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Comparison of percutaneous access and open femoral cutdown in elective endovascular aortic repair of abdominal aortic aneurysms

Elektif abdominal aort anevrizmalarının endovasküler onarımında perkütan erişim ve açık femoral cutdown karşılaştırması

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ABSTRACT

Background: The aim of this study was to compare postoperative outcomes of percutaneous access and femoral cutdown methods for elective bifurcated endovascular abdominal aortic aneurysm repair.

Methods: Between November 2013 and September 2020, a total of 152 patient (135 males, 17 females; mean age: 70.6±6, range, 57 to 87 years) who underwent endovascular repair due to infrarenal abdominal aortic aneurysm were retrospectively analyzed. According to femoral access type, the patients were grouped into two groups as the total percutaneous femoral access and open cutdown femoral access endovascular repair. Intra- and postoperative data were compared, including operative time, amount of contrast media, bleeding requiring transfusion, return to the operating room, access vessel complications, wound complications, and overall length of hospital stay.

Results: Eighty-seven (57.2%) femoral cutdown access repair and 65 (42.8%) percutaneous femoral access repair cases were evaluated in the study. The two groups were comparable in terms of demographic and clinical characteristics (p>0.05), except for chronic obstructive pulmonary disease which was more frequent in the percutaneous access group (p=0.014). After adjustment, age, diabetes mellitus, chronic obstructive pulmonary disease, and obesity were not predictive of percutaneous access failure. Percutaneous femoral access was observed as the only preventing factor for wound infection (odds ratio=0.166, 95% confidence interval: 0.036-0.756; p=0.021).

Conclusion: Although femoral access preference does not affect mortality and re-intervention rates, percutaneous endovascular repair reduces operation time, hospital stay, and wound site complications compared to femoral artery exposures.

Keywords: Abdominal, aorta, aortic aneurysms, common femoral artery, endovascular procedures.

ÖZ

Amaç: Bu çalışmada, elektif bifurkasyonlu endovasküler abdominal aort anevrizması onarımı için perkütan erişim ve femoral cutdown yönteminin ameliyat sonrası sonuçları karşılaştırıldı.

Çalışma planı: Kasım 2013 - Eylül 2020 tarihleri arasında infrarenal abdominal aort anevrizması nedeniyle endovasküler onarım yapılan toplam 152 hasta (135 erkek, 17 kadın; ort. yaş: 70.6±6, dağılım 57-87 yıl) retrospektif olarak incelendi. Femoral giriş tipine göre hastalar iki gruba ayrıldı: total perkütan femoral giriş ve açık femoral cutdown erişim ile endovasküler onarım. Ameliyat süresi, kontrast madde miktarı, transfüzyon gerektiren kanama, ameliyathaneye dönüş, giriş damar komplikasyonları, yara komplikasyonları ve genel hastanede kalış uzunluğu dahil olmak üzere ameliyat sırası ve sonrası veriler karşılaştırıldı.

Bulgular: Çalışmada 87 (%57.2) femoral cutdown erişim onarımı ve 65 (%42.8) perkütan femoral erişim onarımı olgusu değerlendirildi. Perkütan erişim grubunda daha sık görülen kronik obstrüktif akciğer hastalığı dışında (p=0.014) iki grup benzer demografik ve klinik özelliklere sahiplerdi (p>0.05). Ayarlama sonrasında yaş, diabetes mellitus, kronik obstrüktif akciğer hastalığı ve obezitenin başarısız perkütan erişimin belirleyicisi olmadığı gözlendi. Perkütan femoral erişim, yara enfeksiyonunu önleyen tek faktör olarak gözlendi (olasılık oranı=0.166, %95 güven aralığı: 0.036-0.756; p=0.021).

Sonuç: Femoral erişim tercihi mortaliteyi ve yeniden müdahaleyi etkilemese de, perkütan erişim endovasküler onarım, cutdown femoral erişime kıyasla, ameliyat süresini, hastanede kalış süresini ve yara yeri komplikasyonlarını azaltır.

Anahtar sözcükler: Abdominal, aort, aort anevrizmaları, ortak femoral arter, endovasküler işlemler.

Endovascular aneurysm repair (EVAR) is a minimally invasive procedure that was originally developed to reduce the surgical stress levels in anatomically suitable patients with a high risk for open surgical repair of abdominal aortic aneurysm (AAA). Endovascular aortic repair improves clinical outcomes, as evidenced by reduced operative morbidity and mortality and shorter hospital stays.[1,2] Conventional EVAR has been performed by direct surgical common femoral artery access to enable the delivery of large stent graft systems. Suture-mediated closure devices have been developed to facilitate fast and safe common femoral artery hemostasis and provide the opportunity to deliver even large sheathed devices.[3] With the advances in technology and the adoption of more minimally invasive strategies, it is aimed to reduce the incidence of complications associated with incision in surgical care. In addition, utilization of percutaneous access for aortic endografts has been associated with reduced operative time and hospital stay, without increasing local complications.[4] In September 2017, the protocol for total percutaneous EVAR was initiated by our surgical team. In the present study, we aimed to analyze the experience of a single surgical team who performed EVAR through both percutaneous (pEVAR) and surgical (cEVAR) access.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at University of Health Sciences, Kartal Koşuyolu Training and Research Hospital, Department of Cardiovascular Surgery between November 2013 and September 2020. Of a total of 241 consecutive patients, 152 (135 males, 17 females; mean age: 70.6±6, range, 57 to 87 years) who underwent EVAR due to infrarenal AAA were included. Patients who underwent elective bifurcated repairs alone were eligible for the study to compare the results of percutaneous femoral access (pEVAR) with the results the cutdown femoral access (cEVAR). Exclusion criteria were as follows: (i) emergency for ruptured aneurysm; (ii) concomitant procedures for complex anatomy (renal stenting, hypogastric embolization, lower extremity revascularization, and use of iliac branched device or iliac bare-metal stent); (iii) heavy femoral calcification (>50%); (iv) scarred groin from previous intervention; (v) femoral aneurysm/pseudoaneurysm. A written informed consent was obtained from each patient. The study protocol was approved by the Kartal Koşuyolu Training and Research Hospital Ethics Committee (No. 2018.6/3-103). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Data were collected for patients' demographics, risk factors and outcomes. The follow-up protocol included postoperative computed tomography angiography (CTA) before discharge, a clinical examination, and a CTA three months postoperatively and annually thereafter. Intra- and postoperative data were compared, including operative time, amount of contrast media, bleeding requiring transfusion, return to the operating room, access vessel complications (i.e., occlusion, fistula, pseudoaneurysm, hematomas >6 cm, deep venous thrombosis), wound complications (i.e., infection, dehiscence, lymphatic leakage and femoral neuropathy), and overall length of hospital stay. Technical success was defined as a successful arterial closure without the need for conversion to open femoral artery repair, as well as no change in the baseline pulse status of the patient. Obesity was defined as a body mass index (BMI) of >30 kg/m^2. Renal failure was defined as the increase in serum creatinine level higher than 1.8 mg/dL without known previous renal dysfunction. Respiratory failure was defined as prolonged intubation (>72 h) or tracheostomy requirement postoperatively.

Two types of endografts with a catheter outer diameter of 20 F and less were used: Treovance® (Terumo Aortic [formerly Bolton Medical] FL, USA) and Endurant™ (Medtronic Minneapolis, MN, USA). As with open reconstructions, oblique skin incisions were used to expose the common femoral artery. Perclose Proglide™ devices (Abbott Vascular, CA, USA) were used for the percutaneous technique and two devices were placed 90 degrees from each other to ensure optimal closure of the large arteriotomy in each femoral artery. The Proglide™ device and its use have been previously described in detail.[3] In pEVAR cases, the femoral bifurcation and puncture site were determined by taking the lower end of the femoral head as a landmark by preoperative detailed evaluation of the CTA. Vascular puncture was performed by fluoroscopy-guided identification and common femoral artery puncture was confirmed by fluoroscopic oblique projection. At the end of the procedure, the preformed knots were tightened using a knot pusher and temporary hemostasis was achieved by manual compression. After verification of hemostasis, the guidewire was removed. In case of persistent bleeding, a third Perclose™ device was deployed before removal of the guidewire.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). Descriptive data were expressed in

mean ± standard deviation (SD), median (min-max) or number and frequency, where applicable. Categorical variables were compared using the chi-square test, while continuous variables were compared using the Student t-test or the Mann-Whitney U test. A multivariate logistic regression analysis was used to identify independent risk factors for percutaneous access failure and wound complications. A *p* value of <0.05 was considered statistically significant.

RESULTS

There were 87 (57.2%) cEVAR patients and 65 (42.8%) pEVAR patients. Clinical characteristics of the patients in study groups are shown in Table 1. The two groups were comparable in terms of demographic and clinical characteristics (p>0.05), except for chronic obstructive pulmonary disease (COPD) which was more frequent in the pEVAR group (p=0.014). Surgical femoral exploration was performed under general (n=72, 82.8%) and local (n=15, 17.2%) anesthesia, while all percutaneous femoral accesses were performed under local anesthesia. The pEVAR had the same amount contrast agent use (85.2±18.9 mL *vs.* 90.9±21.4 mL, respectively; p<0.136), but shorter operative time (102.5±30.9 min *vs.* 126.3±44.9 min,

respectively; p<0.001) than cEVAR. None of the patients required emergency conversion to open abdominal repair. Operative and postoperative outcomes of patients are shown in Table 2.

No in-hospital mortality was observed in both groups, and there were no pulmonary and renal complications. The prolongation of all hospitalization periods was due to access site complications. There were more wound complications postoperatively in patients undergoing cEVAR, primarily superficial surgical site infection (16% *vs.* 3%, respectively; p=0.014). The wound was revised in three patients in the cEVAR group due to dehiscence. In six patients, lymphatic fluid leakage was observed, particularly related to surgical cutdown. The leakage of lymphatic fluid ceased by application of compression therapy in four patients. However, the remaining two patients who had persisted lymphatic drainage for two weeks were taken up for wound re-exploration. In two patients in the pEVAR group, the incision infection completely healed following oral antibiotics therapy and wound dressing. According to the multivariate logistic regression analysis, for the development of wound infection, no statistically significance was present between sex (odds ratio [OR]=0.788, 95% confidence

Table 1. Baseline characteristics of patients with abdominal aortic aneurysms undergoing pEVAR versus cEVAR

	Overall (n=152)			cEVAR (n=87)			pEVAR (n=65)			
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			70.6±6			68.9±7.4			70.5±8	0.204
Sex										0.797
Male	135	88.8		78	89.7		57	87.7		
BMI (>30 kg/m²)	45	29.6		23	26.4		22	33.8		0.370
Coronary revascularization	84	55.3		46	52.9		38	58.5		0.514
Diabetes	38	25		22	25.3		16	24.6		1
COPD	71	46.7		33	37.9		38	58.5		0.014*
Dialysis (preoperative)	16	10.5		9	10.3		7	10.8		1
Hypertension	126	82.9		68	78.2		58	89.2		0.084
Ejection fraction (<30%)	12	7.9		6	6.9		6	9.2		0.763
Family history	3	2		3	3.4		0	0		0.261
Cerebrovascular accident	11	7.2		8	9.2		3	4.6		0.354
ASA (>4)	29	19.1		18	20.7		11	16.9		0.677
Prior open abdominal surgery	26	17.1		15	17.2		11	16.9		1
Previous cardiac surgery	29	19.1		16	18.4		13	20		0.837
Aneurysm diameter (cm)			64±8.9			63.9±8.8			64.1±8.9	0.909

cEVAR: Cutdown endovascular aneurysm repair; pEVAR: Percutaneous endovascular aneurysm repair; SD: Standard deviation; BMI: Body mass index; COPD: Chronic obstructive pulmonary disease; ASA: American Society of Anesthesiologists.

Table 2. Operative and postoperative outcomes of patients with abdominal aortic aneurysms undergoing pEVAR versus cEVAR

Outcomes	Overall (n=152)			cEVAR (n=87)			pEVAR (n=65)			p
	n	%	Mean±SD	n	%	Mean±SD	n	%	Mean±SD	
Operation time (min)			116.1±41.2			126.3±44.9			102.5±30.9	0.001*
Contrast agent (mL)			88.5±20.5			90.9±21.4			85.2±18.9	0.136
General anesthesia	72	47.4		72	82.8		0	0		0.001*
Local anesthesia	80	52.6		15	17.2		65	100		0.001*
Stent-graft device										
Endurant®	67	44.1		40	45.9		27	41.5		0.623
Treovance®	85	55.9		47	54		38	58.5		0.623
Blood transfusion (≥2 U)	14	9.2		10	11.5		4	6.2		0.396
Wound complications										
Wound infection	16	10.5		14	16.1		2	3.1		0.014*
Wound dehiscence	3	2		3	3.4		0	0		0.261
Lymphatic leakage	6	3.9		6	6.9		0	0		0.038*
Femoral neuropathy	8	5.3		8	9.2		0	0		0.011*
Vascular complications										
Hemorrhage	4	2.6		2	2.3		2	3.1		1
Lower extremity ischemia	6	3.9		3	3.4		3	4.6		1
Length of hospital stay (day)			3.8±2.5			4.7±2.5			2.5±1.7	0.001*
Follow-up										
Mortality	2	1.3		1	1.1		1	1.5		1
Re-intervention	13	8.6		10	11.5		3	4.6		0.155

cEVAR: Cutdown endovascular aneurysm repair; pEVAR: Percutaneous endovascular aneurysm repair; SD: Standard deviation.

interval [CI]: 0.012-0.223; p=0.715), BMI (OR=0.978, 95% CI: 0.376-2.546; p=0.964), and diabetes mellitus (DM) (OR=0.622, 95% CI: 0.224-1.731; p=0.363). Percutaneous femoral access was observed as the only preventing factor for wound infection (OR=0.166, 95% CI: 0.036-0.756; p=0.021). Femoral neuropathy occurred only in eight patients who underwent cutdown femoral artery exploration.

Technical success rate was 96.2% in pEVAR group with successful arterial closure in 125 of 130 groins. Technical failures in pEVAR group requiring conversion to open surgical repair of the artery included hemorrhage in two patients and flow-limiting stenosis or occlusion and dissection of the femoral artery in three patients: For the main body delivery, the success rate of the 20F sheath (n=54 [83.1%]) was 92.7% and two hemorrhages and one limb malperfusion were observed. The success rate of 18F sheath (n=11 [16.9%]) was 100%, with no complications. For all contralateral side delivery, 16F sheath (n=65 [100%]) was used with a success rate of 96.9% and two limb malperfusion were observed. After adjustment,

age, DM, COPD, and obesity were not predictive of percutaneous access failure. In the cEVAR group, five patients were taken to the operating room for surgical exploration, three patients due to postoperative loss of distal pulses, and two patients due to subsequent groin bleeding. Postoperative length of stay was longer in the cEVAR (median 3 days; range 2-12 days) than in pEVAR (median 2 days, range 1-11 days) even if performed under local anesthesia (median 2 days; range 2-10 days) (p<0.001).

There were two late deaths at a mean follow-up time of 45.4±21.7 months. One patient died from each of the groups. The patient of cEVAR group died following reoperation for stent-graft infection two years after endovascular repair. In pEVAR group, the patient died from aneurysm rupture due to late onset type 1a endoleak three years after the intervention. Thirteen reinterventions were performed in 10 patients (endoleak, n=6 and stent-graft occlusion, n=4) and three patients (endoleak, n=3) from the cEVAR and pEVAR groups, respectively. Distribution of endoleaks types in each group is as follows: in

cEVAR group, type 1a endoleak (n=2), type 1b endoleak (n=3), type 3 endoleak (n=1) and in pEVAR group, type 1a endoleak (n=1), type 1b endoleak (n=1), type 3 endoleak (n=1). All received percutaneous endoleak repair. Except for one type 1a endoleak that had open surgical repair, the remaining five of them received percutaneous endoleak repair. For stent graft occlusion in four patients, embolectomy and balloon-expandable stenting were performed. There was no significant difference between re-intervention and total mortality rates between the groups. Arterial-venous fistulae, iliofemoral stenosis, pseudoaneurysm, hematomas >6 cm, and deep venous thrombosis were not observed in either group during follow-up.

DISCUSSION

In the current era of endovascular intervention, the use of percutaneous access through the femoral artery in the repair of elective infrarenal AAA has been increasing. Even in ruptured AAA, percutaneous approaches are preferred due to shortening of the operation time and improving outcomes.[5] Although both approaches are expected to show no superiority over mortality in elective repair, pEVAR is the focus of attention, as it has fewer wound complications (i.e., seroma, dehiscence, femoral neuropathy, and infections) and shortens the duration of hospital stay.

Technical success in pEVAR varies depending on the patient's femoral artery anatomy (calcification width, small vessel diameter), the use of large sheaths or limited operator experience.[4,6] Less access site complications and more than 90% technical success can be achieved with pEVAR.[4] Using the Perclose™ closure device, the total procedure time is shortened by 25 min[4,7,8] and a significant decrease is observed in local anesthesia usage, the duration of ambulation and the length of intensive care unit and hospital stay in this process.[9]

Access site (vascular and wound) complications are the most important factors that shorten the duration of hospital stay and increase the quality of life in EVAR patients. Successful clinical results are possible with procedural technical success. The most important causes of pEVAR technical failure are obesity, femoral artery calcification, and groin scars due to previous intervention.[10] While obesity and groin scar cause Perclose™ suture breakage or premature locking of knot hemorrhage,[11,12] more than 50% calcification of the femoral artery, particularly on the anterior wall, may lead to disruption of the plaque or even accidental suturing of the posterior arterial wall.[4,13] These may result in vessel occlusion,[14]

as well as, bleeding due to unsuccessful needle capture and inability to implant the device.[12,15] Distal embolization and dissection can also be observed, but they are not specific complications for percutaneous closure device.[16]

While planning this study, patients with anterior femoral wall calcifications were excluded from both patient groups, but within the percutaneous procedure performed in 130 groins, three of them necessitated open femoral repair for mechanical failure, which caused flow limiting stenosis (n=2) and dissection (n=1). The third Proglide™ device was placed in seven groins where adequate hemostasis could not be achieved. Upon ongoing hemorrhage due to misplacement despite the third device, two of them had to be converted to open surgery. Pseudoaneurysm, which is frequently mentioned for pEVAR patients in the long-term follow-up, is considered a specific complication.[17] In our pEVAR group patients with at least six months of follow-up, we did not encounter this complication.

In addition to vascular complications, wound complications also increase the length of hospital stay and the cost with the use of antibiotics and wound care. In particular, obesity and female sex are independent risk factors, and up to 3% of wound complications are observed in patients with open femoral exposure for EVAR.[18] Although there was no statistically significant difference between BMI of both groups in our study, wound infections were observed more in the cEVAR group (1.6%) than in the pEVAR group (0.3%). The main reason for the higher incidence of wound complications in cEVAR patients was associated with extensive incision and dissection, and it was reported that hospital discharge durations were prolonged due to delayed mobilization and wound care processes.[7,19,20] Another wound complication encountered in cutdown patients is femoral neuropathy and eight patients in our study had serious complaints.

Furthermore, life-threatening hemorrhage may develop as a result of mechanical failure due to the insertion of the inguinal ligament into the suture, when high puncture is performed.[21] The ability and feasibility to convert to open femoral repair in both occlusion and hemorrhage is critical.[11] Therefore, it has been emphasized that percutaneous endovascular procedures should be performed by the surgical team or in hospitals with conditions that can provide surgical support.[16,22,23]

Maintaining a standardized patient population in both groups is of utmost importance while comparing

two methods. At this point, we considered the exclusion criteria. Patients with the presence of any factors from the criteria were excluded from the study. Given the fact that all those aforementioned patients with positive criteria necessitated cEVAR, none of them were included in the cEVAR group of our study. Related to this, we need to point out that our surgical team has adopted pEVAR as of 2017. Before 2017, we used to perform cutdown (cEVAR) only. Later on, cEVAR was performed only to patients with positive exclusion criteria. The rest of them were all pEVAR. As a result, the groups in the study consisted of cEVAR patients before 2017 (with negative exclusion criteria) and all pEVAR patients after 2017. By this way, both cEVAR and PEVAR groups share similar access vessel and clinical characteristics anatomically, as well as none of the groups include concomitant procedures or emergency interventions that may affect procedure time or hospital stay. In this manner, we believe that we have clarified possible question marks and uncertainty that may arise about patient selection and decision making on surgical methods.

This study has two main limitations. First, this was an observational study from a prospectively collected database. Second, the adaptation of the surgical team to the endovascular repair methods of the cEVAR group was started under general anesthesia and, then, continued for a while with the habit of being a surgical team and provide greater comfort and safety to surgeons and patients. However, hospital stay times were longer in the cEVAR group performed under local anesthesia than in the pEVAR group, which led us to consider that care for the surgical wound had a more pronounced effect on the duration of hospital stay.

In conclusion, percutaneous endovascular aneurysm repair is considered superior to surgical endovascular aneurysm repair with carefully selected patients in elective cases due to less infection in the wound site and shortening of the operation time. However, we believe that since access vessel complications are vital, total percutaneous interventions should not be performed without the necessary conditions for converting to open femoral artery repair are met.

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