

Comparison of early-late results and cost effectivity of open surgical treatment and endovascular interventions in abdominal aortic aneurysms

Abdominal Aort Anevrizmalarında Açık Cerrahi Tedavi ve Endovasküler Girişimlerin Erken-Geç Sonuçlarının ve Maliyet Etkinliğinin Karşılaştırılması

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SUMMARY

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Objective: In this study, we aimed to compare early and late outcomes of patients with abdominal aortic aneurysm (AAA) treated using an endovascular approach and open aneurysm repair technique.

Method: A total of 171 patients who were undergoing EVAR and open surgical therapy were retrospectively analyzed under elective conditions due to abdominal aortic aneurysm via Hospital Info Management System and archive files within May 2006 and June 2014, in the Ankara University Cardiovascular Department. 126 of the patients (73,7%) were treated by endovascular (group 1) and 45 of them (26,3%) were treated with open surgery (group 2) technique. Patients with 5,5 cm or large asymptomatic aneurysms and symptomatic patients with diameter smaller than 5,5 cm are classified by aneurysm morphology evaluating preoperative CT angiography images and risk scores were made and considering the other comorbidities early and late morbidity mortality, reintervention rates, transfusion needs, hospital stay and cost effectiveness of EVAR were compared.

Results: The mortality rate for patients undergoing EVAR was 2,4%, while in patients undergoing open surgical repair was found 8,9% (p <0.05). The mean length of ICU, and hospital stay were significantly lower in the patients undergoing EVAR, in comparison with open surgery. The amount of blood transfusion in patients undergoing EVAR was significantly lower than in patients treated with open surgery. It can be observed an increase in early endoleak (leakage) rates constituting 9,5% in EVAR patients, which was dropped to 3,2% in sixthmonth control. According to the consequences of cost effectiveness, it was obtained that endovascular group is considerably expensive treatment than open surgery. It should be pointed out that the post implantation syndrome rates were 14,2% and there was not noted any change on mortality outcomes.

Conclusions: EVAR is a safe in early and long term follow-up that reduces mortality range in all age groups, especially over 70 years old, and in

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patients with comorbid factors. Therefore, EVAR treatment should be considered as a priority in anatomically suitable patients despite its high cost effectiveness.

Keywords: Abdominal aortic aneurysms, open surgical treatment, endovascular intervention, cost effectivity

ÖZET

Amaç: Endovasküler anevrizma onarımı (EVAR) ve açık cerrahi teknik ile tedavi edilmiş abdominal aort anevrizması(AAA) hastalarının erken ve geç dönem klinik sonuçlarının değerlendirilmesi amaçlanmıştır.

Yöntem: Mayıs 2006- Haziran 2014 tarihleri arasında Ankara Üniversitesi Kalp ve Damar Cerrahisi kliniğinde abdominal aort anevrizması nedeniyle elektif şartlarda EVAR ve açık cerrahi tedavi uygulanmış 171 hasta retrospektif olarak Hastane Bilgi Yönetim sisteminden ve arşiv dosyaları üzerinden incelendi. Bu hastaların 126'sına (%73.7) endovasküler (grup 1), 45'ine (%26.3) açık cerrahi (grup 2) teknik uygulandı. Preoperatif kontrastlı bilgisayarlı tomografi görüntüleri değerlendirilerek (BTAnjiyografi) abdominal aort çapı5.5 cm veya üzerinde olan asemptomatik, 5.5 cm'den küçük semptomatik hastalar anevrizma morfolojilerine göre sınıflandırıldı, risk skorlaması yapıldı ve diğer komorbid sebepler göz önüne alınarak, erken ve geç dönem mortalite morbidite oranları, tekrar girişim oranları, transfüzyon ihtiyacı, yatış süreleri vemaaliyet etkinlikleri karşılaştırıldı.

Bulgular: Mortalite oranı EVAR uygulanan hastalarda %2.4 iken, açık cerrahi onarım uygulanan hastalarda %8.9 olarak saptandı (p<0.05). EVAR uygulanan hastalardaortalama yoğun bakımda ve hastanede yatış süresi, kan transfüzyonu miktarı, açık cerrahi ile tedavi edilen hastalara göre önemli ölçüde daha düşüktü. Erken dönemde endovasküler grupta %9.5 oranında endoleak geliştiği ve 6.ay kontrolünde bu oran %3.2 ye gerilediği görüldü. Maaliyet araştırması sonuçlarına göre endovasküler tedavi, açık cerrahiye oranla oldukça yüksek maliyetli olduğu bulundu. %14.2 oranında Post implantasyon sendromu geliştiği ve mortalite sonuçlarını etkilemediği görüldü .

Sonuç: EVAR tüm yaş gruplarında, özellikle 70 yaş üstü ve komorbid faktörlere sahip hasta gruplarında, erken ve uzun süreli takipte mortaliteyi azaltır ve güvenlidir. Bu nedenle EVAR yüksek maliyet etkinliğine rağmen anatomik olarak uygun hastalarda öncelikli olarak düşünülmelidir.

Anahtar sözcükler: Abdominal aort anevrizması, abdominal aort anevrizması açık cerrahi tedavisi, endovasküler girişim, maliyet etkinliği.

INTRODUCTION

An aneurysm is defined as an enlargement of the aortic diameter greater than 50% and most commonly occurs in the infrarenal abdominal aorta. Abdominal aortic aneurysm (AAA) is defined as an abdominal aortic diameter of 3 cm or more at the infrarenal level. AAA is seen in the 1-4% range in the general population, whereas 5-9% in men older than age of 65 are frequently seen and it is also a pathology that causes high rates of mortality in cases where treatment is not done on time ¹.

It is ranked 13th among all causes of death in studies conducted in the United States. Hypertension and smoking are the most important in the development of AAA.It is also seen due to familial reasons. AAAs are responsible for 1,2% of male deaths and 0,6% of female deaths in the UK and are the 13th cause of mortality, while the third cause of sudden death after coronary artery disease and stroke ²⁻⁴.

Its incidence in the general population was 60/1000, while autopsy studies found that it is between 1,8-6,6%⁵.Studies have shown that 60%

of abdominal aortic aneurysms ruptured within 3 years of diagnosis ⁶.

Dubost et al. described the first open aneurysm repair technique in 1952 and with many innovations in postoperative care, it became the gold standard in the treatment of open surgical technique. However, recent reports still show a mortality rate of 2-5% and significant morbidity associated with open repair⁷.

Parodi from Argentina in 1991 and Volodos from Ukraine in those years described and performed the endovascular treatment technique in aortic aneurysms ^{8,9}.

Compared with open repair, EVAR; which is less invasive, has gained worldwide popularity due to less blood loss, shorter hospital stay and reduced perioperative mortality rates.

Although the short-term results of EVAR patients were excellent, it was criticized for its durability with specific complications such as endoleak, kinking and endograft migration, and even aneurysm rupture in follow-up. In 2001, the authors of the British Journal of Surgery criticized the form of a "failed experiment" due to high costs,

specific complications during follow-up and continued risk of aneurysm rupture.

Advances in technology have increased the efficacy of endovascular treatment, and in recent years, it has become a good alternative to open surgical treatment, while in recent years, it has begun to replace conventional surgery. The short, medium and long term results of the prospective randomized trials provided us with detailed information about the indications, morbidity, and effects on mortality and complications related to both methods ¹⁰.

In this study, patient groups which both treatment methods were performed in our clinic were evaluated retrospectively. In addition to operation results, cost-effectiveness analyzes were also performed.

MATERIAL AND METHODS

In this study, 171 patients who underwent elective open surgery or EVAR for abdominal aortic aneurysm between May 2006 and June 2014 at the Cardiovascular Surgery, Department of Ankara University were evaluated retrospectively. Of these patients, 126 (73,7%) were treated with endovascular intervention (Group 1) and 45 (26,3%) with open surgery (group 2). The treatment planning was performed with contrast-enhanced computed tomography angiography (CTA) and all patients were operated under elective condition. In CTA, asymptomatic patients with abdominal aortic diameter greater than or equal to 5,5 cm and symptomatic patients smaller than 5,5 cm such as abdominal pain and constipation that cannot be associated with another clinical picture were included in the study. Patients who were taken to emergency surgery were not included in the study. Individual patient written and

verbal consents was obtained before the surgical procedure.

Patients who did not develop endoleak during the procedure treated with endovascular method (Group 1) were evaluated routinely by CTA at 1 month according to the follow-up protocol of our clinic. Patients with no endoleak or pathological condition were followed up with Colored Duplex Ultrasonography (CDU) if the control CTA was normal (No endoleak, if the diameter is not increased or reduced) at the 12th month. Patients with endoleak and / or aneurysm diameter increase were re-evaluated with control CTA or CDU at 3 and 6 months. Reintervention or follow-up decision was made according to the pathology.

Statistical Analysis: In the study, continuous variables were expressed as mean \pm SD and categorical variables as frequency (n) and percentage (%). SPSS 24 package statistical program (StataCorp LP, College Station, TX, USA) was used for descriptive statistics and calculations. Inter-group differences were evaluated using the Student t test for normally distributed continuous variables. Pearson chi-square test was used for the comparison of categorical variables. A P value of $<.05$ was considered statistically significant.

RESULTS

171 patients who underwent open surgical treatment or EVAR were evaluated from hospital information system and archive files.

The mean age of the patients treated with endovascular treatment was higher than open surgical treatment ($p=0.008$, $p<0.05$). The demographic dispersion of the groups is given in Table 1.

Table 1: Demographic data of the patients

| Parameters | Group 1 (EVAR) (n, %, min-max) | Group 2 (Open Surgery) (n, %, min-max) | P value |
|---------------------------------------|-----------------------------------|---|---------|
| Age | 71,46 (40-91) | 63,88 (51-77) | 0.008 |
| Male | 118 (93,6%) | 44 (97%) | - |
| Female | 8 (6,4%) | 1 (3%) | - |
| Diabetes | 8 (6,4%) | 2 (4,4%) | - |
| Hypertension | 82 (65%) | 25 (55,6%) | - |
| Chronic Obstructive Pulmonary Disease | 32 (25,5%) | 4 (8,9%) | - |
| Peripheral Arterial Disease | 11 (8,7%) | 4 (8,9%) | - |
| Chronic Renal Failure | 4 (3,1%) | 0 (0%) | - |
| Smoking | 69 (54,7%) | 21 (46%) | - |

According to retrospectively obtained data, diabetes mellitus was present in 10 (5,8%) of patients. 54,7% of the EVAR group patients and 46% of the group who underwent open surgery had a history of smoking.

Six of the patients who underwent EVAR and one of the patients who underwent open surgery had a history of previous coronary artery bypass surgery.

In the patient group who underwent EVAR, 2 of them had pulmonary edema during preoperative period and there were signs of congestive heart failure (Table 2).35,7% of the patients in the EVAR group underwent regional anesthesia and 64,3% underwent general anesthesia. All of the patients who treated with open surgery were undergone with general anesthesia.

Table 2: Comorbid factors of groups. (CABG: Aortocoronary bypass graft)

| Comorbid factors | Group 1 (EVAR) (n) | Group 2 (Open Surgery) (n) |
|--|--------------------|----------------------------|
| Previous CABG | 6 | 1 |
| Congestive Heart Failure | 4 | 0 |
| Carotid Artery Stenosis | 2 | 0 |
| Renal Artery Stenosis | 2 | 0 |
| Thoracoabdominal Aortic Aneurysm | 4 | 2 |
| Behcet 's disease | 1 | 0 |
| Hydatid Cyst | 1 | 0 |
| Lung Malignancy | 1 | 0 |
| Superior Mesenteric Artery Stenosis | 1 | 0 |
| Syringomyelia | 1 | 0 |
| Marfan syndrome | 1 | 1 |
| Nephrolithiasis | 3 | 0 |
| Unilateral Renal Atrophy | 2 | 0 |
| Previous Cerebrovascular Event | 2 | 1 |
| Dementia | 3 | 0 |

According to the distribution of the operations, 95% of the patients who underwent EVAR were implanted with aorto-uniiliac main body and contralateral leg stent graft. Tubular stent graft was implanted in 4 patients with short segment isolated saccular aneurysm. Medtronic Endurant stent grafts were used in all patients. The rate of endovascular group patients whose common iliac arteries were aneurysmatic and where stent graft extension was used to the external iliac artery using iliac extension was 30,1%. Of the patients treated with open surgery, 35,5% had tubular graft, 22,2% had aortobifemoral, and 37,7% had aortobiiliac graft interposition. Jotec Dacron grafts were used in all open surgery patients.

The incidence of endoleak was found 9,5% in the early postoperative period of EVAR patients. Of the 12 patients with endoleaks, 4 had type 2 endoleak and disappeared during follow-up. Endoleak rate decreased to 3,2% at 6 months. Secondary intervention requirement was found in 7,1% of EVAR patients with endoleaks in 1 year follow-up.

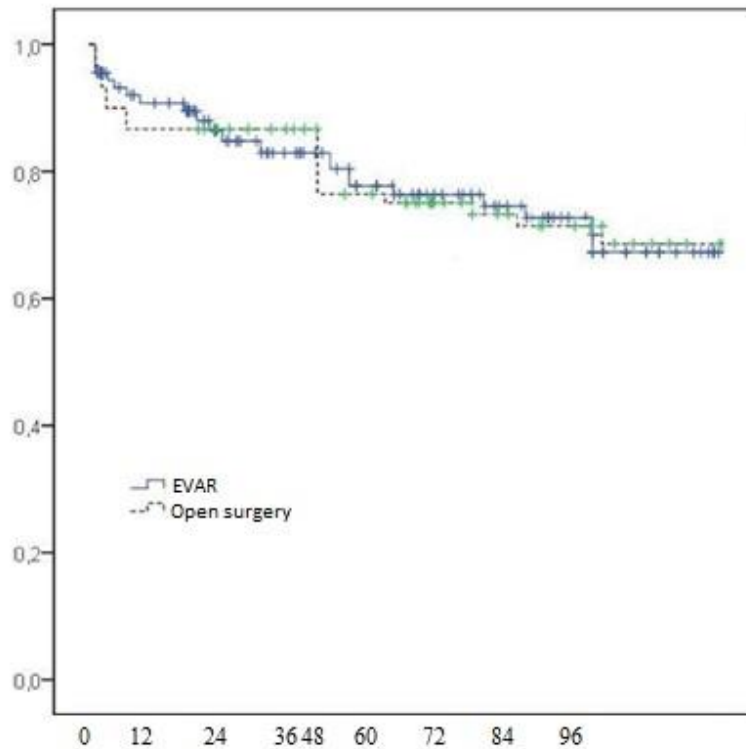
Complications developed in 8,9% of patients treated with open surgery. Of the EVAR patients who were undergoing for elective surgery, there were no patients who underwent open surgery. Four of the patients who were treated with open surgery died in the early postoperative period. Therefore, early surgical mortality rate was 8,9%

in this group. All of these patients were older than 70 years and had severe comorbid factors. Early mortality rate was 2,4% in EVAR group.

The secondary intervention rate was found 7,1% in the EVAR group while in open surgery patients was 6,6%. There was no statistically significant difference between the two groups when evaluated for secondary intervention ($p>0.05$). The secondary intervention rate of EVAR patients was

7,9% when treated patients with early-stage endoleak were added.

Mortality of patients in long-term follow-up was questioned in terms of “aneurysm-related death” through the Central Population Administration System (MERNIS). At 12, 24, 36, 48, 60, 72, 84, 96 months follow-up, both groups were found to be indifferent in terms of aneurysm-related mortality ($p=0,667$ $p>0.05$) (Graph 1).



Graph 1: 96-month survival and Kaplan-Meier Analysis of EVAR and Open Surgery patients.

Post Implantation Syndrome

Biochemical values were compared before and after the procedure (first 3 days postoperatively). Statistically significant increases were found in C-reactive protein, white blood cell and sedimentation rate values (Table 5). Eighteen patients (14,2%) with fever and lumbar pain

accompanied by antibiotic therapy were accepted as “Post-implantation Syndrome” because of negative blood cultures. In addition to prophylactic antibiotic treatment, anti-inflammatory treatment was started. Post-implantation syndrome had no effect on mortality during follow-up.

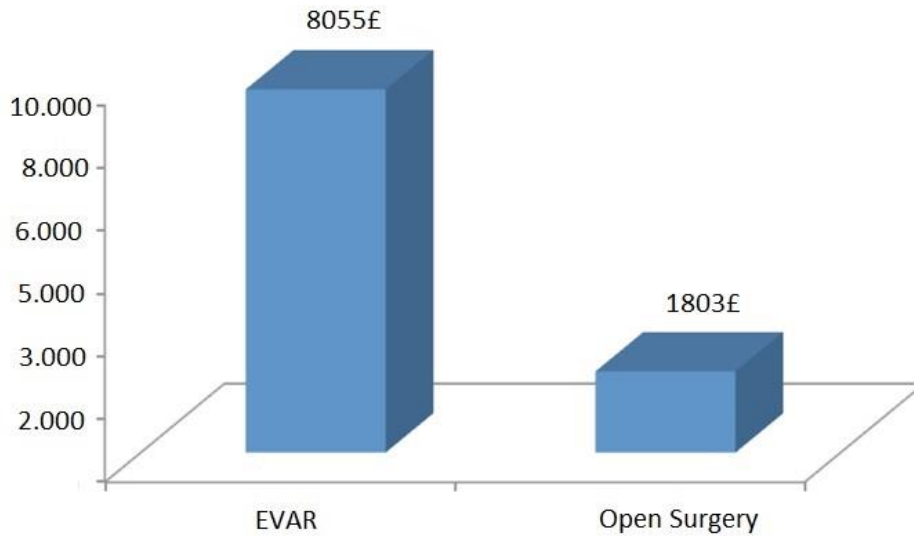
Table 5: Comparison of preoperative and postoperative laboratory parameters in EVAR patients

| | Preoperative (mean,min-max) | Postoperative (mean, min-max) | P value |
|--|--|--|----------------|
| C-reactive protein (mg/L) | 20,59 (1-160) | 77,79 (4-253) | 0 |
| White blood cell (WBC× 109 /µl) | 7,97 (2,3-16,6) | 10,24 (5-23,7) | 0 |
| Sedimentation rate | 35,76 (2-88) | 56,65 (10-130) | 0.013 |
| Creatinine (mg/dL) | 1,03 (0,4-1,21) | 1,08 (0,6-1,23) | 0.073 |

Cost Analysis

The invoice information of the patients after discharge was obtained from the Ankara University Medical Faculty Hospital Information

Management System. As a total cost, the invoice account that emerged after all the procedures from the hospitalization to discharge of each patient was cumulatively compared between the two groups (Graph 2).



Graph 2: Distribution of costs (£).

In our study, the cost was high in EVAR patients. The average cost in patients undergoing open surgery was 1803£ (£ = Pound sign as currency of United Kingdom.), while in patients undergoing EVAR the cost was 8055£. For the endovascular group, stent grafts accounted for a large portion of the cost, especially use of iliac lengthening stent grafts, balloon use, and re-imaging (in the case of endoleak or stenosis) increased the cost. For the open surgery group, prolonged hospitalization (intensive care, service hospitalization) due to complications due to morbid factors was observed to increase the cost (Table 3).

repair between 1998-2000 (OR period) with 195 patients (EVAR period) in the 2010-2012 study. The main cost difference reflected the longer use of the operating room and length of stay in the hospital (and ICU). Reintervention reported similar for OR (24.2%) and EVAR (24.6%) (p 1 p4, 92). When the cost balance is established for EVAR and OR, an average device cost of 13000 euro for EVAR is calculated. Therefore, they conclude that for most routine repairs, the EVAR group is not costly from "Open Repair" up to a minimum of five years of follow-up.¹¹

Ruth MA Bulder et al. Compared one hundred and eighty-six patients who underwent elective AAA

DISCUSSION

EVAR is a widely used treatment method in the last two decades with acceptable morbidity and mortality rates in patients with abdominal aortic aneurysm and anatomically appropriate high-risk patients^{12,13}. Endovascular stent graft therapy has become the most frequently used alternative treatment method with less invasive, low mortality and morbidity, local anesthesia, low blood transfusion requirement, lack of mechanical ventilator requirement, shorter duration of intensive care and hospitalization, and its applicability in patients with advanced age and additional organ problems¹⁴.

Standard EVAR can be performed to patients with Infrarenal Abdominal aortic aneurysms but only to those anatomically appropriate. The most important conditions for endovascular stent graft treatment include the distal neck diameter (landing zone), angulation of the aneurysm, absence of thrombus and severe calcification on the aneurysm neck, and absence of high-grade stenosis and obstruction due to advanced tortiosity and atherosclerosis in the iliac artery¹⁵. Currently, patients with an aortic neck diameter of 34 mm and aneurysm neck length of 1 cm are also considered suitable for EVAR treatment¹⁶. In our study, it was observed that the rapidly developing endovascular treatment methods of our clinic in line with the literature were highly performed in anatomically and morphologically appropriate patients at a high rate.

EVAR trial1 randomized study found that EVAR reduced mortality by 3% compared to open surgery¹⁷. Four -year follow-up showed no difference in all mortality and although the results in terms of morbidity in the first three months were in favor of EVAR in quality of life, no difference was detected in later periods¹⁷.

Konrad Salata et al. Compared abdominal aortic aneurysms with EVAR and Open Surgery Repair, in a population-based cohort study of 17 683 patients, they found no statistically significant

difference in long-term all-cause mortality between the two groups during a maximum follow-up of 13.8 years¹⁸.

Scallan et al. published longterm results of octogenarians in both groups ; EVAR results in an improved 1-year mortality in octogenarians compared with open repair, although 5-year survival reported similar between the groups¹⁹.

In this sense, EUROSTAR is the most comprehensive meta-analysis performed, and in this study, blood loss during surgery, length of hospital stay and intensive care unit, total complication rate and mortality within the first 30 days were found to be less in endovascular intervention. There was no difference between the two groups in terms of two-year survival^{20,21}. Similarly, the early mortality rate was lower in EVAR than in conventional surgery in the study comparing elective treatment of patients with advanced age group (>80 years of age) AAA performed by Raval and Eskandri²². In our study, the early mortality rate was found to be 2,4% in EVAR and 6,7% in open surgery, similar to the literature ($p < 0.05$).

In the study of Schermerhorn et al., The rate of transition from EVAR to open surgery was reported as 1,6%²³. In the study of Jordan et al, the transition to open surgery was reported as 1,9%²⁴. In our study, we did not see any patients who were started with endovascular method in one session and switched to open surgery, but two patients underwent open surgical treatment due to ongoing endoleak diameter increase. This ratio is 1,6% in agreement with the literature.

Another advantage in EVAR is that there is less blood loss during surgery than open surgery and therefore less need for blood transfusions. In the study conducted by Becquemin et al., mean blood transfusion was 0,2 units in EVAR group and 2,1 units in open surgery group²⁵. In our study, we found that the transfusion requirement in the EVAR group was much less similar to the literature (Table 4).

Table 4: Blood transfusion amount

| | Group 1 (EVAR) (mean±sd) | Group 2 (Open Surgery) (mean±sd) | P value |
|---|--------------------------|----------------------------------|--------------|
| Intensive care unit hospitalization (day) | 1±1,4 | 2±3,6 | 0.001 |
| Total hospitalization (day) | 4±2,5 | 8,6±5,6 | 0.001 |

In the study conducted by Maher and colleagues and Becquemin and colleagues, it was determined that AAA patients in the EVAR group had a short duration of hospitalization in the intensive care unit and in the post-operative period^{25,26}. In this study,

it was observed that the duration of hospitalization in the intensive care unit and hospital in EVAR group patients was shorter, similar to the literature (Table 3).

Table 3: Mean duration of hospitalization in intensive care unit and hospital

| | Group 1 (EVAR) (mean±sd) | Group 2 (Open Surgery) (mean±sd) | P value |
|-----------------------------------|-------------------------------------|---|----------------|
| Erythrocyte Suspension (unit) | 0,06±1,0 | 2,4±2,0 | 0.001 |
| Fresh Frozen Plasma (unit) | 0,08±1,0 | 4±2,0 | 0.001 |

One of the factors affecting the duration of hospitalization is the type of anesthesia performed. In the study of Ruppert and his colleagues, it was stated that the patients who underwent surgery under local and regional anesthesia and who underwent EVAR were more advantageous in terms of their hospitalization time than those who underwent EVAR under general anesthesia²⁷. In our study, regional anesthesia and sedation were performed for 35,7% of the EVAR group, and general anesthesia was applied to 64,3% of the patients. It was observed that this difference did not reflect clinically on morbidity and mortality rates due to the short duration of endovascular surgery and the removal of extubated patients from the operation.

Sarah et al. emphasized that selected patients can safely enter EVAR using a short stay strategy. For low-risk patients, a postoperative 6-hour follow-up period will be sufficient. They noted that reducing the current average three-day stay to 1.5 days after EVAR in the UK would free up 4361 bed days and could save around £ 1,800,000 a year²⁸.

In the ACE (ANEURYSME de l'aorte abdominale: Chirurgie ver - sus Endoprothèse) study, the reintervention rate in EVAR patients was 16% and the reintervention rate in the open surgery group was 2,7%. Similar to the ACE study in the OVER study, the recurrence rate was 12% in the EVAR group and 1,6% in the open surgery group²⁹. In our study, reintervention rate was 7,9% in EVAR group and 6,7% in the open surgery group.

The distribution of complications after abdominal aortic aneurysm surgery varies according to the type of treatment. There was no significant difference in terms of complications between EVAR and open surgical treatment in the randomized controlled trial conducted by

Becquemin and colleagues in the low-and medium-risk group of patients. Incisional complications were more common in the open surgery group, while gluteal claudication was more common in the EVAR group. Similarly, wound-related complications were less common in the EVAR group in Jordan et al. And Lederle et al. studies. In the same studies, it was found that gastrointestinal complications were less observed in the EVAR group. In our study, no significant difference was found between EVAR and conventional surgery group in terms of all complications ($p < 0.05$).

The Endoleak can be seen at a rate of 20-40% at any time after EVAR. Endoleaks were reported in 7% of the study in May and colleagues, 21% in the study of Brewster and colleagues, 36% in the study of Zarins and colleagues, 5,6% in the study of Beebe and colleagues, 27% in the study of Becquemin and colleagues, 1,1% in the study of Jordan and colleagues, and 25% in the study of Lederle and colleagues^{25, 29-33}. In our study, endoleak rate was found to be 9,5%. This rate decreased to 3,2% at 6 months after additional intervention and follow-up.

Cost analysis in EVAR trial1 and DREAM Studies calculated that the average cost in EVAR patients was 13258£ while in open surgery patients it was 9946£. Similarly, in our study, the cost was found to be high in EVAR patients. The average cost in patients undergoing open surgery was 1803£, while in patients undergoing EVAR this cost was 8055£. The UK results showed that this difference was 1.33 times, while our clinic results showed that this difference was 4.46 times when compared.

Our study has limitations inherent to a nonrandomized, single-center, retrospective analysis. Another limitations was that the distribution of the two groups in terms of age and

number was not equal. Along with the technological developments, the cheaper EVAR graft prices, and the depreciation of the Turkish lira in the face of global economic crises in the world dynamically affect the cost effectivity results.

CONCLUSION

In patients with abdominal aortic aneurysm, surgery is planned and both surgery techniques are appropriate, endovascular treatment has a significantly lower Interventional mortality. In addition, the need for blood products is less and the duration of intensive care and hospital stay is shorter in EVAR patients. However, there was no significant difference in total mortality rate between EVAR and open surgical treatment in the medium and long term. When the cost survey results were evaluated, EVAR was found to be 4.46 times higher than open surgical treatment even though it provided superiority in terms of patient comfort. Despite this, EVAR is preferred primarily by both patients and surgeons. According to the results of our study, EVAR is a safe and mortality-decreasing treatment for early and long-term follow-up in all age groups, especially in patients with high comorbid factors over the age of 70. In the light of the emerging endovascular graft technologies, we believe that EVAR therapy in anatomically appropriate patients may not only be used in the early postoperative period, but also in the long term as a substitute for open surgical treatment.

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