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Total percutaneous access versus surgical access in endovascular procedures: a retrospective analysis

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ABSTRACT

Objectives: This study aims to compare the outcomes of total percutaneous and surgical access methods in endovascular interventions.

Patients and methods: The results of endovascular aortic repair (EVAR) of abdominal aortic aneurysms were retrospectively analyzed. One hundred and four patients (76 males, 28 females; mean age 67.0±8.4 years; range 31 to 84 years) were operated for EVAR between October 2010 and June 2014. In 55 patients (52.9%), EVAR was performed percutaneously and access repair was made with vascular closure device. In 49 (47%), surgical cut-down was performed.

Results: There was a statistically significant difference in the frequency of chronic obstructive pulmonary disease between the groups, indicating a higher incidence in the percutaneous group (40.0% vs. 20.4%, p=0.031). Obese patients were shown to have a higher incidence of complications. A higher number of obese patients undergoing percutaneous closure developed hematoma (7.7% vs. 50.0%, p=0.0001). Vascular repair was also significantly more frequent in the percutaneous group with a more pronounced difference in obese patients (0 vs. 43.8%, p=0.005).

Conclusion: Pre-close technique is a successful way of performing EVAR procedures. Although wound infections are less common, obese patients may have higher rates of complications with percutaneous technique.

Keywords: Endovascular intervention; percutaneous approach; surgery.

Demand for transarterial catheterization has been increasing for the past decade for various procedures utilizing low (<10F) and high (10-25F) profile systems.[1] Manual compression may be used for lower profile systems (<8F) with drawbacks such as prolonged bed rest, patient discomfort, and cost.[2] The access closure for low profile system may be performed with various devices. However, large profile systems require a specified approach when percutaneous closure is preferred. In addition, the endovascular procedures for infrarenal abdominal aorta (endovascular aortic repair; EVAR), thoracic aorta (thoracic endovascular aneurysm repair; TEVAR), and aortic valve implantations (transcatheter aortic valve implantation; TAVI) conventionally require high profile systems (12-24F).[2] Any percutaneous closure system for this access closure purpose should avoid complications related to the femoral cut-down.

The pre-close technique was originally described by Haas et al. in 1999.[3] The Prostar XL closure device (Abbott Vascular, Santa Clara, CA, USA) has been designed for percutaneous closure of a wide range profile (8.5-24F) systems. Access site closure with Prostar device has also been used successfully in minimally invasive mitral valve surgery.[4] Herein, we aimed to compare the outcomes of total percutaneous and surgical access methods in endovascular interventions.

PATIENTS AND METHODS

The results of endovascular aortic repair (EVAR) of abdominal aortic aneurysm (AAA) were retrospectively analyzed to compare the surgical cut-down technique and percutaneous procedures. The study protocol was approved by the institutional ethics committee. One hundred and four patients (76 males, 28 females; mean age 67.0±8.4 years; range 31 to 84 years) were operated for EVAR from October 2010 to June 2014. Forty-nine (47.1%) patients were operated with surgical cut-down of bilateral femoral

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arteries (group S). In 55 (52.9%) patients, EVAR was performed percutaneously and access repair was made with vascular closure (Prostar XL, Abbott Vascular, Santa Clara, CA, USA) device (group P). All patients were included in the analysis.

Ultrasound-guided puncture was used for arterial access and imaging for all patients. Under this circumstance diameter, calcification and anatomic level of the femoral artery were evaluated. All patients in group S were operated under general anesthesia, while local anesthesia combined with sedation (n=19, 34%) or general anesthesia (n=36, 65%) methods were used in group P. Bilateral femoral access and Talent endovascular graft (Medtronic, Sunrise, FL, USA) were used in all EVAR procedures. The procedures were performed in the cardiac catheterization laboratory by cardiovascular surgeons and cardiologists.

The presence of chronic obstructive pulmonary disease (COPD) was defined as prolonged cough, shortness of breath, and extended use of pulmonary medications or compatible radiological changes.[5] The patients who were diagnosed before hospitalization or on any hypoglycemic medication were considered diabetic. The patients who had a previous diagnosis and whose baseline serum creatinine levels after hospitalization were >1.5 mg/dL were considered to have chronic renal disease (CRD). Obesity was defined as a body mass index of ≥30 kg/m^2.

During percutaneous procedures, a proctor was present to guide through the use of vascular closure device. Vascular access sites were repaired with the pre-close technique, as described previously.[6,7] Both femoral sheaths were placed percutaneously with Seldinger technique. Anticoagulation was made with unfractionated heparin (5000 IU) after the insertion of the sheath. Reversal of heparin with protamine was not routinely used. Deployment of the suture at the onset of the procedure ensures needle penetration into the arterial wall, before the dilatation of arteriotomy with the sheath. The procedure began with the introduction of an 8F sheath via an 18G needle. The sheath was exchanged for a Prostar XL over a non-hydrophilic guidewire of 0.035 inch. The Prostar catheter was removed before endograft introduction for a dilatation catheter of 12F or 14F size. After usual deployment of the endograft, 14F sheath was removed over the extra-stiff 0.035 inch guidewire, while manually compressing the access site.

Longitudinal femoral incisions were used in group S patients. Bilateral femoral arteries were explored surgically after sterile draping. Silastic loops were placed around common (CFA) deep (AFP) and superficial (SFA) femoral arteries. 14F or larger sizes of sheaths were placed under direct vision and patients were anticoagulated with unfractionated heparin. Reversal of heparin with protamine was not routinely used. Arteriotomies were primarily repaired with 6/0 continuous prolene sutures. Small drainage tubes were placed in both femoral sites.

The patients were transferred to the cardiovascular surgery intensive care unit (ICU) after the procedure. Those operated with general anesthesia were extubated during the ICU stay. Blood transfusions were made, when hemoglobin level decreased ≥2 g/dL or ≥100 mL/hour drainage was present from the femoral drainage tubes. Revision surgery was utilized in the presence of an enlarged hematoma, persistent decrease in the hemoglobin levels, or presence of an imaging evidence for a pseudoaneurysm. Renal function was evaluated according to the urea and creatinine levels. Postoperative renal dysfunction was classified according to the Acute Kidney Injury Network (AKIN) criteria.[8,9]

Statistical analysis

Statistical analysis was performed using the NCSS (Number Cruncher Statistical System) 2007 Statistical Software (Utah, USA). Continuous variables were expressed in mean ± standard deviation, while categorical variables were presented in percentage. For comparison of continuous and discrete data, independent t test and chi-square test were used, respectively. A p value of 0.05 was considered statistically significant.

RESULTS

Demographic and perioperative data are summarized in Table 1. There was a statistically significant difference in the frequency of chronic obstructive pulmonary disease (COPD) between the groups, indicating a higher incidence in the percutaneous group (40.0% vs. 20.4%, p=0.031) (Table 1). On the other hand, there was not a statistically significant difference in the amount of postoperative blood transfusions between the groups. The EVAR procedure success was 100% in this patient population.

Prostar deployment failed in three cases (5.5%). Vascular repair with open surgery was necessary in 11 patients. The surgical procedures performed included thrombectomy (n=3), primary repair (n=8),

Table 1
Perioperative parameters

	Group S (n=49)			Group P (n=55)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Age (year)			67.6±7.0			66.6±9.6	0.530
Gender							
Male	39	79.6		37	67.3		0.157
Female	10	20.4		18	32.7		
Hypertension	36	73.4		37	67.3		0.490
Diabetes mellitus	19	38.8		22	40.0		0.899
Chronic renal dysfunction	4	8.2		8	14.6		0.309
Obesity	13	26.5		16	29.1		0.771
Chronic obstructive pulmonary disease	10	20.4		22	40.0		0.031
Ejection fraction <50%	8	16.3		15	27.3		0.179
Blood transfusion (unit)							
None	31	63.3		44	80.0		0.285
1	11	22.5		6	10.9		
2	6	12.2		4	7.3		
3	1	2.0		1	1.8		
Average transfusion (mL)			288.9±123.1			309.1±137.5	0.222

SD: Standard deviation.

arterial bypass (n=2) in group P (Table 2). One Prostar device was used in each patient in group P. Arterial dissection and distal embolization were not observed in any patient. Access site infection was observed more frequently in group S (Table 2). Although the absolute frequency of infection was relatively higher in group S, it yielded a borderline significant trend. Tables 3a and 3b show postoperative complications in the risk groups in detail. Diabetes did not pose any extra risk on the occurrence of postoperative complications. However, obesity was shown to be a significant risk factor for occurrence of complications. Hematoma was more frequent in obese patients in group P. Vascular repair was also significantly more frequent in group P and the difference was more pronounced in obese patients. The requirement for blood transfusions was not significantly different between the two groups (Table 1).

DISCUSSION

Conventional EVAR procedures are performed through the cut-down of both femoral arteries. Postoperative patient discomfort and surgical site infections are critical predictors of postoperative morbidity. Given the fact that these patients are more likely to have repeated transfemoral interventions, groin site cut-down may be risky for the further procedures.[10] Novel vascular closure devices may solve this problem and decrease postoperative morbidity during EVAR procedures.

The success rates of vascular closure devices are highly dependent on patient volume and selection.[11] Primary suspects of failure are obesity, femoral artery calcification, groin scarring and iliac artery tortuosity. The success rate of utilization of the Prostar closure device has been closely associated with the learning

Table 2
Postoperative complications

	Group S		Group P				
	n	%	n	%	*p*	OR	%95 CI
Hematoma	7	14.3	8	14.6	0.970	1.28	0.43-3.82
Infection	10	20.4	4	7.3	**0.047**	0.3	0.09-1.04
Vascular repair	0	0	11	20.0	**0.001**	20.67	1.18-61-39

OR: Odds ratio; CI: Confidence interval.

curve. Pozzi et al.[4] reported that the success rate increased from 80% in the first 50 cases to 98.8% in the following cases. In our series, the success rate was 80% showing consistency with reported series due to high failure in the learning curve.[4] On the contrary, McDonnell et al.[12] reported a success rate of 71% regardless of the level of experience.

In addition, Thomas et al.[1] reported 93.6% primary success and 10.3% major complication rates with Prostar XL in their series of 50 patients who underwent endovascular aortic and iliac procedures. Pseudoaneurysms were detected in 6.4% of the operated groins (five patients) in the first three months after the procedure and two of them healed conservatively. Manual compression for continuing bleeding was necessary in six patients (12.0%) and five patients (10.0%) required immediate surgical cut-down. The authors found that the difference of complication rates were not statistically significant in small and large profile systems. Inconsistent with these findings, Starnes et al.[13] reported higher complication rates using sheaths larger than 20F. However, we did not use such high profile systems in our patient population.

Furthermore, Eisenack et al.[14] analyzed the risk factors of procedure failure in 500 patients. They demonstrated that anterior calcification of femoral artery and fibrosis at the access site were possible predictors of failure and operator experience was a predictor for success. They found no correlation of obesity or sheath size with the success rate. In another study, although Starnes et al.[13] reported higher complication rates in morbid obese patients, they did not show any correlation of obesity with conversion to open repair. However, Teh et al.[15] reported a significant association between obesity and groin fibrosis and device failure. Similarly, in our series, obese patients had higher rates of complications and the difference was strongly marked for hematoma formation (Table 3b).

In general, the rate of general anesthesia is high in our EVAR experiences; however, surgical conversion is a serious complication for aortic procedures. To avoid possible complications, general anesthesia was preferred for primary cases. Of note, as the EVAR experience increased, the use of general anesthesia decreased.

Table 3
Postoperative complications according to the patient groups

(a)	DM (–)		DM (+)		
Diabetes	n	%	n	%	*p*
Hematoma					
Group S	5	16.7	2	10.5	0.550
Group P	4	12.1	4	18.2	0.532
Infection					
Group S	7	23.3	3	15.8	0.523
Group P	2	6.1	2	9.1	0.672
Vascular repair					
Group S	0	0	0	0	-
Group P	6	18.2	5	22.7	0.680
(b)	Obesity (–)		Obesity (+)		
Obesity	n	%	n	%	*p*
Hematoma					
Group S	6	16.7	1	7.7	0.428
Group P	0	0	8	50.0	0.0001
Infection					
Group S	8	22.2	2	15.4	0.600
Group P	1	2.6	3	18.8	0.036
Vascular repair					
Group S	0	0	0	0	-
Group P	4	10.3	7	43.8	0.005

DM: Diabetes mellitus.

To the best of our knowledge, only one study on the use of percutaneous systems which included seven patients is available in Turkey.[16] Although the authors reported their initial experience in the published paper; they failed to address the technique and device of vascular closure. Therefore, our report is the largest series of percutaneous experience in Turkey for the time being.

On the other hand, there are some limitations to our study. The primary limitation is the retrospective design of the study. The conclusions, therefore, were drawn more hesitantly. Second, the patients were not randomized in both groups; however, the preoperative data comparison did not show significant differences between the two groups. Third, anatomical analysis was not made in detail. However, the primary goal was to evaluate the outcomes in patients with various risk factors reported in the literature such as diabetes and obesity.

In conclusion, pre-close technique is a successful way of performing EVAR procedures. Inherent limitations such as open repairs may be challenging which can be solved with increasing experience. In addition, although wound infections are less common, obese patients show higher rates of complications with percutaneous technique. We believe that further studies are required to identify the optimal access technique in this patient population.

Declaration of conflicting interests

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