

A case of transcatheter aortic valve implantation complication with total femoral artery thrombosis due to failure of the ProStar device

ProStar cihazı başarısızlığı nedeniyle femoral arterin trombüs ile tam tıkanmasıyla komplike olan transkateter aortik kapak yerleştirilmesi olgusu

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Summary– Vascular complications in transfemoral transcatheter aortic valve implantation are relatively frequent and there is increased morbidity and mortality risk in the procedure. This report presents successful surgical repair of a femoral artery thrombosis case following an implantation procedure.

Özet– Transfemoral transkateter aort kapak yerleştirilmesinde vasküler komplikasyonlar sık görülür ve bu durum işlemin morbidite ve mortalite riskini artırır. Bu yazıda femoral arter trombozu gelişip yerleştirme işlemi yapılan ve cerrahi olarak başarılı bir şekilde tedavi edilen bir olgu sunuldu.

Transcatheter aortic valve implantation (TAVI) has emerged as a recommended therapeutic option for those patients with severe symptomatic aortic stenosis ineligible for conventional surgical aortic valve replacement.^[1,2] Vascular complications are among the most frequent and serious complications of transfemoral TAVI, and have been associated with significantly increased patient morbidity and mortality.^[3]

CASE REPORT

A 61-year-old man, diagnosed 2 years earlier with degenerative aortic stenosis, presented with a one-year history of increasingly labored breathing and edema in the legs. He had undergone coronary artery bypass surgery 9 years previously. Transthoracic echocardiography (TTE) revealed severe aortic stenosis (mean gradient; 40 mmHg), mild aortic regurgitation, and a left ventricular ejection fraction (LVEF) of 0.55. The patient's Society of Thoracic Surgeons (STS) risk score was 11% and he was at high risk for surgery. Because of these comorbid conditions, it was decided to perform TAVI. Transesophageal echocardiography (TEE) showed aortic annulus size as 25 mm. Periph-

eral angiograms showed no tortuosity or calcification of the iliofemoral arteries (Figure 1a), but revealed severe cal-

cium deposits on the leaflets. The patient was 168 cm in height and weighed 80 kg. The sheath outer diameter/femoral artery ratio (SFAR) was 0.84. Coronary angiography revealed no significant atherosclerotic lesion and patent by-pass grafts.

Deep sedation was administered with an anesthetic in the catheter laboratory. Right common femoral artery perpendicular cannulation to the geometrical middle line of the vessel was performed to position the Prostar XL device. The vessel was then predilated using an 18F cannula. Initially, in the absence of pulsatile blood flow when placing the Prostar device, tissue around the common femoral artery was explored to provide comfortable access. In this way, the Prostar device could be made to reach the vessel and be placed. Using TTE guidance and rapid tem-

Abbreviations:

TAVI	Transcatheter aortic valve implantation
TTE	Transthoracic echocardiography
SFAR	Sheath outer diameter/ Femoral artery ratio
STS	Society of Thoracic Surgeons
VARC	Valve Academic Research Consortium

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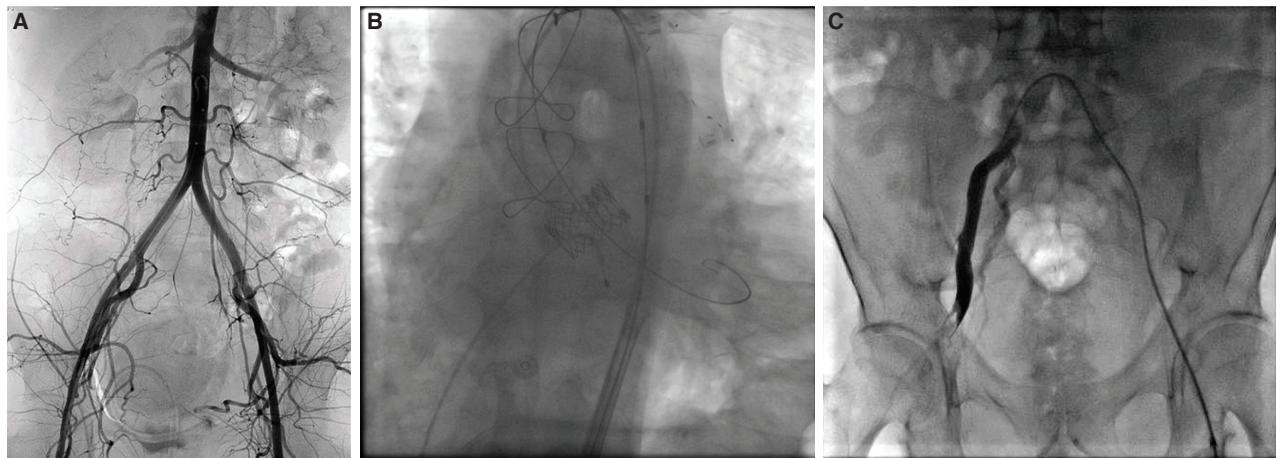


Figure 1. (A) Peripheral angiograms showed absence of tortuosity or calcification of iliofemoral arteries. (B) Arcus aortography following aortic valve implantation demonstrating the aortic arch and valve and no aortic regurgitation. (C) Peripheral angiography following TAVI showing thrombus formation on the right ilio-femoral artery after protamine administration and manual compression.

porary pacing, we performed an aortic balloon valvuloplasty and transfemoral implantation of a 26-mm Edwards Sapien XT Transcatheter Heart Valve (Edwards Lifesciences Corporation; Irvine, Calif). Afterwards, TTE showed appropriate positioning of the prosthetic valve, no paravalvular aortic regurgitation, and a mean gradient of 9 mmHg. Aortic arch angiograms under fluoroscopic guidance showed patency of the right and left coronary arteries nonselectively, and no aortic regurgitation (Figure 1b, Video 1*). Following valve implantation, a ProStar XL® Percutaneous Vascular Surgical System (Abbott Vascular, unit of Abbott Laboratories; Redwood City, Calif) was used to close the right common femoral artery percu-

taneously. However, despite the closure, the ProStar device at this stage showed continued pulsatile bleeding. Because of this ProStar failure, manual compression was applied for approximately 10 minutes, and 5000 units of protamine administered intravenously due to ongoing pulsatile bleeding. Control angiography was performed right common femoral artery thrombus formation was observed (Figure 1c, Video 2*). Several unsuccessful attempts were made to pass the thrombotic lesion in the right femoral artery using a 0.035-inch hydrophilic wire making the crossover through the opposite femoral artery. This failure suggested dissection as well as vascular thrombosis and it was decided to treat the patient surgically. The thrombus was removed from the femoral artery and tearing in the vessel wall repaired (Figure 2) following which flow was restored. The patient was discharged 5 days later with no complications.

DISCUSSION

Transcatheter aortic valve implantation has emerged as a new therapy for patients with severe aortic stenosis who are inoperable or very high risk for open heart surgery. Vascular complications remain a principal limitation of TAVI as they may result in life-threatening bleeding and hemodynamic compromise among patients considered high risk for the procedure itself.

Sari et al.^[4] reported that vascular complications occurred in 10.1% of patients. There was negative



Figure 2. Thrombus material removed from the common femoral artery during surgery.

correlation between vascular complications and diameter of the common femoral artery, external iliac artery, and common iliac artery, but positive correlation between diabetes mellitus, SFAR, sheath to external iliac artery ratio (SEIAR), procedure time, discharge time and STS score.^[4] Hayashida et al.^[5] reported that Valve Academic Research Consortium (VARC) major vascular complications were associated with a 3-fold increase in the relative risk of death.^[5]

Transfemoral TAVI represents the most widely used and least invasive approach. Initially, surgical arteriotomy was required for femoral artery access and closure. Among the disadvantages of this technique were the necessity for general or spinal anesthesia, prolonged procedure duration, and increased post-procedure morbidity.^[6] More recently, a true percutaneous approach to transfemoral TAVI using the Prostar vascular closure system (Abbott Vascular, Santa Clara, California) has been performed. In an 18-center study comprising 402 patients, Bernardi et al.^[7] compared the surgical cut down and percutaneous approaches for TAVI implantation. The incidence of combined adverse events was the same in the percutaneous and the surgical group at 30 days and 1 year. Total percutaneous techniques or surgical cutdown and closure may provide similar safety and effectiveness during the first year of follow-up in patients undergoing transfemoral TAVI.

Vascular access and successful closure remain important issues in TAVI. The Prostar device has important limitations; potential for femoral artery stenosis or occlusion, puncture difficulty in heavily calcified vessels, and a single device length that may result in increased failure in obese patients. The most important factor may be quality of the femoral arterial puncture: common femoral artery, avoiding calcified plaques, and in the center of the artery. All these parameters are related to the experience of the operator. Further improvements in patient outcome will be allied to optimal screening, sheath downsizing, and the development of newer, operator-friendly, vascular closure systems.

The ProStar device require experience, and there is a significant learning curve. With experience, it should be possible to achieve a success rate >90%.^[8] The study show a Prostar success rate of 90.7%, and VARC major and minor vascular complications in 8.6% and 11.4% of patients respectively. Also a

predictor of Prostar failure is SFAR.^[8] This, combined with experience, and femoral artery calcification are shown as independent predictors for vascular complications by multivariate analysis.^[5]

Pre-operative evaluation of the vascular access site aims to define vessel size, tortuosity, and extent of calcification in order to identify the best vascular access site and minimize the risk of complications. Nevertheless, vascular injury and access site complications remain the most frequent adverse event, occurring in 12% to 30% of cases.^[9] These complications may give rise to life-threatening bleeding, and require surgical or interventional treatment in most cases. A true percutaneous procedure, if performed appropriately, has the potential to reduce the requirement for general or spinal anesthesia, shorten procedure duration, reduce the risk of wound infections, and shorten both post-operative patient immobilization and discomfort, and hospital stay.^[6]

Management of vascular complications are at the operator's discretion. Most often, iliofemoral dissections or stenoses are treated with conventional balloon angioplasty or, if necessary, balloon-expandable or self-expandable stents. Small iliofemoral perforations, insufficiently managed with manual compression or balloon angioplasty, are treated with covered stents, and vessel ruptures managed emergently with temporary balloon angioplasty and covered stents, or emergency surgery if percutaneous therapy fails. Vascular complications after TAVI can be treated percutaneously as a bailout procedure with a high rate of technical success, and clinical outcomes are comparable to patients without vascular complications.^[10] In our case, our relatively limited experience with Prostar and the complications likely to be accompanied by thrombosis as well as dissection may explain why we were unsuccessful in resolving the complications using the percutaneous method. It is not clear whether the dissection occurred during placement of the Prostar device or in the attempt to place the wire in the thrombus.

Thrombosis can occur after hemostasis; for example, after crossover balloon-inflation, manual compression, and protamine administration. These patients may be treated with surgical revascularization or balloon angioplasty, but there is a risk of distal thromboembolization resulting in reduced perfusion of the limb.^[11] Heparin effect reversal with protamine

may be helpful if there is persistent oozing, but this is rarely necessary and may increase the risk of femoral artery thrombosis, particularly when femoral compression is also used.^[12] In the case presented, the authors believe that the manual compression and application of protamine as a result persistent pulsatile bleeding due to failure of the ProStar device were the cause of the femoral artery thrombosis.

Vascular complications remain the principal limitation of TAVI. Therefore, in TAVI procedures, pre-procedural detailed evaluation of the vascular anatomy and choice of appropriate vascular path are of vital importance in reducing the risk of vascular complications. Moreover, in the event of vascular complications, morbidity and mortality are reduced in the presence of both experienced operators who can treat the complication using percutaneous methods, and vascular surgeons experienced in complications.

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***Supplementary video files associated with this article can be found in the online version of the journal.**

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