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Our mid-term results of endovascular repair of abdominal aortic aneurysms

Abdominal aort anevrizmalarının endovasküler tamirinde orta dönem sonuçlarımız

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ABSTRACT

Background: This study aims to report our mid-term results of endovascular repair of abdominal aortic aneurysms.

Methods: Between January 2006 and December 2013, a total of 203 patients (187 males, 16 females; mean 69.1±8.8 years; range 38 to 89 years) who underwent endovascular aortic repair electively or emergently due to a ruptured abdominal aortic aneurysm were retrospectively analyzed. Mortality, morbidity, survival rates, mean duration of operation, mean duration of mechanical ventilation, mean length of intensive care unit and hospital stays, the type and incidence of endoleaks, contrast nephropathy rates, effects of use of stent grafts with bare-metal tips and aortic diameter on endoleak, complication rates, and secondary intervention rates were recorded. The mortality rates and quality of life were compared with that of open surgery within the same period of time.

Results: There was no significant difference in the mortality rates between the groups. No significant difference was observed in the quality of life in the long-term, although the results were in favor of endovascular aortic repair in short-term.

Conclusion: Endovascular aortic repair can be selected as a treatment option in abdominal aortic aneurysm patients with co-morbidities and high mortality risk. Based on our study results, the rates of complication and secondary intervention in EVAR treatment can be reduced with improved stent graft technology, operator experience, and selection of patients with suitable anatomy.

Keywords: Abdominal aortic aneurysm; conventional surgical treatment; endovascular treatment.

ÖZ

Amaç: Bu çalışmada abdominal aort anevrizmalarının endovasküler tamirinde orta dönem sonuçlarımız bildirildi.

Çalışma planı: Ocak 2006-Aralık 2013 tarihleri arasında abdominal aort anevrizması yırtığı nedeniyle elektif veya acil endovasküler aort tamiri yapılan toplam 203 hasta (187 erkek, 16 kadın; ort. yaş 69.1±8.8 yıl; dağılım 38-89 yıl) retrospektif olarak incelendi. Mortalite, morbidite, sağkalım oranları, ortalama ameliyat süresi, ortalama mekanik ventilasyon süresi, ortalama yoğun bakım ünitesinde ve hastanede kalış süresi, kaçak tipi ve insidansı, kontrast nefropati oranları, çıplak metal uçlu stent greftlerin kullanımı ve aort çapının kaçak üzerindeki etkileri, komplikasyon oranları ve ikincil girişim oranları kaydedildi. Mortalite oranları ve yaşam kalitesi aynı zaman dilimi içinde açık cerrahi ile karşılaştırıldı.

Bulgular: Gruplar arasında mortalite oranları açısından anlamlı bir fark yoktu. Sonuçlar kısa dönemde endovasküler aort tamiri lehine olmakla birlikte, yaşam kalitesi açısından uzun dönemde anlamlı bir fark gözlenmedi.

Sonuç: Endovasküler aort tamiri, abdominal aort anevrizmalı ve eşlik eden hastalığı ve yüksek mortalite riski olan hastalarda bir tedavi seçeneği olabilir. Çalışma sonuçlarımıza göre, EVAR tedavisinde komplikasyon ve ikincil girişim oranları stent greft teknolojisinin gelişmesi, cerrahın deneyimi ve uygun anatomili hastaların seçilmesi ile azaltılabilir.

Anahtar sözcükler: Abdominal aort anevrizması; konvansiyonel cerrahi tedavi; endovasküler tedavi.

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Thanks to the technological improvements and increased experience, less invasive endovascular treatment options have become an alternative treatment option to the standard conventional treatment in selected patients with abdominal aortic aneurysms.[1] Series of randomized clinical trials comparing endovascular stent grafting and conventional treatment in aortic aneurysms are present, as it is shown in the Table. Endovascular treatment has important disadvantages such as contrast material nephrotoxicity, mechanical problems (failure of graft opening, location etc.), endoleak which is ongoing perfusion of aneurysmal cavity after the procedure, and secondary intervention necessity caused by endoleak, as seen in other studies.[2-4] However, it is considered that this treatment option will be performed with higher rates in the future due to advantages of endovascular treatment, particularly lower rates of complications seen during the operation and in the early period [shorter operation duration, less blood and blood products transfusion, lower morbidity, mortality and paraplegia rates, shorter intensive care unit (ICU) duration, lower cerebral, renal, and respiratory complications] compared to surgical and medical treatment.[2-4]

PATIENTS AND METHODS

A total of 203 patients (187 males, 16 females; mean 69.1±8.8 years; range 38 to 89 years) with the diagnosis of infrarenal abdominal aortic aneurysm, who underwent either emergency endovascular aortic repair (EVAR) due to rupture or elective between January 2006 and December 2013 were retrospectively analyzed. Our institution does not require any approval by local ethics committee for retrospective studies of commonly performed interventions. The study was conducted in accordance with the principles of the Declaration of Helsinki.

Treatment was planned for all patients according to the suitable neck diameter and angling, the length of neck in which the graft was landed; length, diameter and angling of the iliac artery with detailed evaluation of contrast computed tomography (CT) results and selection of an appropriate graft. A total of 191 elective patients included patients with an abdominal aortic diameter of ≥5.5 cm or symptomatic patients with a diameter of <5.5 cm with either fusiform or saccular aneurysms. Twelve patients with ruptured aortic aneurysms were also included. Thirty-five patients with the American Society of Anesthesiologists (ASA) scores III-IV (17.2%) were operated under regional, 56 patients (27.6%) under local, 112 patients (55.2%) with ASA scores below III under general anesthesia.

Each patient was prepared with surgical discipline and covered sterile. Operations were performed with hybrid operation room standards in which advanced fluoroscopy devices (C-arm fluoroscopy device-Philips BV Endura) and radiolucent operation table were available. Common femoral artery was used as the access route in the majority of the patients, and this access was enhanced with the assistance of Dacron® grafts anastomosed to the iliac artery with limited retroperitoneal approach in the patients with the diameter of common femoral artery not suitable for the intervention. Either femoral artery on one side was explored and the femoral artery on the other side was entered percutaneously or both common femoral arteries were explored according to the characteristics of the selected graft. Tunnel for femorofemoral bypass graft was prepared in the suprapubic region in the patients undergoing aortouniiliac grafting. Arteriography starting from the level of renal arteries and reaching down to the iliac arteries was performed. Endovascular stent grafts (EVSG) were placed after the correlation of measurements on arteriography for one last time.

The patients who underwent EVAR were followed at one, six, and 12th months and once per year with abdominal Doppler ultrasound or contrast CT. Mortality, morbidity, survival rates, mean duration of operation, mean duration of mechanical ventilation, mean length of ICU and hospital stays, the type and incidence of endoleaks, contrast nephropathy rates, effects of use of stent grafts with bare-metal tips and

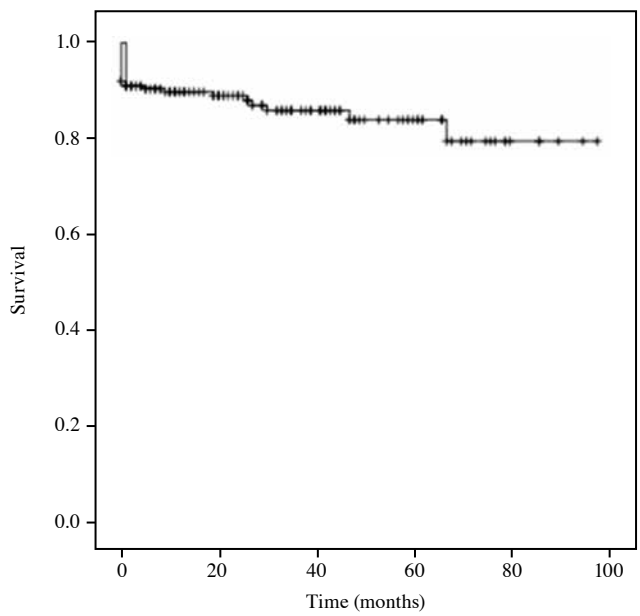

Figure 1. Kaplan-Meier survival curve.

aortic diameter on endoleak, complication rates, and secondary intervention rates were compared.

Statistical analysis

Statistical analysis was performed by using PASW version 18.0 for Windows (SPSS Inc., Chicago, IL, USA) software with a 95% confidence interval. Constant variables were expressed in mean ± standard deviation and categorical variables in n (%) with tables. The relationship between aorta diameters and endoleak presence was analyzed by using independent sample t test. Paired sample t-test was used for the comparison of pre- and postoperative blood urea nitrogen and creatinine levels. The relationship between the use of grafts with bare-metal tips and endoleak occurrence was analyzed with chi-square test. Survival was estimated with Kaplan-Meier curve. A p value <0.05 was considered statistically significant.

RESULTS

The mean follow-up was 41.7 months (range: 1.1 to 98.3 months). Of patients, 12 were operated emergently due to ruptured abdominal aortic aneurysms. Six patients had co-existent iliac artery aneurysms, while four patients had accompanying thoracic aorta aneurysms. A total of 144 patients underwent aortobiiliac stenting, 53 aortouniiliac, and remaining five tube grafts. Among patients, 89.2% had hypertension, 59.6% had chronic obstructive pulmonary disease, 44.8% had coronary artery disease, 51.7% had hyperlipidemia, and 13.8% had diabetes mellitus. Additional pathologies which potentially increased the risk for open surgery were also analyzed.

At baseline, 16 patients (7.8%) underwent additional interventions. A Dacron® graft was sewn to the common iliac arteries of three patients, which was accessed retroperitoneally. Left internal iliac artery (IIA) coil embolization was done in one patient. Three patients underwent iliofemoral bypass with polytetrafluoroethylene (PTFE) graft, three patients underwent bypass grafting from external iliac artery (EIA) to IIA with PTFE graft and one patient from common femoral artery to superficial femoral artery. Three patients underwent ballooning/stenting in common iliac artery (CIA). One patient was performed off-pump coronary bypass in the same session following diagnosis of coronary artery disease in preoperative evaluation. Preoperative and early period (30 days) complications are shown in Table 1. The most common early period complication seen in 26 patients (12.8%) was fever and the patients were treated with paracetamol. Renal artery was partially occluded in one patient and renal arterial stenting procedure was performed. Early-period endoleak was detected in 12 patients (6%). Type I endoleak was observed in eight patients in this group and additional aortic or iliac extension grafts were implanted for the treatment. Four patients had type II endoleak and the decision was to follow these patients. Those endoleaks spontaneously diminished on repeated Doppler ultrasound and contrasted CT examinations. Eight of 14 deceased patients had abdominal aortic aneurysm ruptures with ASA scores IV. One patient underwent open surgery due to the rupture on the first postoperative day.

Secondary intervention was observed during the follow-up in 33 (16.2%) patients who were treated with EVAR. The distribution and rates of secondary interventions are shown in Table 2. Two patients with graft thrombosis underwent embolectomy and balloon dilatation with favorable results. One patient had aortic

Table 1. Preoperative and early period (30-day) complications

	EVAR	
	n	%
Arterial obstruction	3	1.5
Femoral artery injury	1	0.5
Endoleak	12	6
Iliac artery injury	1	0.5
Renal artery obstruction	2	1
Monoplegia	1	0.5
Postoperative need for hemodialysis	3	1.5
Rupture	1	0.5
Fever	26	12.8
Mortality	14	6.8
None	139	68.4
Total	203	100

Table 2. The distribution and rate of secondary interventions

	EVAR	
	n	%
Femorofemoral bypass, embolectomy	2	1
Endoleak	18	9
Femorofemoral graft infection	1	0.5
Iliac aneurysm iliac extension	3	1.5
Graft trombosis	3	1.5
Open surgery due to rupture	1	0.5
Aortoenteric fistula aortic extension + open surgical repair of fistula	1	0.5
Suprarenal aneurysm aortic extension + debranching	3	1.5
Femoral pseudoaneurysm	1	0.5
Total	33	16.2

Table 3. Endoleak types and distribution

Endoleak	n	%
Type		
IA	12	40.0
IB	13	43.3
II	5	16.7
III	0	0
IV	0	0
V	0	0
Total	30	14.8
No	173	85.2
Total	203	100.0

thrombosis and endograft was removed with open surgery followed by aortobifemoral bypass. Seventeen of 18 patients (9%) with endoleak had type IA and IB endoleaks and aortic or iliac extension grafts were implanted, whereas one patient with type II endoleak was followed without any additional intervention. Type III, IV and V endoleaks were not observed in any patients. Endoleak types and distribution characteristics are shown in Table 3. Proximal bare metal tip was present in 116 (57.1%) of all endovascular grafts. The correlation of use of stent grafts with bare metal tips and occurrence of endoleak is presented in Table 4. Stent grafts with bare metal tips were used to form a suprarenal attachment area in the aneurysms with a short or angled neck. No significant difference was detected in the occurrence of endoleak with either bare metal tips or not between the groups ($p>0.05$).

The mean duration of operation was 2.92±0.8 hours, the mean length of ICU stay was 1.82±1.6 days, the mean duration of mechanical ventilation for patients operated under general anesthesia was 3.45±3.2 hours, and the mean hospital stay was 5.7±0.8 days. In our study, preoperative and postoperative 24 and 48 hour blood urea nitrogen and creatinine levels of 190 patients were compared, excluding 13 patients with chronic kidney failure at baseline. Results are shown in Table 5. There was a significant difference in the mean preoperative and postoperative creatinine values ($p<0.05$), whereas such difference was not detected between pre- and postoperative blood urea nitrogen values ($p\geq0.05$). The relation between the mean aneurysm diameter and endoleak occurrence was also analyzed. The mean value of aortic diameter was 65.8±14.9 mm (range: 40 to 130 mm). The mean diameter was 64.7±17.0 mm in the patients with endoleaks and 68.2±14.6 mm in the patients without any endoleak.

Table 4. Correlation of use of stent grafts with bare metal tips and occurrence of endoleaks

	Endoleak					
	No		Yes		*Total*	
Bare metal	n	%	n	%	n	%
No	75	86.3	12	13.7	87	100.0
Yes	98	84.5	18	15.5	116	100.0
Total	173	85.3	30	14.7	203	100.0

In our study, the number of total mortality was 26 out of 203 patients during eight year follow-up. Early postoperative mortality (within first postoperative month) was 14 patients, including eight patients who were operated emergently with ruptured aneurysms and had ASA scores IV. The early postoperative survival rate was 93.2%. Five-year and eight-year survival rates were 84.1% and 79.7%, respectively. Early period (30 days) aneurysm-related mortality rate was 3.1%. Aneurysm-related mortality rate was 3.6% at five years, while eight-year-survival rate was 91.7% among electively operated patients (n=191).

DISCUSSION

Open surgery or endovascular surgical approach is selected for the treatment of abdominal aortic aneurysms after evaluation of life expectancy, comorbidities, and estimated perioperative, postoperative mortality risks of the patients.[2] Endovascular repair is carried out with acceptable morbidity and mortality rates in high-risk group of patients, if the anatomical characteristics of the aneurysm are suitable.[2]

The most important conditions taken into consideration for endovascular stent graft treatment could be assumed as distal and proximal aneurysm neck diameter, angling, presence of thrombus or severe calcification in aneurysm neck, and presence of high degree stenosis and occlusion due to high degree tortuosity and atherosclerosis in iliac artery.[5] Currently, endovascular treatment is

Table 5. Preoperative and postoperative blood urea nitrogen creatinine levels

	Mean±SD
Preoperative	
Blood urea nitrogen (mg/dL)	24.6±11.3
Creatinine (mg/dL)	1.3±0.7
Postoperative (24-48 hours)	
Blood urea nitrogen (mg/dL)	24.1±11.7
Creatinine (mg/dL)	1.3±0.9

SD: Standard deviation.

successfully performed in angled aneurysms with shorter neck due to technological improvements.

Randomized studies are present comparing early, mid and late period results of both open surgical approach and endovascular procedures. Data obtained from multi-center Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR 1-2), Dutch Randomised Endovascular Aneurysm Management (DREAM), Endovascular vs Open Repair of Abdominal Endovascular Repair (OVER), European Cobalt Stent With Antiproliferative for Restenosis (EUROSTAR) trials showed favorable EVAR results for early period mortality.[6] It was demonstrated that this method had many advantages such as no requirement of laparotomy, shorter ICU and hospital stays, use of lesser amount of blood products, and lower morbidity.[6-10] The mortality rates of randomized studies revealed that it was 1.2% in the first 30 days among 173 patients in the DREAM trial, and there was 68.9% survival rate at six-years. There was 1.8% mortality in the first 30 days among 614 patients, 2.3% total in-hospital mortality, and 7.5% long-term mortality in EVAR1-2 trials. All-cause mortality was 7% during six-year-follow-up and 0.5% in the first 30 days; mortality rate was 3.8% in the first 30 days among 1.190 patients, and total mortality rate was 19.9% during one-year-follow-up and abdominal aortic aneurysm related long-term mortality rate was reported as 2.9% in the EUROSTAR trial.[8-11] Early period (30 days) aneurysm-related mortality rate in electively operated patients (n=191) was 31.5%, one-year-follow-up aneurysm-related mortality rate was 3.6%, eight-year-follow-up survival rate was 91.7%, and cumulative mortality rate was 12.8% among 203 patients in our study in consistent with the literature data. Early period mortality rates were better in EVAR than conventional surgery; however no significant difference was observed at the end of four years. The reason for that is the development of a secondary rupture which is seen during follow-up after treatment with EVAR method.[6,8-11] High operative mortality is an issue in conventional surgery.[7] Early term mortality rates were 9.3% for the conventional treatment and 1.9% for the endovascular treatment compared to conventional and endovascular surgery conducted by Güneş et al.[12] in our clinic.

Another issue in EVAR is lesser amounts of intraoperative blood loss and, therefore, smaller numbers of units needed for blood transfusion compared to conventional surgery.[6] In the OVER trial, blood loss was around 200 to 1000 mL and the mean amount of blood transfusion was 1 unit with a length of hospital stay varying between three and seven days.[10] Hospital stay was found to be shorter in the EVAR group. The mean amount of blood transfusion was 2.1±4.0 units in the conventional approach group, while it was 0.2±0.9 in the EVAR group.[13] The mean amount of blood transfusion was calculated as 2.0±1.4 units for whole blood, 2.6±2.4 units for fresh frozen plasma, and 2.2±1.6 units for packed red blood cells in our study. Blood products were usually administered to the patient group who was operated with ruptured aortic aneurysms and longer ICU stays. Intensive care unit and hospital stays were 2.3±2.6 and 5.7±2.6 days, respectively. The EVAR group patients who required less blood transfusion, shorter ICU and hospital stays returned to their daily routine in a shorter period of time in consistent with the previous study findings.

Another factor influencing the length of hospitalization is the type of anesthesia. Ruppert et al.[14] reported that the patients who underwent EVSG under local and regional anesthesia had more advantages than those who underwent EVAR under general anesthesia in terms of the length of hospital stay. Similarly, 44.8% of EVAR patients were operated under local or regional anesthesia in our study. Nevertheless, the ratio of our patients undergoing EVAR under general anesthesia was relatively high. This is due to the preference of our anesthesiologists to stay in their comfort zone to keep the patient calm and hemodynamically stable.

In addition, the operation time and duration of mechanical ventilation are observed to be shorter in EVAR patients. In the OVER trial, operation time ranged from 2.9 to 3.7 hours with an intubation time of 2.3 to 5.9 hours.[10] In the study conducted by Ren et al.[15] operation duration and duration of mechanical ventilation were shorter in the EVAR group. These durations were also shorter in our previous study[12] in consistent with these two study findings.

Moreover, renal complication rate varied between 0.7% and 14% in the patients with elective endovascular surgery.[16] A total of 0.7% to 2% of the patients with renal dysfunction were reported to be due to contrast nephropathy.[17] Preoperative and postoperative 24 to 48 hours serum creatinine levels were found to be 1.25±0.9 mg/dL and 1.33±0.73 mg/dL, respectively and the increase was also statistically significant (p=0.02) in our study. Bulut and Demirağ[18] showed that prolonged aortic clamp and anesthesia, and increased blood transfusion necessity caused significant increase in the urea-creatinine levels.

Re-intervention necessity was found to be 14% in the EUROSTAR trial, 13.7% in the DREAM trial and 5.1% in EVAR1-2 trial (100 patients per year).[8-11] Secondary intervention rate is often higher than that of open approach.[12] However, in the OVER trial, no significant difference in relation to secondary interventions was detected, as third and fourth generation grafts were used, and design and resistance of endografts has been improved widely within the past 10 years. Similarly, secondary intervention rate was 16.2% and it was considered to be consistent with the literature. Nevertheless, most of these re-interventions were detected in the relatively earlier cases with grafts of more primitive technology.

Besides all these pros, endovascular treatment has its own complications. There are surgery related complications (failure to fix stent graft, perforation, distal embolization, dissection, pseudoaneurysms, infection, post-implantation syndrome), stent graft related complications (endoleak, aneurysm rupture or enlargement, graft migration, graft infection, problems of structural components, hip claudication due occlusion of the internal iliac artery by the graft) among them.[3]

Endoleak was detected in 12 (6%) of patients during perioperative and early postoperative period (30 days). Type I endoleak was observed in eight patients in this group and perioperative graft extension was performed for treatment. Four patients had type II endoleak and no intervention was carried out. Those endoleaks regressed spontaneously. Seventeen (9%) of 18 patients with endoleak in the mid-term had type IA and IB endoleak and received aortic or iliac extension grafts, while one patient with type II endoleak was followed. Endoleak was detected in varying rates in different series. Dalanis et al.[19] reported 9%, Cuypers et al.[20] reported 18% in the early period, 12% and 44% in the mid-term over 18 months, 13% was reported in the EUROSTAR trial,[11] and 4.1% in the OVER trial.[10] In recent studies conducted in Turkey, Yavuz et al.[21] detected endoleak in nine of 72 patients between 2006 and 2012, Hastaoğlu et al.[22] reported two of 28 patients between 2010 and 2013, and Tayfur et al.[23] reported 10 of 92 patients between 2010 and 2013. Total rate of endoleak occurrence was detected as 14.7% during perioperative, early and mid-term analyses in this study. In our study, the relationship between the aortic diameter and endoleak was also evaluated. The mean diameter of the patients with endoleaks was 64.7±17.0, while it was 68.2±14.6 in the patients without any endoleak, indicating no statistically significant difference ($p>0.05$). Endoleak rate was 15.5% in the group with stent grafts containing bare metal proximal fixators and 13.7% in the group with stent grafts not containing bare metal proximal fixators, showing a non-significant difference ($p>0.05$). Actual factors after stent graft implantation for the occurrence of endoleak were short neck of aneurysm, neck angle more than 60º, thrombus or ulcerated plaque or mural thrombus on neck wall, and increased neck diameter towards distal.

In conclusion shorter operation time, shorter intensive care unit and hospital stays, shorter recovery period, lesser units of blood transfusion necessity, and lower early period mortality and morbidity rates are the main advantages of endovascular aortic repair over open surgery. Furthermore, possibility of local or regional anesthesia is the main reasons to choose endovascular aortic repair in elderly patients with suitable anatomical structures and with more co-morbid factors who are scheduled for surgery for abdominal aorta aneurysm. Therefore, both patients and surgeons for all these reasons may choose endovascular aortic repair which seems that this will continue to stay as a good alternative to conventional treatment.

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