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Novel Use of an Apical-Femoral Wire Rail to Assist With Transfemoral Transcatheter Aortic Valve Replacement

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Abstract

The inability to reposition or retrieve balloon-expandable transcatheter aortic valves once they have been deployed requires implantation of the valve in the descending aorta or open surgical procedures to extract the valve. We describe the challenging transfemoral delivery of an Edwards Lifesciences Sapien valve wherein we had difficulty crossing the aortic valve and the guidewire position was compromised. We performed a transapical puncture to snare the guidewire and create a left ventricular to femoral wire rail, allowing us to deliver the transfemoral transcatheter valve, salvaging a situation where we would have been required to implant the valve in the descending aorta. We believe this is the first time this technique has been reported and represents an important method to facilitate delivery of transcatheter valves where guidewire support is insufficient or lost.

Keywords

aortic valve disease; transcatheter valve implantation; structural heart disease intervention; percutaneous valve therapy

Balloon-expandable transcatheter aortic valves are gaining worldwide acceptance as an alternative to surgery in selected patients. The technology and techniques for valve implantation have improved greatly, resulting in thousands of successful implants worldwide.^{1,2} The inability to reposition or retrieve these valves once they have been partially or fully deployed, however, may require deployment of the valve in the descending aorta, or salvage procedures including sternotomy to extract the valve.^{3,4} We report the transfemoral delivery of an Edwards Sapien valve (Edwards Lifesciences), in which a left ventricular (LV) to femoral wire rail was created to salvage a situation where we had difficulty crossing the aortic valve and the guidewire position was compromised.

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Case Report

An 87-year-old man with severe aortic stenosis with a history of atrial fibrillation and twovessel coronary artery bypass graft surgery presented with worsening dyspnea on exertion. He had New York Heart Association class 2 symptoms, without syncope or chest pain. He had a preserved ejection fraction, a severely calcified aortic valve with a calculated area of 0.58 cm^2 , a peak aortic velocity of 5.5 m/s, mean gradient of 77 mm Hg, and aortic annulus of 21 mm. Computed tomographic evaluation of the aortic annulus demonstrated an annulus area of 400 mm² and sinus measurements of $34 \times 33 \times 33$ mm. The right coronary to annulus distance was 11.6 mm and the left coronary distance was 13.7 mm. His surgical mortality risk was 8.2% estimated by the Society of Thoracic Surgeons risk estimator and 47% by Euroscore. Additionally, he had a very high surgical risk due to severe chest wall scarring and proximity of the coronary bypass grafts to the chest wall. He had adequately sized iliac and femoral arteries, and therefore qualified for transcatheter aortic valve replacement (TAVR) using a 23 mm Sapien valve (Edwards Lifesciences) via transfemoral approach.

Under general anesthesia, left femoral cut-down was performed. After placement of an 11 Fr sheath, the aortic valve was crossed with a straight wire and exchanged for a 0.035'' Amplatz extra-stiff wire, which was looped in the LV apex. Aortic valvuloplasty was performed with inflation of an 18×40 mm Tyshak balloon catheter using rapid ventricular pacing. The balloon and 11 Fr sheath were removed and successive dilations of the left iliac-femoral artery were performed, allowing placement of a 22 Fr delivery sheath.

The Sapien valve delivery system containing a 23 mm Edwards Sapien valve was advanced over the wire and into the aortic root without difficulty. However, despite multiple attempts of advancing the valve, using flexion and rotation of the delivery system, we were unable to cross the native aortic valve with the Sapien valve. As the valve delivery system had already exited the delivery sheath, valve retrieval was impossible. Therefore, via right femoral artery, a second Amplatz extra-stiff wire was placed in the left ventricle to utilize as a "buddy wire." Nonetheless, after multiple attempts, valve passage into the annulus was not possible. Using a 20×30 mm Edwards Sapien balloon over the buddy wire, valvuloplasty was again performed at high pressure with rapid ventricular pacing. There was minimal difference in the mobility of the valve leaflets on echocardiogram and multiple subsequent attempts to advance the valve delivery system across the native aortic valve were unsuccessful. Use of the "buddy-balloon" technique was also not successful. Additionally, in the course of aggressive advancement of the delivery system, the Amplatz guidewire was pulled back. Although the soft tip of the wire was still across the aortic valve, its position would not provide adequate support for further advancement of the valve. It is not entirely clear why we had difficulty crossing the valve, but review of the computed tomography angiogram was notable for significant calcification of all three coronary leaflets, with near complete calcification of the non-coronary cusp (Figure 1), so it is possible that this bulky leaflet was catching the Sapien valve, preventing advancement. Furthermore, the iliac vessels were very tortuous, therefore compromising the pushability and torquability of the delivery system from the transfemoral route.

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At this juncture, it was initially felt that only three options were available: (1) implant the valve in the descending aorta and abort the procedure; (2) implant the valve in the descending aorta, and introduce a new valve utilizing a transapical approach to complete the procedure; or (3) perform a high-risk surgical aortic valve replacement and retrieve the valve surgically. A multidisciplinary discussion ensued, after which the novel approach of creating a femoral artery-LV apical rail for additional support to facilitate valve positioning via transfemoral approach was proposed and executed.

A left mini-thoracotomy was performed similar to that employed for a transapical TAVR procedure. The buddy wire was removed from the ventricle. A short, 8 Fr sheath was placed in the LV apex, and the soft tip of the original Amplatz extra-stiff wire that was still in the LV was snared with a 25 mm Amplatz Gooseneck snare (ev3). The soft tip of the Amplatz wire is 6 cm from the stiff body of the wire; therefore, there was ample wire to snare and prolapse through the 8 Fr sheath. The Amplatz wire was then externalized through the LV apical sheath, establishing a femoral artery-LV apical rail (Figure 2A). This procedure allowed additional tension and control of the Amplatz wire, thereby allowing easy passage of the valve delivery system into the annulus. The delivery balloon was then inflated to the appropriate volume using rapid ventricular pacing. However, the valve appeared to be seated too aortic (Figure 2B) in the annulus, resulting in 3–4+ aortic insufficiency. Unfortunately, due to the patient's hemodynamic instability and the length of the case, the initial deployment was rushed.

Therefore, the decision was made to implant a second Sapien valve, which was to be positioned more ventricular and overlapping with the first Sapien valve. While maintaining the femoral artery-LV apical rail, the first delivery system was removed and a second 23 mm Edwards Sapien valve was advanced through the left femoral artery. With 5 mm of overlap, the second valve was deployed using rapid ventricular pacing. Aortography and echocardiography demonstrated resolution of the aortic insufficiency (Figure 2C). All wires were then removed. The LV apex was oversewn with pledgeted sutures. The left femoral artery was repaired under direct vision.

The patient was recently seen at 6-month follow-up exam, and continues to maintain good cardiac and prosthetic valve function.

Discussion

Delivery of the Sapien transcatheter valve system has been largely successful due to rigorous preoperative imaging and planning. Nonetheless, procedure failure has been reported to be 2.2%–4.6% from a multitude of causes.^{1–3} Both transfemoral and transapical approaches have had instances of valve maldeployment leading to significant morbidity, and the literature includes numerous demonstrations of novel salvage techniques.^{3,4} In most instances of salvage, close collaboration between practitioners resulted in optimal results. This case report represents an example of both close collaboration as well as a novel approach to salvage in a potentially very unstable situation.

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The current commercially available delivery system for the Edwards Sapien valve dictates that once the valve exits the delivery sheath, it cannot be recaptured within it. Therefore, if the valve cannot be deployed in the anatomically intended position, it must be sacrificed elsewhere in the aorta. Although such valve sacrifice does not pose significant risk to the patient, it fails to address the primary problem of aortic stenosis. There are other instances following valvuloplasty when the ventricular wire is inadvertently pulled back into the ascending aorta while advancing the delivery system into position. In such instances, once again due to the inability to recapture the device within the sheath, the valve must be sacrificed. Furthermore, once the Sapien valve is deployed, it is impossible to retrieve and recapture.⁴ As a result, in cases of inadvertent valve embolization, additional high-fidelity control of wires may become necessary in the salvage of the patient.

The technique described in this report has the potential to address such technical issues in a relatively simple and elegant manner. In the case of an inadvertently displaced wire or the inability to advance the valve delivery system into position across the annulus, a small sheath can be placed in the LV apex, and a snare advanced through it to capture and externalize the wire to reestablish a stable and supportive transannular wire position. A novel suggestion has been made to deliver a snare over the buddy wire and pull the original wire further into the left ventricle. Although this strategy is appealing, we did not consider it at the time. Even if we had been able to reestablish wire position, we still may not have been able to cross the native valve from a retrograde approach without the transapical rail given our previous failed attempts.

In the unfortunate case of valve embolization, externalization of the wire through a transapical sheath may allow better control of the embolized valve, and potentially aid safe placement of the valve elsewhere in the descending aorta.

Conclusion

Our understanding and experience with hybrid approaches to cardiovascular diseases continues to evolve. The use of a femoral-apical wire rail for TAVR is a novel technique to aid valve delivery and exemplifies the benefit of constant and collaborative relationship between interventional cardiology and cardiac surgery for the safe and judicious application of novel cardiovascular technology.

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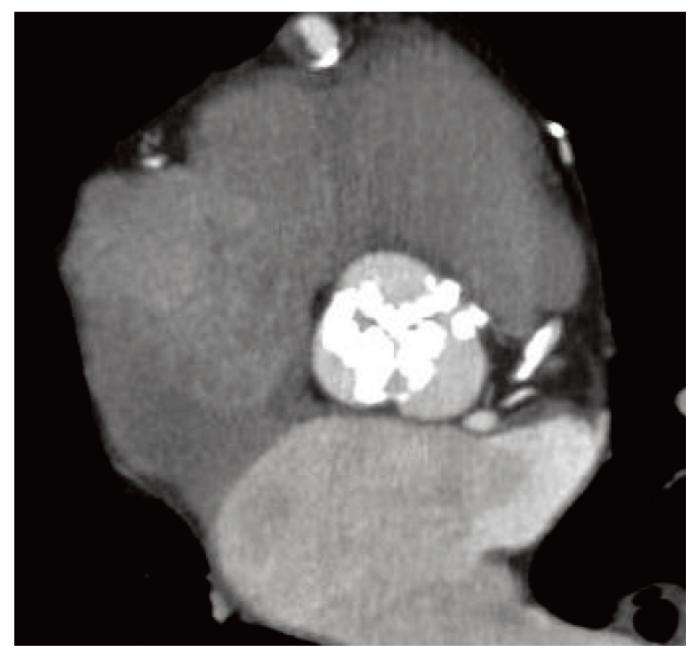


Figure 1.

Computed tomographic angiogram showing severely calcified leaflets, with near complete calcification of the non-coronary cusp.

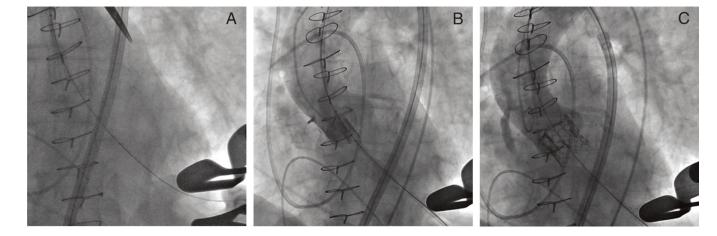


Figure 2.

Successful deployment of two overlapping 23 mm Edwards Lifesciences Sapien valves using a femoral artery-left ventricular (LV) apical rail for support. (A) Creation of a femoral artery-LV apical rail with the LV wire snared from the apex. (B) Predeployment positioning of the Sapien valve using the transfemoral delivery system. (C) Postdeployment angiogram after two Sapien valves have been deployed, with resolution of aortic insufficiency.

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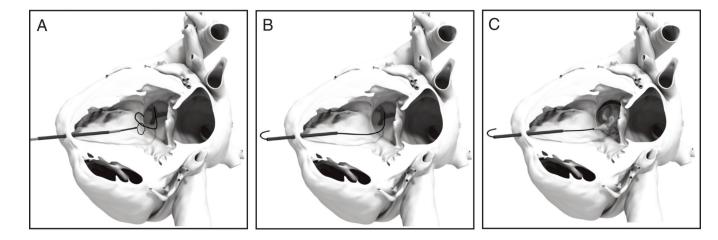


Figure 3.

Steps involved in creating a femoral artery-left ventricular (LV) apical rail. (A) Snaring of the Amplatz wire through a transapical sheath. (B) Externalization of the Amplatz wire through the transapical sheath. (C) Advancement of the transcatheter valve delivery system across the aortic annulus using the transapical rail for support.