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Sheathless transcatheter self-expanding aortic valve implantation: An alternative approach to reduce vascular complications

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Transcatheter aortic valve implantation (TAVI) is a well-recognized therapeutic option for high-risk patients with aortic stenosis. Its application is booming, and new devices will soon increase the chance to treat more patients. Despite encouragingly good results, vascular complications remain the Achilles' heel of this procedure. According to Valve Academic Research Consortium (VARC) criteria, major vascular complications vary between 10.7% and 15.3% in predicting 30-day mortality.[1,2] The rate of vascular complications has been diminishing thanks to the downsizing of the introducer from 24F to 18F and the choice of alternative vascular access besides the transfemoral (subclavian, transaortic, and transapical).

CLINICAL EXPERIENCE

Among 51 patients treated with TAVI between July 2009 and August 2012, 7, with vascular access less than 6 mm, were deemed not suitable for the transapical or transaortic approach. The Heart Team opted to implant the Medtronic CoreValve (Medtronic, Minneapolis, Minn) through the femoral or subclavian artery without the introducer (sheathless). Device success was 100%, and no vascular complication occurred. According to VARC criteria, before and after procedural data are reported in Table 1.

TABLE 1. Before and after procedural data

Data	Value
Baseline characteristics	
Age, y	84 ± 5
NYHA III-IV	2 (28.57)
Diabetes mellitus	4 (57.14)
Coronary artery disease	2 (28.57)
COPD	3 (42.86)
Renal dysfunction	2 (28.57)
Logistic EuroSCORE, %	22 ± 9
Left ventricle ejection fraction, %	44 ± 8
Previous cardiac intervention	4 (57.14)
Previous endovascular procedure	2 (28.57)
Porcelain aorta	2 (28.57)
Procedural outcome	
Successful valvuloplasty	7 (100)
Emergent cardiac surgery	0 (0)
Postprocedural aortic regurgitation	
Mild	3 (42.87)
Moderate	1 (14.29)
Severe	0 (0)
Postprocedural gradient, mmHg	9 ± 3
Safety end points at 30 d follow-up according to VARC definition	
Overall death	0 (0)
Stroke	0 (0)
Major bleeding	0 (0)
Major vascular complications	0 (0)
Minor vascular complications	0 (0)
PM implantation	1 (14.29)

Values are given as mean ± SD or number (percentage). *NYHA*, New York Heart Association; *COPD*, chronic obstructive pulmonary disease; *VARC*, Valve Academic Research Consortium; *PM*, pacemaker; *EuroSCORE*, European System for Cardiac Operative Risk Evaluation.

SURGICAL TECHNIQUE

With local anesthesia and minimal sedation, we perform a surgical incision of 4 cm for femoral and 6 cm for subclavian access; the artery is secured with two tourniquets proximally and distally, and two 5-0 prolene-pledgeted purse strings are placed around the incision site for hemostasis. A 6F sheath is inserted for guide positioning, then replaced with a 12F for balloon valvuloplasty; finally, after removing the 12F sheath, the CoreValve System is gently inserted directly into the artery on a stiff wire. A further small extension of the artery incision avoids any vessel damage. If postdilatation is required, the system is retrieved and the 12F is repositioned, securing hemostasis with the purse string. The artery is closed directly at the end of the procedure.

DISCUSSION

As cardiovascular surgeons, we are used to the ''sheathless technique'' because of practice with sheathless endovascular prosthesis (ie, Endurant; Medtronic). Accutrack (Medtronic) is the CoreValve delivery system that allows navigating and delivering the valve in the correct position. All 4 different sizes of the CoreValve are mounted into the 18F Accutrack that protects and keeps the valve crimped, with a smooth plastic cover. The maximum outer diameter of the Accutrack is 18F (6 mm) for the first 7 cm,

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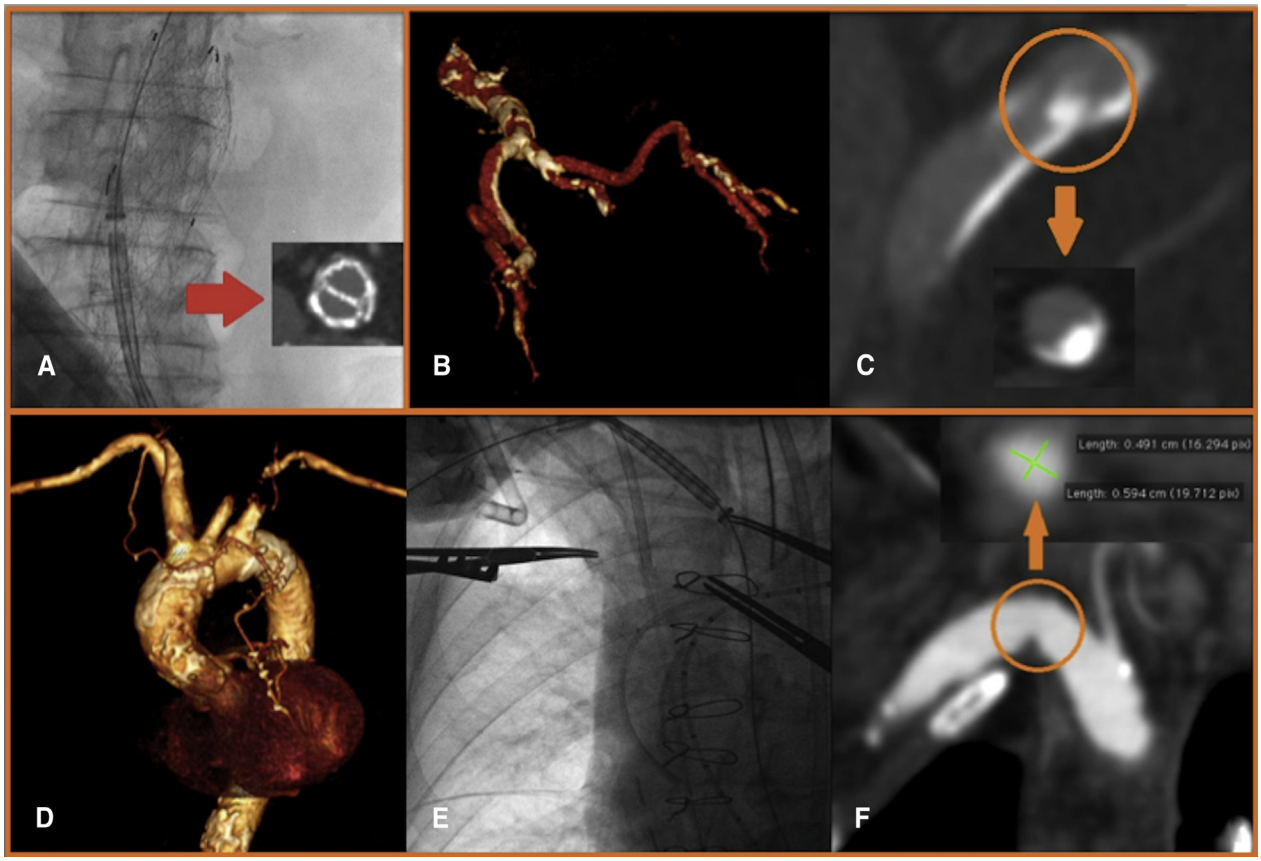

FIGURE 1. Sheathless femoral transcatheter aortic valve implantation (TAVI) in a patient with aortoiliac endoprosthesis (A) and in a patient with severe calcifications of aortic carrefour (B and C); sheathless right subclavian TAVI in a patient with previous coronary artery bypass grafting, porcelain aorta, diseased femoral and iliac access, occluded left subclavian artery, and small right subclavian artery (D-F). *Arrows* indicate the axial computed tomography scan details. The computed tomography scan vessel diameters are in *green*.

12F for the middle 14.6 cm, and 15F for the last 90.7 cm, whereas the outer diameter of a compatible 18F introducer is 7.2 mm. The difference between a sheath and sheathless procedure is only 1.2 mm, but it means a reduction in access vessel diameter of 16.7%. This technique allows us to avoid keeping a stiff 30-cm length introducer in the access vessel for the entire procedure. The 6-mm delivery system passes through the vascular access for a few seconds and, for just 7 cm, reducing the risk of artery recoil or dissection. The smoother Accutrack's nose follows curvature or indentation of the artery better than the rigid introducer's dilatators. Moreover, avoiding introducer obstruction, subclavian sheathless access allows a greater flow to the internal thoracic artery (ITA) also in case of patent ITA to the left anterior descending artery.[3] Indeed, thanks to the flexibility of the delivery system, it becomes possible to perform a TAVI procedure even in case of important vessel tortuosity or in case of previous aortic stent or endovascular prosthesis implantation (Figure 1). As reported by Hayashida et al,[4] a sheath to femoral artery ratio (SFAR) of 1.05 predicted a statistically significantly higher rate of VARC major complications and 30-day mortality. The authors identified, for an 18F introducer, a minimal noncalcified ileofemoral artery access of 6.5 mm and of 7.2 mm for calcified artery access. A sheathless procedure allows 6-mm artery access.

The main drawback of this off-label approach is the impossibility to recapture the CoreValve. However, also using the introducer, this procedure may be difficult and risky (particularly for the subclavian access).[5] To minimize the risk of suboptimal positioning or device displacement during a sheathless procedure, we always deploy the CoreValve under rapid pacing. With the advent of new device generation, with a smaller diameter, a sheathless technique will remain a valid option, particularly in cases of small and diseased vessels.

CONCLUSIONS

Patients with major vascular complications had a 2-fold increase in mortality, and vascular complications are strictly related to SFAR.[4] The sheathless technique, allowing a smaller 16.7% artery diameter, is an alternative to standard access. The ''Heart Team'' should consider this off-label option when conventional access is precluded

and to avoid intricately more invasive access, such as transaortic and transapical, that requires general anesthesia.

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