2 years; range, 52 to 84 years) who were diagnosed with an iAAA and were electively operated with Endologix AFX® endograft in our cardiovascular clinic were included in this study. Urgent procedures and patients with simultaneous coronary artery bypass grafting or percutaneous coronary interventions were excluded from the study. The patients were divided into two groups as those aged under 70 years (Group 1, n=35) and over 70 years of age (Group 2, n=28). Pre-, intra-, and postoperative data of the patients were retrospectively analyzed. All operations were performed in a hybrid operating room.

A written informed consent was obtained from each patient. The study protocol was approved by the Türkiye Yüksek Ihtisas Training and Research Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Patient data

For both groups, all data were collected pre-, intra-, and postoperatively and for the first postoperative year. All patients were evaluated by electrocardiogram, transthoracic echocardiography, coronary angiography, if symptomatic, pulmonary functional test, telecardiography, and computed tomography (CT) for anatomic aortic evaluation. Conventional CT and three-dimensional (3D) CT scan, which is a process that CT images are reformatted in planes perpendicular to the vessel in 3D space, were used to assist the proper endograft selection. During the follow-up period, conventional CT scan was performed at one and three months and at six and 12 months, according to patients' procedural status. We also performed abdominal aortic colored Doppler ultrasonography in case of borderline renal impairment.

Anesthetic management

According to the patients' risk profile, anesthetic management was chosen as local, locoregional, or general anesthesia. General anesthesia was performed, if there was possibility for conversion to open repair or if there would be intense femoral dissection for exposure or if the patient was unable to tolerate local anesthesia well. Local anesthesia was mandatory in high-risk morbid patients.

Endologix AFX®(bifurcated endograft system) specifications

The AFX® device consists of a main bifurcated unibody and a proximal aortic extension, which affix firmly to the aorta and provides sealing, while reducing the possibility of stent migration at the same time. The skeleton of the device is made of a cobalt-chromium alloy in a multilinked self-expanding unibody. External fabric is made of a multilayer expanded polytetrafluoroethylene (ePTFE) material (STRATA). Bifurcated AFX® endograft system for EVAR is the only graft with anatomical fixation to the aortic bifurcation compared to the most other grafts using the infrarenal neck. The device is delivered with the 17-F AFX® introducer system ipsilaterally and 9-Fr sheath contralaterally.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). Continuous variables with normal distribution were expressed in mean ± standard deviation (SD), while categorical variables were expressed in number and percentage. The variables were analyzed using the visual (histograms, probability plot) and analytic methods (Kolmogorov-Smirnov test) to determine whether they were normally distributed. Demographic features and perioperative variables which were not normally distributed were compared using the Mann-Whitney U test and chi-square test. Pre- and postoperative laboratory values were assessed by the Wilcoxon signed-rank test for both groups. A p value of less than 0.05 was considered statistically significant.

RESULTS

Baseline demographic and clinical characteristics of the patients are summarized in Table 1. The most associated comorbidities were hypertension (63.5%), coronary artery disease (57.1%), and chronic obstructive pulmonary disease (38.1%). There was no statistically significant difference in baseline demographic and clinical characteristics between the groups.

Table 1. Baseline demographic and clinical characteristics of patients

	Group 1 (<70 years) (n=35)		Group 2 (>70 years) (n=28)		Total (n=63)			
	n	Mean±SD	n	Mean±SD	n	%	Mean±SD	*p*
Age (year)		63.5±5		74.4±4.4			68.2±7.2	0.001
Gender Male	33		27		60	95.2		1.000
Hypertension	23		17		40	63.5		0.795
Coronary artery disease	17		19		36	57.1		0.151
Chronic obstructive pulmonary disease	13		11		24	38.1		0.795
Coronary artery bypass grafting	9		10		19	30.2		0.497
Hyperlipidemia	10		7		17	27.0		0.803
Diabetes mellitus	7		6		13	20.6		0.845
Chronic renal failure	5		6		11	17.5		0.628
Peripheral arterial disease	4		2		6	9.5		0.688
Congestive heart failure	4		2		6	9.5		0.688
Smoking	12		12		24	38.1		0.287
Malignancy	5		4		9	14.3		0.964
Symptomatic	15		15		30	47.6		0.344
Previous operation	5		3		8	12.7		1.000
Aneurysm diameter (mm)		59.5±7.1		62.3±10.3			60.71±8.72	0.489
Ejection fraction (%)		53.6±10.4		49.9±9.9			51.97±10.38	0.043

SD: Standard deviation.

Two thoracic endovascular procedure were performed simultaneously through the same incision. These patients were in the elderly group. Iliac extensions were utilized in 13 patients: seven (19.4%) and six (21.4%) for Group 1 and 2, respectively.

In the early postoperative period, there was no early (30-day) mortality, or no renal or cardiac morbidity. Early morbidities were mostly due to the femoral access. One patient experienced femoral thrombus, as the sheath was not removed. There was no Type 1 or Type 3 endoleak. Only three Type 2 endoleaks were detected intraoperatively. In the first postoperative year, there was no Type 2 endoleak left, and they were all thrombosed. The early postoperative results are shown in Table 2.

The EVAR procedure was performed under local anesthesia in 34 patients (54%). The choice of anesthesia is given in Table 3. In high-risk and

Table 2. Early postoperative results

	Group 1 (<70 years) (n=35)		Group 2 (>70 years) (n=28)		Total (n=63)		
	n	Mean±SD	n	Mean±SD	n	Mean±SD	*p*
Early mortality	0		0		0		
Early morbidity	9		10		19		0.735
Renal injury	0		0		0		
Cardiac morbidity - myocardial infarction	0		0		0		
Endoleak	2		1		3		0.242
Type II endoleak	2		1		3		0.441
Migration	0		0		0		
Iliac occlusion	0		1		1		0.438
Femoral thromboendarterectomy	5		6		11		0.428
Graft interposition	2		2		4		0.683
Intensive care unit PERIOD (hours)	7.4		11.1			9±6.37	0.193
Length of stay (days)	2.89		3.68			3±1.42	0.418
Procedure time (min)		134.7±29.4		126.7±18.4		131.3±25.4	0.544
Radiation time (min)		17.5±4.2		18.1±3.6		17.8±4	0.299
Amount of contrast material (cc)		66.1±19.02		68.15±13.9		66.98±16.9	0.395

SD: Standard deviation.

Table 3. Anesthesia type chosen

	Group 1	Group 2	Total	
Anesthesia type	n	n	n	%
Local	18	15	34	54.0
Locoregional	2	1	3	4.8
General	15	12	26	41.3

elderly patients, interventions were done under local anesthesia. The mean procedural time was 131.3±25.4 min, the mean radiation duration was 17.8±4.0 min, and the mean opaque volume was 67.0±16.9 cc.

However, there was a statistically significant difference between the pre- and postoperative total hematocrit values, but not between the two groups. There was no massive blood loss during surgery, although the decrease was thought to be due to dilutional volume loads after the procedure. There was no transfusion requirement perioperatively. There was no significant difference in renal functions and serum creatinine levels between pre- and postoperative measurements.

At the first postoperative year, there was Type 3 endoleaks in only two patients. One of these patients was operated and discharged uneventfully, while the other came with aortic rupture and died. There were three mortalities at the first postoperative year. The reasons for mortality were cardiac event, malignancy, and aortic rupture.

DISCUSSION

During the past decade, EVAR has gained wide acceptance as the preferred method in the treatment of anatomically suitable patients with iAAA. Besides the noninvasive nature of the procedure, lower 30-day mortality and morbidity, rapid discharge, and fewer complications are the main advantages. Last decades have witnessed this revolution, with many endograft concepts emerging and disappearing from the clinical landscape. The human aorta is an unforgiving environment and only selected designs have proven staying power.

The pros and cons of pursuing elective iAAA in the elderly population is a topic of considerable debate. However, the potential risk of rupture and high mortality rates of ruptured aneurysm repairs make the observational medical management of iAAAs over-venturesome. Our results showed successful early mortality and morbidity rates compared to younger patients. There were three mortalities at the first postoperative year. The mortality causes were cardiac event, malignancy, and one aortic rupture. Correspondingly, compared to OR, significant advantages were achieved with EVAR. In our OR study, the early mortality was 3.9% and 8.7% for patients aged under 70 years of age and over respectively.[7]

Lederle et al.[4] reported that the one-year risk of AAA rupture ranged from 9 to 32% among patients of all ages depending on the aneurysm size. The natural history studies reported death with aortic rupture at three years as 36% for AAAs 5.5 to 5.9 cm in diameter, and as 50% for AAAs 6.0 to 7.0 cm.[9] Furthermore two-thirds of AAA ruptures were shown to occur in patients aged over 75 years, with a resulting estimated 30-day mortality risk of 69%.[4,9] As a consequence, a considerable debate is focused on the management of AAA repair whether OR or EVAR in the elderly.[4,10] Most centers reported 30-day mortality as exceeding 5% for all patients operated electively for iAAA.[11] For octogenarians, early mortality was 8% in a registry study, although the numbers could vary.[12] In our study, there was no early mortality in both groups for EVAR with Endologix AFX®. Furthermore, early mortality for elderly patients with OR was 8.7% being nearly more than two-fold compared to the younger patients.[7]

Furthermore, older patients experience more postoperative complications or are less able to be rescued from those complications than younger patients. Morbidity after AAA repair has been recently estimated to be 24% for OR and 13% for EVAR in matched cohorts.[13] For octogenarians, these rates double up. Similarly, the mortality rates associated with both OR and EVAR are nearly double for octogenarians compared to non-octogenarians.[10] In our study, 30-day mortality and early morbidities for both groups were significantly very low. In addition, there were no cardiac or renal complications (Table 2).

As the Endologix AFX® may be performed more easily under local anesthesia, its utilization is more acceptable for high-risk and elderly patients. In our study, EVAR with Endologix AFX® endograft was performed under local anesthesia in 34 patients (54%). It can be utilized with ipsilateral femoral surgical exposure and contralateral sheath insertion percutaneously; therefore, it is easier to perform under local anesthesia. Similarly, this endograft does not require contralateral limb cannulation which is a time-consuming procedure. In our study, general anesthesia was used, if the patient's mood or psychologic status was not suitable, or if there was a possibility of

conversion to open surgery, or if the patient was obese and intense femoral dissection seemed to be needed (Table 3).

Moreover, EVAR is less invasive than conventional surgery. The risk of renal hypoperfusion secondary to hemodynamic instability and cross clamping is eliminated, surgical trauma is reduced, and ischemia-reperfusion injury is attenuated.[14-16] Nonetheless, EVAR still causes a significant systemic reaction, possibly through a combination of ischemia-reperfusion injury and surgical trauma to the aorta and visceral vessels. In addition, embolization, contrast media, and suprarenal endograft fixation may also play roles. Silingardi et al.,[14] compared modular endograft types to unibody endografts and found out that unibody endografts might reduce nephrotoxicity of the contrast medium, particularly with existing renal insufficiency and might also reduce ionizing radiation exposure for both the patients and operators. As the placement of the first bifurcation graft may be done under scopy without contrast material. In adddition to this, there is no rate-limiting step as contralateral limb cannulation. These are the main advantages of AFX endograft.

The eligibility of the patient has been identified as a major determinant of the need and outcome of iAAA repair (OR and EVAR).[17] In addition to anatomic suitability, comorbidities are also important. Anatomic suitability for EVAR is determined according to neck anatomy (diameter, length, angulation), iliac artery morphology, aneurysm angulation and tortuosity, defined according to the Society for Vascular Surgery (SVS)/American Association for Vascular Surgery (AAVS) standards.[18] In the EVAR procedures, the key point is the preoperative evaluation of aorta and anatomic suitability of the patient. In our study, there was no conversion to OR. However, all patients should be informed of such a possibility.

In addition, an individualized risk/benefit analysis must be undertaken for each patient. Extremely high-risk patients who has a short life-expectancy due to non-aneurysmal disorders may be appropriate candidates for watchful waiting with the awareness of natural AAA history studies. However, for the rest who has a suitable aortic anatomy, EVAR is the most optimal option for today. Delayed surgery is also associated with an increase in the risk of perioperative mortality for asymptomatic patients who meet criteria for repair of iAAA. There is a need for surgeons to incorporate this increasing risk into discussion with patients.

There are some limitations for the current study. Firstly, there was no comparison of this graft with the other available grafts. Therefore, the results were limited to AFX endograft. Secondly, even if there was no significant differences between some measures such as intensive care unit period, it was much higher in elderly patient groups (11 vs 7 hours). This unsignificant difference may be due to smaller number of patients.

In conclusion, EVAR achieved successful and satisfactory early results in the elderly patients with an Endologix AFX® endograft in this study. We, therefore, suggest that non-operative management of iAAAs is not acceptable, if the aortic anatomy is suitable. The postoperative first-year results were also satisfactory with the Endologix AFX® endograft. It should be kept in mind that patients should be closely followed for endoleaks or complications including aortic rupture after the procedure. Further long-term results would lead the final judgement not only for EVAR procedures, but for Endologix AFX® endograft.

Declaration of conflicting interests

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