Turkish Journal of Thoracic and Cardiovascular Surgery 2019;27(1):29-34
http://dx.doi.org/doi: 10.5606/tgkdc.dergisi.2019.16328

Original Article / *Özgün Makale*

Our early and mid-term results for endovascular repair of abdominal aortic aneurysms

Abdominal aort anevrizmalarının endovasküler tamirine ilişkin erken ve orta dönem sonuçlarımız

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ABSTRACT

Background: In this study, we present our early and mid-term results of endovascular aneurysm repair in patients with infrarenal abdominal aortic aneurysms.

Methods: Between December 2011 and January 2017, a total of 154 patients (136 males, 18 females; mean age 71.7 years; range, 55 to 94 years) who underwent endovascular aneurysm repair were retrospectively analyzed. Data including demographic characteristics of the patients, pre-procedural additional diagnoses, mortality and morbidity rates, length of intensive care unit and hospital stays, amounts of blood products used, complications and reinterventions were recorded.

Results: Seven patients underwent intervention in the emergency setting due to aneurysm rupture, while 147 patients received elective surgery. The mean follow-up was 35 (range, 12 to 72) months, the mean length of intensive care unit stay was 1.1 (range, 1 to 4) days, and the mean length of hospital stay was 3.1 (range, 3 to 7) days. A mean 0.3 units of erythrocyte suspension was used during the treatment. Endoleak developed in 16 patients, occlusion in the graft leg in two patients, increased aneurysmal diameter in six patients, and wound healing problems in five patients. Cross femoral bypass was applied in two patients, balloon dilation in three patients, proximal extension in three patients, and distal extension in four patients. Intraoperative mortality occurred in one patient. The total mortality rate was 7% and first 30-day mortality rate was 2%.

Conclusion: Our study results suggest that endovascular aneurysm repair has certain advantages including a low operative mortality rate, short intensive care unit and hospital stays, and less blood product use. In addition, this technique can be performed with regional anesthesia in high-risk comorbid patients.

Keywords: Abdominal aortic aneurysm; endovascular aortic repair; stent graft.

ÖZ

Amaç: Bu çalışmada, infrarenal abdominal aort anevrizması olan hastalarda endovasküler anevrizma tamirine ilişkin erken ve orta dönem sonuçlarımız sunuldu.

Çalışma planı: Aralık 2011 - Ocak 2017 tarihleri arasında endovasküler anevrizma tamiri yapılan toplam 154 hasta (136 erkek, 18 kadın; ort. yaş 71.7 yıl; dağılım, 55-94 yıl) retrospektif olarak incelendi. Hastaların demografik özellikleri, işlem öncesi ek tanıları, mortalite ve morbidite oranları, yoğun bakım ünitesinde ve hastanede kalış süreleri, kullanılan kan ürünü miktarları, komplikasyonlar ve yeniden girişimler dahil olmak üzere veriler kaydedildi.

Bulgular: Yedi hastaya anevrizma rüptürü nedeniyle acil koşullarda girişim uygulanırken, 147 hastaya elektif cerrahi yapıldı. Ortalama takip süresi 35 (dağılım, 12-72) ay, yoğun bakım ünitesinde kalış süresi 1.1 (dağılım, 1-4) gün ve hastanede kalış süresi 3.1 (dağılım, 3-7) gün idi. Tedavi süresince ortalama 0.3 ünite eritrosit süspansiyonu kullanıldı. On altı hastada kaçak, iki hastada greft bacağında tıkanıklık, altı hastada anevrizma çapında artış ve beş hastada yara iyileşme problemi görüldü. İki hastaya kros femoral baypas, üç hastaya balon dilatasyon, üç hastaya proksimal ekstansiyon ve dört hastaya distal ekstansiyon uygulandı. İşlem sırasında bir hastada mortalite gelişti. Total mortalite oranı 7% ve ilk 30 günlük mortalite oranı 2% idi.

Sonuç: Çalışma sonuçlarımız endovasküler anevrizma tamirinin düşük cerrahi mortalite oranı, kısa yoğun bakım ünitesi ve hastane yatışı ve daha az kan ürünü kullanımı dahil olmak üzere birtakım avantajlara sahip olduğunu göstermektedir. Ayrıca, bu teknik yüksek riskli komorbid hastalarda rejyonel anestezi ile birlikte gerçekleştirilebilir.

Anahtar sözcükler: Abdominal aort anevrizması; endovasküler aort tamiri; stent greft.

Received: April 06, 2018 *Accepted*: June 06, 2018

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Cite this article as:
Karakişi SO, Ergene Ş, Hemşinli D, Küçüker ŞA. Our early and mid-term results for endovascular repair of abdominal aortic aneurysms. Turk Gogus Kalp Dama 2019;27(1):29-34

An abdominal aortic aneurysm (AAA) is defined as a localized enlargement of the abdominal aortic diameter exceeding 3 cm or 1.5-fold greater than the normal diameter.[1] Since the incidence increases with age, it also involves several morbidity factors.[2,3] These aneurysms are reported in 12% of men and 5.2% of women aged between 74 and 84 years.[3] The two main approaches in the surgical treatment of AAAs are open surgical repair (OSR) and endovascular aneurysm repair (EVAR).[3]

With technological advances and increasing experience, EVAR has become increasingly commonly used, since it can be safely performed in patients with comorbidities.[2-4] Compared to OSR, EVAR has the advantages of a short operation time and intensive care unit (ICU) stay, low blood product use, lower early morbidity and mortality rates and fewer cerebral, renal and respiratory complications. However, it has also significant disadvantages, such as contrast material nephrotoxicity, mechanical problems after graft insertion, endoleak development, possible requirements for secondary procedures after treatment, and higher cost.[4,5]

In the present study, we present our early and mid-term results of patients with infrarenal AAAs treated using EVAR.

PATIENTS AND METHODS

This retrospective study included a total of 154 patients (136 males, 18 females; mean age 71.7 years; range, 55 to 94 years) who underwent EVAR due to an infrarenal AAA at Recep Tayyip Erdoğan University, Faculty of Medicine, Department of Cardiovascular Surgery between December 2011 and January 2017. A written informed consent was obtained from each patient. The study protocol was approved by the Recep Tayyip Erdoğan University Hospital Ethics Committee. The study was conducted in accordance with the principles of the Declaration of Helsinki. The suitability for aneurysm repair procedures was investigated preoperatively for each patient using contrast-enhanced computed tomography (CT) with 3-mm sections. The site and dimensions of the aneurysm, presence of calcification or thrombus in the arterial wall, and the structure of the iliac and femoral arteries were evaluated. The requisite measurements were taken, and sites where the graft would be inserted in the proximal and distal aspects of the healthy arterial wall were assessed. The graft diameter was measured as 10 to 30% more than the diameter of the healthy artery in these regions. The procedure was performed in cases of aneurysm dimension ≥5.5 cm or symptomatic patients with an aortic diameter <5.5 cm. Procedures were performed in the interventional radiology department by a team consisting of two cardiovascular surgeons and an anesthetist under appropriate sterilization conditions. General anesthesia was performed due to aneurysm rupture on three patients who were hemodynamically unstable and intubated in the emergency department, while spinal anesthesia and sedation support were applied to all the other patients. The procedure was performed with open surgical exploration from the femoral arteries. After the proximal part of the stent-graft was installed beginning from the distal aspect of the renal arteries, the patency of the graft and potential leaks were assessed using control aortography. In cases in which leakage was observed in the proximal (type 1A) or distal (type 1B) aspect of the stent-graft, improved placement was achieved through the inflation of an aortic balloon. Eleven patients received Powerlink® (Endologix Inc., Irvine, CA, USA), 26 patients Anaconda™ (Vascutek, Terumo, Inchinnan, Scotland), 56 patients Gore® Exluder® (W.L. Gore & Associates Inc., Flagstaff, AZ, USA), and 73 patients Endurant™ (MedtronicVascular, Santa Rosa, CA, USA) stent-grafts. All patients were placed under observation in the ICU after the procedure. The patients with stable clinical status were transferred to the ward after one day. Follow-up was performed at one, six, and 12 months and annually, thereafter. Complications including an increased diameter in the aneurysm, endoleak, and graft migration were assessed during follow-up using with abdominal contrast-enhanced CT. Additional clinical monitoring was applied, when necessary, in patients with complications. Operative mortality was defined as death within the first 30 days after the procedure.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 14.0 software (SPSS Inc., Chicago, IL, USA). The analysis results were expressed as number (percentage, %) for categorical data. Test for normality of distribution for continuous variables was performed using the Kolmogorov-Smirnov test. A p value of <0.05 was considered statistically significant.

RESULTS

Iliac artery aneurysms and AAAs were present in 32 patients who underwent EVAR, while 122 patients had an isolated AAA. Seven patients underwent the procedure under emergency conditions due to aneurysm rupture and 147 patients under elective

Table 1. Baseline characteristics of the patients

	n	%	Median	Min-Max
Age (year)			72	55-94
Gender				
Males	136	88		
Smokers	132	86		
Diabetes mellitus	46	30		
Obesity	35	23		
Chronic obstructive pulmonary disease	54	35		
Hypertension	145	94		
Coronary artery disease	42	27		
Chronic renal failure	11	7		
Atrial fibrillation	15	10		

Min: Minimum; Max: Maximum.

Table 2. Secondary intervention rates

	n	%
Cross femoral bypass	2	1
Balloon dilatation	4	3
Proximal extension	3	2
Distal extension	4	3

conditions. Aorto-uniiliac stent grafts were applied to all patients who underwent interventions under emergency conditions. Data including pre-procedural characteristics and additional diagnoses are given in Table 1.

The mean length of ICU stay was 1.1 (range, 1 to 4) days, and the mean length of hospital stay was 3.1 (range, 3 to 7) days. The mean pre-procedural diameter of infrarenal AAA was 65.3 (range, 52 to 110) cm, and the mean post-procedural aneurysm diameter was 57.8 (range, 46 to 103) cm. A mean 0.3 units (range, 0 to 3) of erythrocyte suspension were used during the treatment.

The mean follow-up was 35 (range, 12 to 72) months. Lower extremity ischemia developed in two patients due to occlusion in the graft leg at one and two years. Cross-femoral bypass with polytetrafluoroethylene graft was performed in these cases. The data related to secondary intervention rates are shown in the Table 2. Endoleak developed in 16 patients during follow-up. Data including endoleak are shown in Table 3. Balloon dilation was applied in four cases of type 1A endoleak and proximal extension in three cases. Distal extension was applied in four cases of type 1B endoleak, while endoleak resolved without any intervention in three cases with limited endoleak in the first month. Endoleak resolved without intervention in two patients with type 2 endoleak. An increase in the aneurysm diameter was observed in six patients during follow-up. Type 1A endoleak was present in four of these and type 1B in two patients. Healing problems in the femoral incision line were observed in five patients. Seroma developed in one of these, and the incision line healed late due to delayed scar tissue formation in four diabetic patients. The data related to complications and mortality rates are shown in the Table 4.

Mortality occurred in 11 cases. One patient with rupture in the right common iliac artery and switched to open surgery died during the procedure. Three

Table 3. Endoleak types

	1 Month	6 Month	1 Year	2 Year	3 Year	4 Year	5 Year	6 Year
Type 1A	1	3	1	-	1	1	-	-
Type 1B	3	-	3	-	-	1	-	-
Type 2	1	1	-	-	-	-	-	-

Data expressed as number values. Type 1A: Leak into the aneurysm sac between the proximal stent graft and arterial wall; Type 1B: Leak into the aneurysm sac between the distal stent graft and arterial wall; Type 2: Backflow of blood from aortic collaterals into the aneurysmal sac.

Table 4. Complications and mortality rates

	n	%
Endoleak	16	10
Occlusion in graft leg	2	1
Increased aneurysm diameter	6	4
Healing problem in femoral incision	5	3
Mortality during intervention	1	1
Operative mortality*	3	2
Total mortality	11	7

* Mortality within the first 30 days.

of the patients in whom mortality occurred within the first three days were those taken for emergency surgery due to aneurysm rupture with the American Society of Anesthesiologists (ASA) Class IV. These patients with hypovolemic shock and transferred from the emergency department in an intubated state for procedures died due to multiorgan failure during intensive care monitoring. No mortality or complications such as intestinal ischemia, extremity ischemia, or compartment syndrome were seen in the other four patients taken for emergency surgery due to aneurysm rupture. One diabetic patient died under internal diseases intensive care monitoring due to ketoacidosis at two years, and one patient died due to pneumonia-related respiratory failure at four years, postoperatively. The cause of death was reported as malignancy in three other patients and myocardial infarction in two patients.

DISCUSSION

Abdominal aortic aneurysms have increasingly become prevalent in elderly patients. The risk of rupture increases in line with the size of the aneurysm.[6,7] Prophylactic prosthetic graft replacement for aneurysm is, therefore, recommended. An aortic diameter of 5.5 cm in infrarenal and juxtarenal AAAs is used as a cut-off point for elective surgery in several protocols.[3]

The conventional technique applied since 1952 in AAA repair is open surgical resection and prosthetic graft insertion in the aneurysmal segment.[8] In addition to several advantages such as cost and elimination of the effect of the aneurysmatic mass, OSR has proved long-term durability and efficacy in preventing aneurysm rupture. However, it also has certain disadvantages, such as high postoperative mortality and morbidity rates due to high respiratory and renal complications, and development of mesenteric ischemia, and erectile dysfunction.[8-10] Although improved results have been obtained compared to the past, a hospital mortality of approximately 5% and a complication rate as high as 20% have raised the subject of new therapeutic options.[6,11] Endovascular aneurysm repair, which is less invasive than OSR, was first performed by Parodi et al.[12] in 1991. The rate of mortality and morbidity are acceptable, if the anatomical characteristics of the aneurysm are appropriate, particularly in high-risk patients.[8,13]

Several multi-center, prospective, randomized clinical studies compared the early-, mid-, and late-term outcomes of OSR and EVAR. The Dutch Randomized Endovascular Aneurysm Management (DREAM) trial involving 351 patients reported that, compared to OSR, EVAR was associated with much lower operative mortality (1.2% vs. 4.6%) and systemic complication rates, particularly pulmonary complication, (3.5% vs. 10.9%).[14] However, these early advantages of EVAR disappeared after two-year follow-up, and similar survival rates were found. The authors, hence, reported that this was due to a high non-aneurysm-related mortality rate in the EVAR group during follow-up. In contrast, the endograft-related complication rate was 16.4% in the EVAR group and 8.6% in the OSR group, and the reintervention rate was nearly three-fold higher in the EVAR group.[14] In the UK Endovascular versus Open Repair of Abdominal Aortic Aneurysm (EVAR) trial involving 1252 patients and a six-year follow-up time, early results were better for EVAR than for OSR, although this advantage disappeared in the long-term.[8] Similar total mortality rates between the two groups were attributed to late graft ruptures in the EVAR group. The mean primary and reintervention costs in the aforementioned study were about $4,600 higher in the EVAR group.[6,8] In the Open versus Endovascular Repair Veterans Affairs Cooperative (OVER) trial, operative mortality was significantly lower in the EVAR group, compared to the OSR group (0.5% vs. 3.0%), while no significant difference was observed between the groups in terms of long-term all-cause mortality (7.0% vs. 9.8%).[15] Another randomized-controlled study showed that EVAR did not increase the survival rates in patients with poor health status and considered unsuitable for OSR, and that it resulted in significantly higher costs due to continuous monitoring and reintervention requirements.[16]

In general, these studies concluded that, compared to OSR, EVAR offered early advantages in terms of operative mortality and complication rates; however, this superiority disappeared in the mid- and long-term. A higher number of vascular and endograft-related complications were also observed, more reintervention

was required, and costs were higher in the EVAR group.[1,6,13-19] In our study, the operative mortality rate among patients undergoing EVAR due to AAAs was 2%, while the total mortality rate during follow-up was 7%. Our vascular and endograft-related complication rate was 11.6%, and our reintervention rate was 8.4%. Our results are consistent with previous multi-center, prospective, randomized-clinical studies.

Endoleak which can lead to increased reintervention and costs, OSR for rupture, and mortality continues to represent an important problem for EVAR. Major factors affecting the development of endoleak include a short aneurysm neck, a neck angle exceeding 60º, increased distal neck diameter, and thrombus or ulcerated plaque in the neck wall.[2,4,11] Several studies reported an incidence of endoleak of 4.1 to 26.4%.[1,2,4,11,15] In our study, endoleak developed in 10% of our EVAR patients. Type 1A endoleak was particularly observed in patients with a short neck segment and/or a neck angle exceeding 60º. Although an increased aneurysm diameter was found in four of seven patients with type 1A endoleak, the leak resolved through a reintervention in all patients. An increased aneurysm diameter was detected in two of these seven patients with type 1B endoleak. In addition to these two patients with endoleak in the first year after the procedure, distal extension was performed in other two patients with type 1B endoleak at one and four years. Three patients with limited type 1B endoleak in the first month after the procedure were monitored without any intervention. In addition, reintervention was not applied in the case of two patients with type 2 endoleak at one and six months after the procedure. Endoleak resolved during follow-up in all these cases.

Other advantages of EVAR over OSR include shorter ICU and hospital stays, and significantly lower levels of blood loss and blood product requirements. In the OVER study, the length of stay in the ICU (1 vs. 4 days) and in hospital (3 vs. 7 days) were significantly shorter in the EVAR group, compared to the OSR group.[8] The mean blood loss (200 vs. 1000 mL) and transfusion volumes (0 vs. 3.0 unit) were also significantly lower. Similarly, in the DREAM study, the length of stay in the ICU (16 vs. 72 h) and in hospital (6 vs. 13 days) were significantly shorter in the EVAR group.[8] The EVAR group also showed significantly less blood loss (394 vs. 1654 mL) and lower transfusion requirements than the OSR group. Another study reported a shorter hospital stay in the EVAR group with a mean blood transfusion amount of 0.2±0.9 units in the EVAR group and 2.1±4.0 units in the OSR group.[20] In our study, the mean length of stay in the ICU was 1.1 (range, 1 to 4) days, the mean length of hospital stay was 3.1 (range, 3 to 7) days, and the mean transfusion amount was 0.3 (range 0 to 3) units. In consistent with previous studies, less blood transfusion was needed in our EVAR group, ICU and hospital stays were shorter, and return to daily life was quicker. In addition to the procedure being much less traumatic, another factor affecting the length of hospital stay in patients undergoing EVAR is the type of anesthesia administered. A study reported a shorter hospital stay in EVAR patients receiving local or regional anesthesia than in those administered general anesthesia.[21] We also performed EVAR with spinal anesthesia and sedation support being administered to all patients, with the exception of three patients who were hemodynamically unstable due to aneurysm rupture and who were intubated in the emergency department. We believe that this is an important factor affecting short ICU and hospital stays in our patients.

Limitations of this study include the retrospective, single-center design with small sample size. The purpose of the present study is to contribute to the debate concerning the treatment of abdominal aortic aneurysms by reporting the early and mid-term EVAR results in our clinic and discussing these in the light of the current literature.

In conclusion, low operative mortality and early complication rates, particularly in terms of pulmonary complications, shorter intensive care unit and hospital stays, lower blood transfusion requirements, particularly in patients with higher comorbid factors, and the ability to use local anesthesia in patients with high American Society of Anesthesiologists scores all represent basic advantages of endovascular aneurysm repair over open surgery. However, vascular and endograft-related complications leading to increased mid- and long-term reintervention and total mortality rates are significant disadvantages of this technique. We believe that endovascular aneurysm repair would later become a more reliable therapeutic option, as complications decrease in line with advances in graft technologies and accumulated experience.

Declaration of conflicting interests

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

Funding

The authors received no financial support for the research and/or authorship of this article.

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