Turk Gogus Kalp Dama 2016;24(4):680-688
doi: 10.5606/tgkdc.dergisi.2016.12821

Original Article / Özgün Makale

A comparison of conventional surgery versus a vascular closure device for femoral artery repair following transcatheter aortic valve replacement

Transkateter aortik kapak implantasyonun sonrasında femoral arter tamiri için vasküler kapama cihazı ile konvansiyonel cerrahinin karşılaştırması

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ABSTRACT

Background: This study aims to compare the results of a percutaneous closure device versus conventional surgery for femoral artery access site closure during transcatheter aortic valve implantation.

Methods: Between June 2013 and September 2015, a total of 111 consecutive patients (56 males, 55 females; mean age 77.7±7.4 years; range, 52 to 95 years) who underwent transcatheter aortic valve implantation via transfemoral artery access were included in the study. Femoral artery access site was closed by a percutaneous closure device in 67 patients (60.4%) and by conventional surgery in 44 patients (39.6%). Safety and efficiency of both techniques were assessed in terms of the complications, re-interventions, and re-hospitalizations during the postoperative 30 days.

Results: Four patients (6%) experienced technical complications with the percutaneous closure device. A total of 53 (79.1%) patients in the percutaneous closure device group and 42 (95.5%) patients in the conventional surgery group achieved technical success without any need for re-intervention. A significantly higher number of percutaneous closure device patients experienced total vascular complications [22 (32.9%) vs 5 (11.4%); p=0.012] and needed secondary vascular interventions [12 (17.9%) vs 2 (4.6%); p=0.043], [emergency surgical intervention 2 (3%), percutaneous balloon angioplasty 12 (17.9%), and graft-stent implantation 7 (10.4%)], compared to the conventional surgery group. However, the rate of postprocedural wound complications, including lymphorrhea and infection, was higher [15 (34%) vs 6 (9%)] and the length of hospital stay was longer in conventional surgery group (4.7±1.2 vs 4.2±1.6 days; p=0.04).

Conclusion: Our study findings suggest that conventional surgery is more effective and safer than the percutaneous closure device for femoral artery access site closure during transcatheter aortic valve implantation procedures with a lower rate of periprocedural complications and re-interventions. In contrast, femoral artery access site closure by a percutaneous closure device seems to be associated with less postprocedural wound site complications than conventional surgery.

Keywords: Endovascular intervention; percutaneous closure; transcatheter aortic valve implantation; vascular complication.

ÖZ

Amaç: Bu çalışmada, transkateter aort kapak implantasyonunda femoral arter bölgesinin kapatılmasında perkütan kapama cihazı ile konvansiyonel cerrahi karşılaştırıldı.

Çalışma planı: Haziran 2013 - Eylül 2015 tarihleri arasında transfemoral arter girişinde transkateter aort kapak implantasyonu uygulanan toplam 111 ardışık hasta (56 erkek, 55 kadın; ort. yaş: 77.7±7.4 yıl; dağılım, 52-95 yıl) çalışmaya alındı. Femoral arter giriş bölgesi, 67 hastada (%60.4) bir perkütan kapama cihazı, 44 hastada (%39.6) konvansiyonel cerrahi ile kapatıldı. Her iki tekniğin güvenliliği ve etkinliği ameliyat sonrası 30 gün süresince komplikasyonlar, girişim tekrarı ve yeniden hastaneye yatış açısından değerlendirildi.

Bulgular: Dört hastada (%6) perkütan kapama cihazına bağlı teknik sorunlar yaşandı. Girişim tekrarına gereksinim olmaksızın, perkütan kapama cihazı grubunda hastaların toplam 53 (%79.1)'ünde ve konvansiyonel cerrahi grubunda hastaların 42 (%95.5)'sinde teknik başarı elde edildi. Konvansiyonel cerrahi grubuna kıyasla, anlamlı düzeyde daha yüksek sayıda perkütan kapama cihazı hastasında vasküler komplikasyonlar görüldü [22 (%32.9)'e karşı 5 (%11.4); p=0.012] ve bu hastalarda ikincil vasküler girişim [12 (%17.9)'e karşı 2 (%4.6); p=0.043] [acil cerrahi girişim 2 (%3), perkütan balon anjiyoplasti 12 (%17.9) ve greft-stent implantasyonu 7 (%10.4)] gerekti. Bununla birlikte, konvansiyonel cerrahi grubunda lenfore ve enfeksiyon dahil olmak üzere, işlem sonrası yara komplikasyonu oranı daha yüksek [15 (%34)'e 6 (%9)] ve hastanede yatış süresi daha uzundu (4.7±1.2'e 4.2±1.6 gün; p=0.04).

Sonuç: Çalışma bulgularımız, daha düşük işlem sırası komplikasyon ve yeniden girişim oranları ile transkateter aort kapak implantasyonu işlemleri sırasında femoral arter giriş bölgesinin kapatılmasında perkütan kapama cihazına kıyasla konvansiyonel cerrahinin daha etkili ve güvenli olduğunu gösterdi. Buna karşın, femoral arter girişim bölgesinin bir perkütan kapama cihazı ile kapatılması, konvansiyonel cerrahiye kıyasla, daha az işlem sonrası yara bölgesi komplikasyonları ile ilişkili görünmektedir.

Anahtar sözcükler: Endovasküler girişim; perkütan kapatma; transkateter aort kapak implantasyonu, vasküler komplikasyon.

Available online at
www.tgkdc.dergisi.org
doi: 10.5606/tgkdc.dergisi.2016.12821
QR (Quick Response) Code

Received: December 27, 2015 *Accepted:* April 05, 2016

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As catheter-based endovascular approaches have increased, the transcatheter aortic valve implantation (TAVI) procedure has become more widespread. The common femoral artery is often used as a catheter access region in the TAVI procedure. In recent years, percutaneous closure devices (PCD) have been increasingly used to close the arterial access site.[1-4]

Currently, PCDs developed for percutaneous approaches work with a system known as 'preclose', which is used to close the percutaneous catheter puncture sites with a diameter of ≥10 French.[5] Within this system, a catheter of 10F diameter is first used, and, then, the entry hole of this catheter is dilated for wider catheters. Around these catheters, there are two cross-over sutures and there are four needles at the end of these sutures. During the procedure, these needles pull on the vessel, and, then, the needles are pulled out, piercing the artery around the puncture site. In this way, the ends of the two sutures which pass diagonally across the puncture sites are drawn outside the arterial wall.[6] With the percutaneous approach, smaller surgical wounds, quicker patient mobilization and a shorter in hospital stay are predicted, compared to the surgical preparation.[7] The surgical preparation for endovascular approaches by catheter from the groin carries risks such as bleeding, lymphorrhea, infection of the wound site, and prolonged hospital stay.[5-7] When the procedure with a PCD fails, arterial injury, dissection, bleeding, thrombosis, pseudoaneurysms, and late pseudoaneurysms may develop, thereby, bearing a need for additional intravascular catheter interventions or surgical interventions.[8-10] In our clinic, both conventional surgery (CS) and percutaneous approaches are used in TAVI procedures. In the percutaneous approach, a Prostar® XL PCD (Prostar XL Percutaneous Vascular Surgical Device, Perclose ProGlide Suture-Mediated Closure System, Abbott Vascular, Santa Clara, CA, USA) is used.

In this study, we aimed to compare the results of a PCD versus CS for femoral artery access site closure during TAVI.

PATIENTS AND METHODS

This retrospective, observational, single-center study included a total of 111 patients (56 males, 55 females; mean age 77.7±7.4 years; range, 52 to 95 years) who underwent TAVI between June 2013 and September 2015. Patients who were ineligible for an iliofemoral artery system catheter approach, patients who intraoperatively died due to aortic root rupture, dislocation of the prosthetic valve into the ventricle, and myocardial infarction, and those with an anterior wall or circumferential calcification in the femoral artery which would hinder performance of the approach by PCD, as assessed by Doppler ultrasound (DUS) and computed tomography (CT) angiography were excluded. Of the patients, 67 were operated with the Prostar® XL 10F PCD and 44 underwent CS.

The study protocol was approved by the Clinical Research Ethics Committee of Sifa University, Faculty of Medicine No: 311-82). The study was conducted in accordance with the principles of the Declaration of Helsinki.

All procedures were performed under general anesthesia. The aortic valve region and the annulus diameter were measured by CT angiography, which allowed the determination of the valve size to be implanted. The common femoral artery and iliofemoral artery diameters were measured in millimeter from the inner wall to the inner wall by CT angiography.

In patients who were scheduled for TAVI through the femoral route, the degree of arterial wall calcification was measured by DUS and defined as a percentage of the total wall circumference. All patients were divided into three categories: Grade 1 (non or less than 25%), grade 2 (25 to 50% without an anterior wall), and grade 3 (more than 50% without an anterior wall). The patients with more than 25% anterior wall or circumferential femoral artery calcifications in the CS group were excluded from the study.

Following a skin incision, the patients were prepared for surgery, the cutaneous and subcutaneous tissues were divided to leave lymphatic structures medially, and the main, surface, and deep femoral arteries were identified. Intravenous 100 IU/kg heparin was given. The activated clotting time (ACT) was kept at 200 to 250 sec. Arteriotomy was performed on the main femoral artery and the catheters needed for the TAVI procedure were positioned. Meanwhile, snare was applied with a 5 mm tape to prevent bleeding from the proximal end of the femoral artery. The distal femoral artery and the deep femoral artery were closed with cross-clamps. At the end of the procedure, the clamps were removed and arteriotomy was closed with 5/0 prolene sutures. A Penrose drain was inserted. At the end of the procedure, heparin was neutralized with protamine.

For the Prostar® procedure, arterial access was achieved with an 18-gauge needle by ultrasound guiding, and, then, an 8 F sheath implantation was performed. A guide wire was implanted and the 8F sheath was replaced with a 10 F Prostar® sheath. After ensuring that the needles holding the threads were located in the

artery walls, the threads were stabilized, until the end of the procedure. Subsequently, 18-22 F sheaths were implanted on the guide wire for the TAVI procedure. At the end of the TAVI procedure, the ends of the threads were knotted consistent with the technique.[5] At the end of the procedure, local pressure was applied, until heparin was neutralized by the protamine. In all patients, an Edwards Sapien XT balloon-expandable valve was implanted. Technical success was defined as the completion of procedure, irrespective of the technique used (i.e., CS or PCD) without periprocedural complications and achievement of hemostasis.

Technical failure necessitating percutaneous re-intervention or open surgery and vascular injury or bleeding while still in the operation room were defined as the periprocedural complications. Complications including bleeding, hematomas, pseudoaneurysms, infections, or lymphorrhea after the procedure were completed and the patient was taken to the intensive care unit referred to the postprocedural complications.

Vascular complications were evaluated according to the classification of the Valve Academic Research Consortium (VARC)-2.[11] The VARC is a guideline to score the risk in the selection of patients for TAVI. According to the guideline, any vascular or interventional complication necessitating unplanned endovascular stent or surgical intervention (i.e., dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, hematoma, or percutaneous closure device failure) is defined as a vascular complication. In this regard, vascular complications in our study which were life-threatening or could cause disability or the loss of an extremity were classified as the major vascular complications, while, those which were not life-threatening were classified as the minor vascular complications.

Furthermore, bleeding-related complications were evaluated according to the classifications in the VARC-2 guideline as major and minor bleeding.[11] In general, bleeding requiring surgical intervention or which causes a fall in the hemoglobin level of at least 3.0 g/dL, or which necessitates the transfusion of two or more units is defined as major bleeding. On the other hand, bleeding which is not clinically severe at the intervention site, which does not threaten life, and which can be managed by local pressure and bandaging is defined as minor bleeding.[11]

All complications at the femoral artery intervention site 30 days postoperatively were recorded. The wound infections were erythema or an increased heat at the intervention site and exudative flow.

With daily systemic examination, the femoral intervention site and abdomen were examined and the intervention site was monitored for lymphatic leakage. In case of more than two days, lymphorrhea with complications was considered. Hematocrit level monitoring was performed on a daily basis. Before discharge from hospital, DUS was performed at the intervention site to check for possible pseudoaneurysms or arterial flow problems. The surgical procedure was performed by experienced cardiovascular surgeons, whereas the PCD procedure was carried out by experienced invasive cardiologists.

Preoperatively, all patients were given intravenous 1 g sulbactam + 1 g cefoperazone as prophylaxis. Twenty four hours before the procedure, they were also given oral 300 mg clopidogrel and 100 mg acetylsalicylic acid.

Statistical analysis

Statistical analysis was performed using SPSS 12.0 version statistical software (SPSS Inc., Chicago, IL USA). Variables in the study were calculated for normal distribution by the Kolmogorov-Smirnov test. Normally distributed continuous variables were analyzed using t-test. Abnormally distributed continuous variables were analyzed using the Mann-Whitney U test. The Fisher's exact test was used to compare categorical variables. A p value of <0.05 was considered statistically significant.

RESULTS

Of the patients undergoing PCD procedure and CS, 53 patients (79.1%) and 42 patients (95.5%) achieved technical success without re-intervention.

Four of the patients included in the study died on postoperative day 22±6 from pneumonia, sepsis, or severe COPD.

Baseline demographic and clinical characteristics of the patients including age, gender, and cardiac parameters, risk factors (STS and EuroSCORE II), femoral artery calcification levels, and the sizes of sheath used were similar in both patient groups (Table 1).

However, four PCD patients experienced technical problems with the devices. In two of these, one of the two sutures integrated into the PCD broke off, while pulling out of the device. In one of these patients, hemostasis was achieved with a single suture, while urgent surgical intervention was needed due to bleeding in the other patient. In the remaining two patients, one of the four needles on the PCD became bent, and it was difficult to retrieve it from the tunnel. Nevertheless, it was possible to tie knots, and no complications developed.

Table 1. Demographic parameters and risk factors of the patients

	CS			PCD			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Number of patients	44	40		67	60		
Age (years)			79.5±5.4			76.9±8.2	0.065
Female	22	50.0		34	50.7		0.225
Risk factors							
STS score			11.6±5.3			11.8±7.1	0.912
Logistic EuroSCORE II			30.5±11.5			33.9±11.3	0.329
Ejection fraction			44.8±10.3			40.7±11.1	0.079
Mean aortic gradient (mmHg)			47.4±8.9			50.9±11.4	0.116
Aortic valve area (cm^2)			0.6±0.1			0.6±0.1	0.195
Aortic annulus (mm^2)			22.1±1.6			21.9±1.9	0.532
Maximum annulus computed tomography (mm)			26.5±3.8			27.0±2.7	0.711
Minimum annulus computed tomography (mm)			22.2±2.5			21.9±2.5	0.243
RCF minimum diameter (mm)			7.2±1.3			7.7±1.0	0.036
Left common femoral minimum diameter (mm)			7.1±1.3			7.4±0.9	0.310
18 F sheath	23	52.3		34	50.7		0.515
20 F sheath	15	34.1		28	41.8		0.250
22 F sheath	6	13.6		5	7.5		0.228
Femoral artery calcification							
Grade 1	36	81.8		61	91.5		0.29
Grade 2	4	9.1		4	6		
Grade 3	4	9.1		2	3		
Diabetes mellitus	11	27.5		21	28.4		1.000
Hypertension	27	61.4		39	58.2		0.448
Renal insufficiency (Crea >2 mg/dL)	10	23.8		15	24.6		0.560
Chronic obstructive pulmonary disease	21	52.5		47	63.5		0.173
Obesity (BMI ≥30.0)	2	4.5		2	3		0.648
Previous CABG	7	15.9		7	10.4		0.286
Percutaneous coronary intervention	6	13.6		14	20.9		0.238
Access site							
Right common femoral artery	40	44.0		51	56.0		0.212
Left common femoral artery	2	4.8		10	16.4		0.043

CS: Conventional surgery; PCD: Percutaneous closure devices; SD: Standard deviation; STS: Society of thoracic surgeons; RCF: Right common femoral artery; BMI: Body mass index; CABG; Coronary artery bypass surgery.

Table 2 reveals that in the stepwise backward multi regression analyses of all patients with complications (without distinguishing groups), the use of a vascular closure device, grade 3 femoral artery calcification, and an increase in sheath size were predictive variables for the development of ilio-femoral vascular complications. However, there were no any significant differences between PCD and CST groups in terms of complications and the femoral artery diameters, calcification levels and sheath sizes.

Periprocedural complications

In the PCD group, major vascular complications occurred in three patients (4.5%) and minor vascular complications in 19 patients (28.4%). Major complications included intimal dissection + intimal flap in one case (in the external iliac artery) and bleeding in two cases. The case of intimal dissection was treated performing percutaneous balloon angioplasty by the contralateral femoral entry, while the other two cases of bleeding (3%) underwent urgent open surgical repair (Figure 1).

Eight of 19 patients who developed minor vascular complications had local small intimal dissections in the access point; however, no intervention was needed. In the other 11 patients (16.4%), intimal dissection occurred in the access point (n=8) and external iliac artery (n=3), treated by percutaneous balloon angioplasty. In seven of these, graft-stent implantation was additionally performed.

For major and minor complications in the PCD group, percutaneous angioplasty was performed on 12 patients (17.9%), urgent surgical intervention

Table 2. Multivariate Hazard ratios for periprocedural vascular complications of all patients (n=111)

	Univariate analysis			Multivariate analysis		
	OR	95% CI	*p*	OR	95% CI	*p*
Femoral artery calcification grade 3	8.8	2.6-21.2	<0.001	4.2	1.9-7.8	0.026
Minimum ilio-femoral artery diameter	2.1	0.9-4.1	0.038	0.9	0.4-1.1	0.164
Aortic annulus	0.8	0.5-1.1	0.564	-	-	-
Vascular closure device	3.2	1.6-7.0	0.002	1.8	0.9-3.2	0.045
Aortic calcification	1.0	0.8-1,2	0.246	-	-	
Obesity (BMI >30)	1.1	0.6-1.5	0.128	-	-	
Sheath size	9.2	3.2-16.4	<0.001	4.3	1.8-8.3	0.018
Coronary artery disease	0.8	0.5-1.0	0.345	-	-	
Diabetes mellitus	1.4	0.7-2.2	0.096	0.9	0.5-1.4	0.204
Society of thoracic surgeons score	1.2	0.8-1.7	0.298	-	-	

BMI: Body mass index; OR: Odds ratio; CI: Confidence interval.

on two (3%), and graft-stent implantation on seven (10.4%) patients (Table 3, Figure 1).

In the CS group, no major vascular complications were seen, while minor vascular complications developed in five patients (11.4%). These were intimal dissections in the common femoral artery (n=2) and external iliac artery (n=3), as the sheath induced damage to the arterial wall. The dissections diagnosed using contralateral angiography. In three of these patients, no intervention was performed, as the intimal dissection was minimal. However, in two patients with external iliac arteries (4.6%), percutaneous balloon angioplasty was performed.

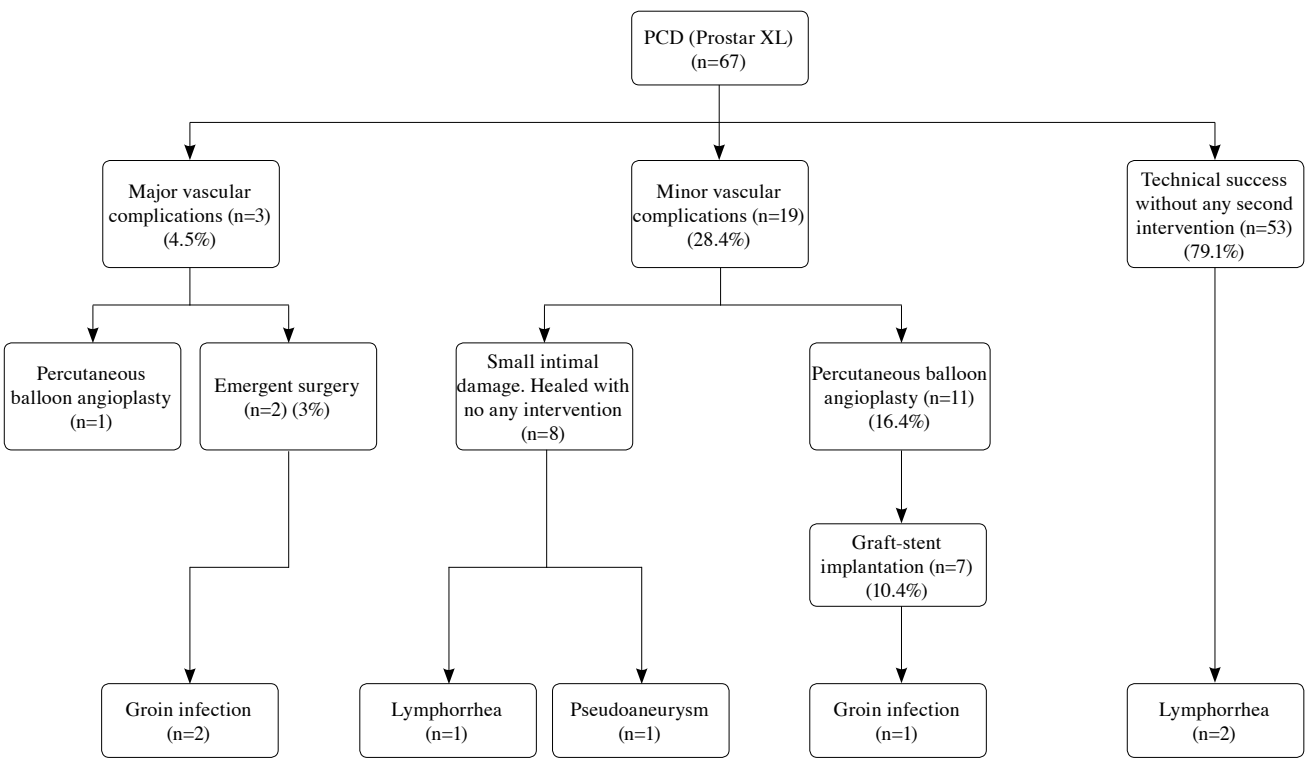

Figure 1. The diagram of percutaneous vascular closure device application results.

PCD: Percutaneous vascular closure device.

Table 3. Comparision of peri- and postprocedural complications of conventional surgical technique and percutaneous closure devices groups

	CS (n=44)			PCD (n=67)			
	n	%	Mean±SD	n	%	Mean±SD	*p*
Hemoglobin (pre-opration)			11.6±1.8			11.7±1.7	0.925
Hemoglobin (post-operation)			10.7±1.3			10.6±1.6	0.824
Hemoglobin loss, (mg/dL)			0.93±0.37			1.12±0.43	0.455
Blood transfusion	13	31.0		15	24.6		0.311
Intensive care unit stay (days)			1.6±0.6			1.4±0.9	0.155
In-hospital stay (days)			4.7±1.2			4.2±1.6	0.048
Peri-procedural complications							
Technical error with device	0	0		4	6		
Major vascular complication	0	0		3	4.5		0.275
Minor vascular complication	5	11.4		19	28.4		0.036
Total vascular complication	5	11.4		22	32.9		0.012
Percutaneous intervention	2	4.6		12	17.9		0.043
Graft stent implantation	0	0		7	10.4		0.040
Major bleeding	4	9.1		11	16.4		0.396
Postprocedural complications							
Lymphorrhea	8	18.2		3	4.5		0.045
Femoral infection	7	16.0		3	4.5		0.049
Pseudoaneurysm	0	0		1	1.5		1.000
Minor bleeding	11	25.0		15	22.4		0.820
Re-hospitalization because of access site wound complications	6	13.6		2	3.0		0.563

CS: Conventional surgery; PCD: Percutaneous closure devices; SD: Standard deviation.

As a result, a significantly higher number of PCD patients experienced total vascular complications (p=0.012) and needed secondary vascular interventions (p=0.043) [emergency surgical intervention (3%), percutaneous balloon angioplasty (17.9%), and graft-stent implantation (10.4%)], compared to the CS group (Table 3).

On the other hand, there was no significant difference in the femoral artery diameters, calcification levels, and sheath sizes between the PCD and CS patients. In addition, none of the patients had embolism or thrombosis.

Postprocedural complications

In the PCD patients, postprocedural wound complications developed in seven patients (10.4%). This was in the form of femoral access site infection in three patients, lymphorrhea in three patients, and a late pseudoaneurysm in one patient. Two patients who developed infection were those who underwent urgent surgical repair for major vascular complications. The other patient underwent graft-stent implantation for minor vascular complications. One of the three patients who developed lymphorrhea and the patient who developed a pseudoaneurysm were later re-hospitalized for surgery (Figure 1).

In the CS patients, wound complications developed in 15 patients (34.1%). These included femoral access site infection in seven patients, and lymphorrhea in eight patients. Four of these patients who developed wound complications were re-hospitalized for lymphocele, and two for the wound site infection (Figure 2).

There was also a significant difference in the postprocedural complications (p=0.04) and length of hospital stay (p=0.04) between the PCD and CS patients. The mean length of hospital stay was 4.7±1.2 days for the CS group and 4.2±1.6 days for the PCD group (p=0.048). The re-hospitalization rate relating to the wound complications at the access site was 3% (n=2) in the PCD group and 13.6% (n=6) in the CS group (Table 3).

In addition, the rate of loss of hemoglobin compared to baseline was measured as 0.9±0.4 mg/dL in the CS group and 1.1±0.4 mg/dL in the PCD group.

DISCUSSION

Our study results showed that CS was more effective than PCD with lower periprocedural complications and vascular re-interventions. In addition, the rate of percutaneous angioplasty and the use of graft-stent for

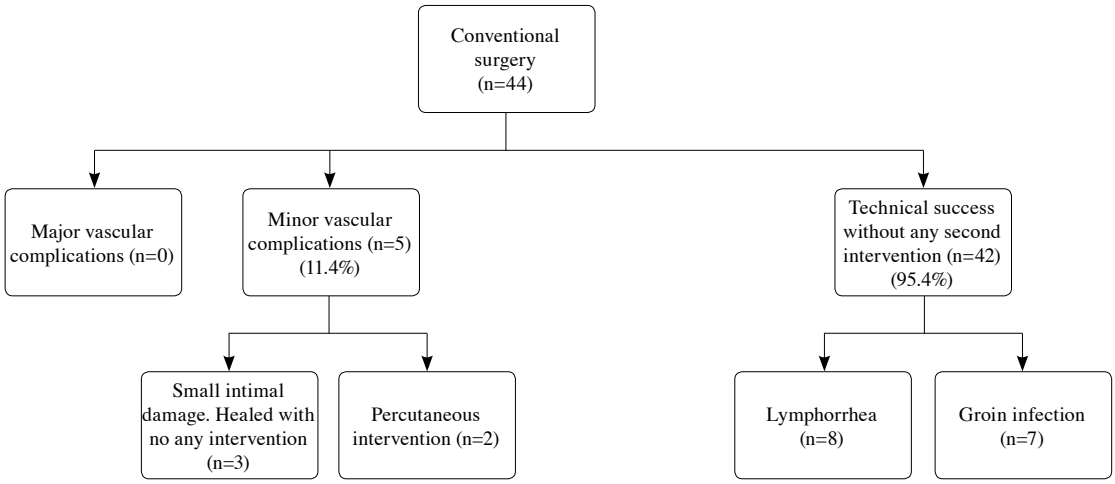

Figure 2. The diagram of conventional surgery results.

major and minor complications in PCD patients were significantly higher than for CS patients. However, the postprocedural wound complications were significantly fewer in the PCD group than CS group.

Using a catheter smaller than 8 F, bleeding can generally be stopped by primary pressure. In spite of this, many vascular closure devices have been developed to reduce possible complications.[12] However, depending on the type of device to be implanted, the diameter of catheters and sheaths used for endovascular aneurysm repair (EVAR) thoracic endovascular aneurysm repair (TEVAR), and TAVI procedures particularly makes it virtually impossible to control bleeding by primary compression.[13] Currently, PCDs developed to close the holes of large-diameter sheaths (>10 F) promise the possibility of less invasive intervention than surgical preparation.[1,6,14-16] They also offer the advantages of shorter operation time, earlier patient mobilization, and earlier discharge.[7]

The success rate with PCDs ranges between 71.4 and 96%.[5,14-19] It corresponds to a failure rate for PCDs of between 4 and 28%. In a multicenter study, major vascular complications or in-hospital mortality rate were reported to be 9.5% with Prostar.[20]

On the other hand, the main reasons for failure are obesity, calcific femoral arteries, and tortuosity in iliac arteries.[2,7,8,21,22] The main complications include bleeding, dissection, thrombosis and lack of technical success.[1,6,8,10,16] In our study, technical success rate were 79.1% for PCD group and 95.5% for CS group.

Several meta-analyses reported that complication rates for PCD were similar to those for CS.[7,12] In our study, the rate of major and minor complications seen in the PCD group was significantly higher than CS group. For the treatment of these complications, percutaneous angioplasty was performed on 12 patients (17.9%), emergency surgical intervention on two patients (3%), and graft-stent implantation on seven patients (10.4%) (Table 3).

Furthermore, the rate of femoral artery complications and conversion to open surgery due to the technical failure in PCD was reported to be higher in calcific arteries.[21,22] In addition, the need for urgent open surgery can still arise, due to technical problems relating to PCD or uncontrolled bleeding. In their study, Teh et al.[6] reported this rate as 13.4%. In the present study, the patients with severe femoral artery calcifications who were referred to CS were excluded from the study. According to our results, the rate of urgent open surgery was %3 in PCD group. In particular, patients who underwent urgent surgery due to unsuccessful PCD suffered more postprocedural wound-related complications, such as infection and lymphorrhea than elective CS patients (Figure 1).

In a systematic study, the use of PCD in EVAR procedures caused less access site problems than open surgical repair.[2] The complication rate was higher in obese patients, particularly. Similarly, the rates of femoral access site wound infection and lymphorrhea were significantly higher in CS patients than in PCD patients in our study. However, no predictor was able to be identified to show the difference between the groups.

In the literature, there are few comprehensive studies comparing PCD and CS in terms of length of hospital stay. Although these studies usually found no difference

between the patient groups, some authors reported that the length of hospital stay was shorter among the PCD patients.[7] Consistent with these findings, the length of hospital stay was significantly longer for CS group, compared to PCD group (p=0.048) due to wound site complications. The main reasons relating to the wound site complications for prolonged hospital stay and re-hospitalization were lymphorrhea and wound site infection.

In the present study, although the re-hospitalization rates relating to access complications were similar in both groups, the rate in the CS group was higher than PCD group. The main causes for wound-related re-hospitalization were lymphorrhea, lymphocele, and wound site infections.

In addition, both groups were similar in terms of bleeding and blood transfusion rates. The main reason for loss of blood was leakage from around the guide wire, as it moved forward from inside the sheath. There was a need for blood transfusion in both groups (CS 31%, PCD 24%), due to the loss of blood. Although it was similar between the groups, this is a considerably high rate. It can be attributed to the length of the procedure. In our first TAVI patients, the longer the procedure took, the greater the amount of bleeding from around the guide wire inside the sheath. However, as the team gained technical experience and the procedure was completed in a shorter time, further cases had less need for blood transfusions.

From the point of view of periprocedural and postprocedural complications, there were statistically significant differences between PCD and CS groups. In PCD group, the rates of total vascular complications, percutaneous angioplasty, and graft-stent implantation were significantly higher. In addition, major vascular complications were slightly more in PCD group. In contrast, the rate of postprocedural complications was significantly higher in the CS group. Although the rates of re-hospitalization due to the wound site complications were similar, they were found to be higher in the CS group.

We used Single Prostar® device for PCD in our center. However, Saleh et al.[23] reported that double Prostar® is more effective than single device with higher technical success and lower vascular complications. On the other hand, although we do not have an experience on double Prostar®, we believe that more sophisticated devices can yield improved results.

Nonetheless, there are some limitations to this study. First, this is a retrospective single-center experience with a limited number of patients.

Second, due to only one type of percutaneous device (Prostar®) used, the results cannot be generalized to all patient populations and percutaneous catheter trademarks. In addition, femoral calcification levels were classified by bedside DUS, but not by CT angiography. Finally, the access site complications such as lymphorrhea and infection were evaluated by clinical examinations, but not using laboratory studies. Therefore, no attempt was made to quantify the infection.

In conclusion, our study results suggest that, although percutaneous closure devices have the advantages of being less invasive procedures with a shorter hospital stay, conventional surgery is a more effective and safer method for femoral artery access site closure during transcatheter aortic valve implantation with a lower rate of periprocedural complications and re-interventions.

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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