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Implantation of a Sapien XT aortic bioprosthesis with the NovaFlex catheter through a subclavian access

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Transcatheter aortic bioprosthesis implantation is a new option for patients at high surgical risk with severe symptomatic aortic valve stenosis.[1] The main alternatives to transfemoral access are currently the transapical approach with an Edwards Sapien prosthesis (Edwards Lifesciences, Inc, Irvine, Calif) and the subclavian approach with the Medtronic CoreValve prosthesis (Medtronic, Inc, Minneapolis, Minn),[2] with some observational and noncontrolled data indicating that the latter could be less invasive.[3] The subclavian approach was not developed with the new generation Sapien XT bioprosthesis delivered by its NovaFlex catheter (Edwards Lifesciences) because of theoretic technical issues, including difficulties in aligning the prosthesis over the balloon in the patient, outside the delivery sheath in the ascending aorta.

We report the implantation of a Sapien XT bioprosthesis with the NovaFlex catheter through a left subclavian approach.

CLINICAL SUMMARY

An 82-year-old woman was referred for symptomatic severe aortic stenosis with New York Heart Association functional dyspnea class III, indexed effective orifice area of 0.45 cm^2/m^2, mean gradient of 38 mm Hg, maximal gradient of 61 mm Hg, peak aortic jet velocity of 3.7 m/s, stroke volume of 70 mL, and left ventricular ejection fraction of 25%.

The patient had a history of diabetes mellitus, obesity (body mass index 36.7 kg/m^2), chronic obstructive and restrictive pulmonary disease (forced expiratory volume in 1 second of 800 mL [55%], forced vital capacity of 1.4 L [56%]), peripheral artery disease, and coronary artery disease with history of previous percutaneous coronary intervention on the left anterior descending artery with no remaining significant stenosis. Low-dose (15 μg) dobutamine echocardiography detected contractile reserve (effective orifice area of 0.49 cm^2/m^2. mean gradient of 49 mm Hg, maximal gradient of 75 mm Hg, peak aortic jet velocity of 4.3 m/s, stroke volume of 87 mL, and left ventricular ejection fraction of 37%).

A transcatheter aortic valve implantation was proposed, because this patient was considered a high-risk surgical candidate for whom conventional surgery was contraindicated (logistic EuroSCORE of 46.48%, Society of Thoracic Surgeons Score of 13.4%).

The aortic annulus, as measured by transesophageal echocardiography, was 24 mm. The iliofemoral arteries were not suitable for transarterial access (Figure 1, *A*). A transapical approach was contraindicated because of severe respiratory dysfunction. The computed tomographic scan showed a left subclavian artery without stenosis with a diameter of 8 mm (Figure 1, *B* and *C*) and a distance of 13.6 mm between the aortic annulus and the ostium of the left subclavian artery (Figure 1, *D* and *E*).

The procedure was performed with the patient under general anesthesia through surgical cutdown and isolation of the left axillary artery. After heparinization (50 UI/kg, activated clotting time of 200–250 seconds), the 19F sheath was directly inserted in the axillary artery toward the aortic arch over an Amplatz extra stiff wire (Cook Medical Inc,

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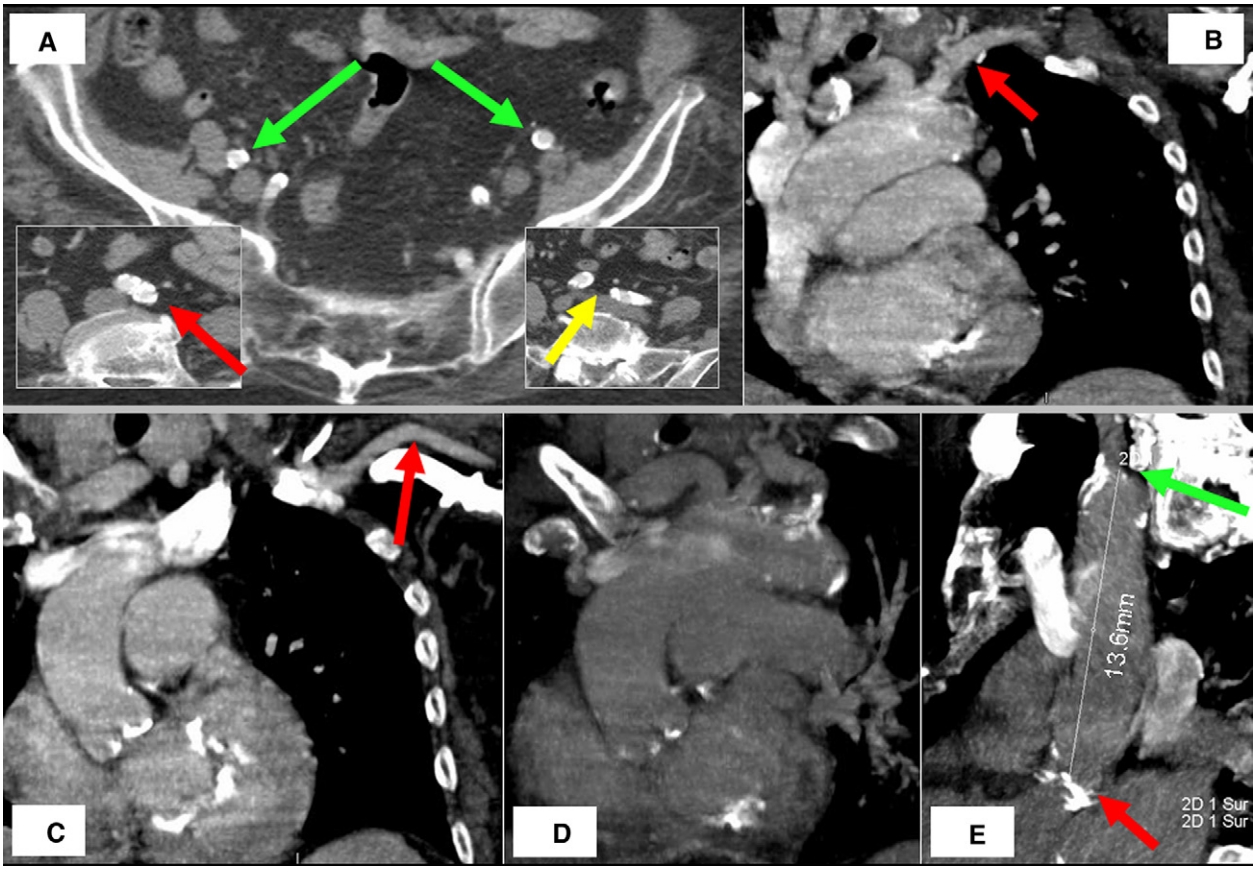

FIGURE 1. A, Multislice computed tomography showing calcified iliofemoral vessels (*red arrow,* ostia of the primary iliac arteries; *yellow arrow,* primary iliac arteries; *green arrows,* external iliac arteries). B, Multislice computed tomographic reconstruction showing left axillary artery *(red arrow)*. C, Multislice computed tomographic reconstruction showing left axillary artery *(red arrow)*. D, Multislice computed tomography demonstrating the aortic annulus, the ascending aorta, the aortic arch, and the ostium of the left subclavian artery. E, Multislice computed tomographic reconstruction demonstrating the distance between the aortic annulus *(red arrow)* and the ostium of the left subclavian artery *(green arrow)*.

Bloomington, Ind), which allowed clear attenuation of the axillary tortuosities (Figure 2, *A*). A 26-mm Edwards Sapien XT valve was then inserted with the NovaFlex catheter after a balloon aortic valvuloplasty (23 mm) performed through the 19F sheath. Alignment of the prosthesis over the balloon was easily performed within the ascending aorta and the aortic arch (Figure 2, *B*). The prosthesis was then classically implanted with the flex portion of the NovaFlex catheter under fluoroscopic and transesophageal echocardiographic guidance and under right ventricular rapid pacing (temporary pacing lead placed from the right femoral vein).

Angiographic and echocardiographic control examinations showed good positioning, with no significant intravalvular or perivalvular regurgitation (Figure 2, *C*). After surgical suture of the axillary artery, a final angiographic check did not show any arterial injury (Figure 2, *D*).

The postoperative course was uneventful. At discharge (day 7), the patient was in New York Heart Association functional class II. Transthoracic echocardiography showed left ventricular ejection fraction of 33%, prosthesis mean gradient of 10 mm Hg, indexed effective orifice area of 1.69 cm^2, and no paravalvular leak.

DISCUSSION

The axillary subclavian approach has been reported with the Medtronic CoreValve bioprosthesis. Modine and colleagues demonstrated that the axillary approach was safe and that positioning and controlling the prosthesis was easier than with the retrograde transfemoral approach.[4]

To date, the subclavian access has been reported once with the RetroFlex catheter (Edwards Lifesciences).[5] Concerning the NovaFlex catheter, the main issues were the suitability of the 19F Edwards sheath within the tortuosities of the subclavian artery and the possibility of alignment of the prosthesis over the balloon.

The insertion of the 19F Edwards sheath over the extra stiff guidewire allowed clear attenuation of subclavian

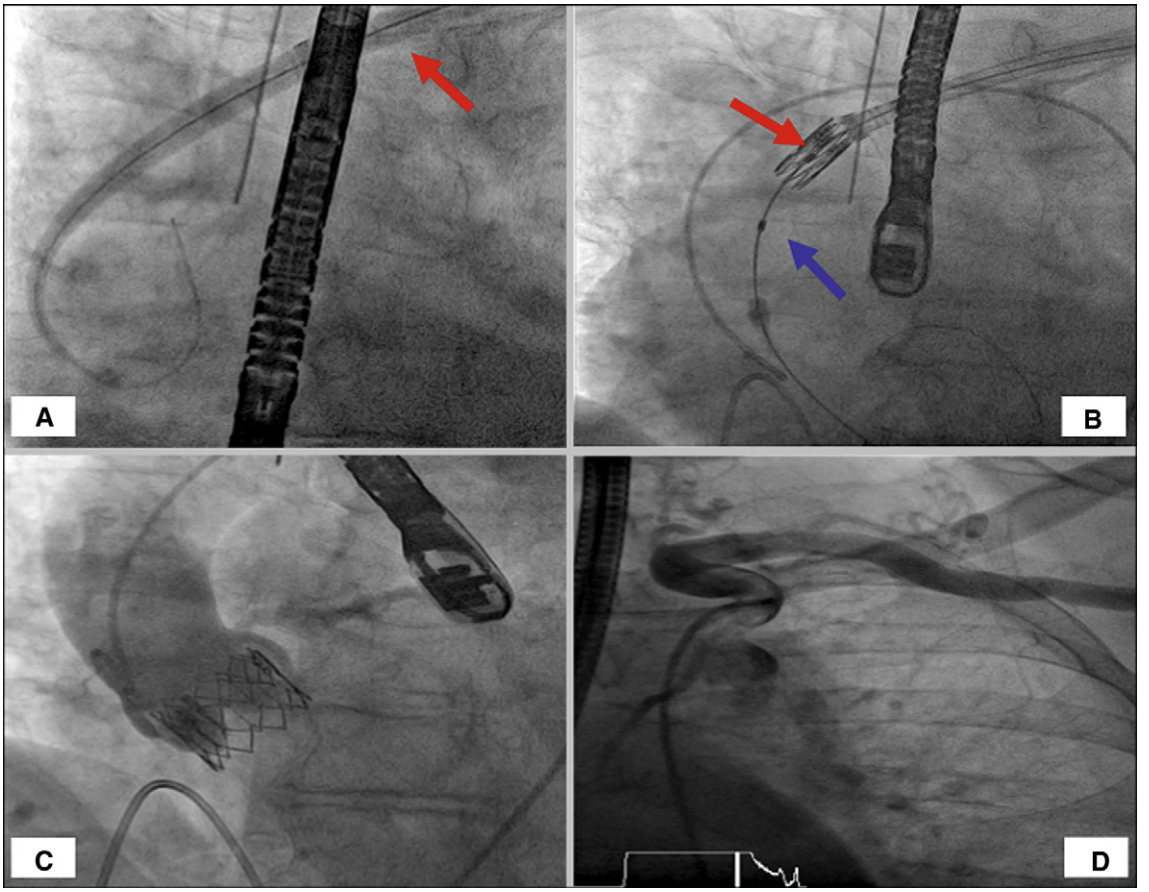

FIGURE 2. A, A 19F sheath *(red arrow)* with its dilator introduced into the left axillary subclavian artery over the stiff wire. B, Alignment of the Sapien XT prosthesis (*red arrow;* Edwards Lifesciences, Inc, Irvine, Calif) on the NovaFlex balloon catheter (*blue arrow;* Edwards Lifesciences) inside the ascending aorta and the aortic arch. C, Final angiographic control examination after implantation of the 26-mm Sapien XT prosthesis showing optimal positioning, with no significant paravalvular leakage. D, Final angiographic control of the left subclavian axillary artery after withdrawal of the 19F sheath, showing neither dissection nor arterial injury.

artery tortuosities. We did not observe any kinking of the sheath in this patient, and the prosthesis was easily inserted.

The alignment of the prosthesis over the balloon was performed between the distal part of the sheath and the aortic annulus. A minimal distance of 10 cm appears to be necessary for correct alignment. This distance needs to be documented on preoperative computed tomographic scan (Figure 1, *D*).

To our knowledge, this case is the first implantation of a Sapien XT aortic bioprosthesis with the NovaFlex catheter through an axillary subclavian approach. As an alternative to transfemoral access, this approach could be considered feasible with the Edwards XT valve.

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