Transthoracic Access for Transcatheter Aortic Valve Replacement: Technique Using the Edwards Sapien Retroflex Delivery System

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We describe our experience using the Edwards Sapien transfemoral Retroflex 3 catheter delivery system for transcatheter aortic valve replacement through the transapical and transaortic approaches. Transthoracic transcatheter valve replacement by the transapical and transaortic approaches can be safely and effectively performed with the Retroflex 3 delivery catheter, which affords several advantages over other available delivery devices.

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A number of procedural issues make transapical (TA) and transaortic (TAo) transcatheter aortic valve replacement (TAVR) more technically difficult, including device and operator positioning, size and length characteristics of the sheath, and transition points when entering weak myocardium or fragile aorta. We describe procedural details using the Edwards Sapien transfemoral Retroflex 3 (RF3; Edwards Lifesciences, Inc, Irvine, CA) delivery system for transthoracic TAVR, and highlight specific RF3 design advantages for TA and TAo procedures.

**Technique**

Between November 2, 2011, and October 1, 2012, 26 patients were prospectively studied who underwent TAVR using the RF3 catheter delivery system under commercial status by TA (n = 15) or TAo (n = 11) approach at our institution. All procedures were performed under general endotracheal anesthesia and monitoring by three-dimensional transesophageal echocardiography.

**Transapical Approach**

A standard left minithoracotomy incision was made after fluoroscopic confirmation of the appropriate intercostal space, and the left ventricular (LV) apex was exposed. Before anticoagulation with heparin, two perpendicular horizontal mattress polypropylene stitches with soft-felt pledgets were placed in a location just superior and lateral to the true LV apex. Echocardiographic guidance was used to locate an ideal puncture site. Concurrently, the transfemoral RF3 sheath was concurrently prepared: (1) the hydrophilic coating was removed by vigorous rubbing with a dry towel to increase the frictional surface, (2) a bumper was created by securing a 1-cm-wide soft-felt pledget at 5 cm from the end of the sheath to prevent inadvertent excessive sheath insertion (Fig 1A), and (3) a long working table was prepared alongside the patient’s left side to accommodate the longer device sheath and other components. Importantly, the valve was loaded in preparation for an antegrade TA approach. The apex was accessed percutaneously with a standard 0.035-inch guidewire advanced across the aortic valve into the descending aorta. The guidewire was replaced with an extra-stiff wire (260 cm). The RF3 device sheath was advanced over the Amplatz wire into the ventricle to an appropriate position (Fig 1B), and the remainder of the procedure was performed in the standard fashion.

**Transaortic Approach**

An L-shaped upper hemisternotomy was performed with extension to a fluoroscopically selected intercostal space (usually the second intercostal space), and the pericardium was retracted for exposure. Two diamond-shaped polypropylene sutures with bovine pericardial pledgets were placed in the ascending aorta. The valve was prepared identical to a transfemoral approach. After valve crimping, the loader cap (Fig 2A) was placed directly over
the valve and balloon, and an extra 0.5 mL of saline solution was inflated into the balloon to create a smooth transition from valve to edge of the loader cap. A strip of soft felt was wrapped around this to only permit approximately 2 cm of the device into the aorta. The aorta was first accessed with an 18-gauge needle with a short wire. After placing a 5F sheath into the ascending aorta, a short 4F angled glide catheter and straight stiff glide wire were used to cross the aortic valve. A short extra-stiff wire (180 cm) was placed into the LV, and the 5F sheath was replaced with a 14F sheath. The balloon aortic valvuloplasty was performed through the 14F sheath. Afterward, the 14F sheath was removed, the aortic puncture site controlled with digital manual pressure, and the valve and loader cap were advanced over the Amplatz wire to the aorta (Fig 2B). The valve and loader cap were slowly but steadily placed into the aorta up to the felt pledget. From this point forward, the loader cap was secured in place manually by the assistant surgeon.

The valve was advanced across the native valve, deployment took place under rapid pacing, and the valve was pulled back into the ascending aorta after deployment. Under rapid pacing to lower the systemic blood pressure, the valve and loader cap were pulled out of the aorta, along with the wire, and the aortic pursestring sutures were tied. The sternum and soft tissues were closed with wires and absorbable sutures.

Comment

Alternative access through exposure of the LV or ascending aorta has been developed for patients with inadequate vascular access for TAVR, cited as up to 30% of patients screened [1]. Our primary modification for TAI and TAo procedures consists of using the transfemoral RF3 sheath for entry, rather than the Ascendra sheath. Our motivation arises from key advantages after handling the RF3 system versus the original Edwards Ascendra sheath. Specifically, first, the transition point at the RF3 sheath tip entering the LV apex contains a noticeably more contoured transition from dilator to sheath, which has minimized perisheath bleeding. This bleeding, although not life-threatening, would previously lead to extra blood loss or hasten the procedure unnecessarily. The felt bumper is a valuable technique that grants the surgeon a tactile sense of the depth of placement to avoid migration rather than constantly visually checking sheath markers. With the bumper in place, a catastrophic inward motion is prevented. Second, the balloon deflation time of the RF3 system is considerably shorter than that of the Ascendra, leading to shorter rapid pacing deployment runs, and has improved post-pacing ventricular recovery. Finally, the smaller outer diameter of the RF3 sheath compared with the Ascendra sheath (outer diameter, 25/28F for the RF3 versus 28F for the Ascendra) has reduced the ventricular defect and also facilitated ease of sheath manipulation. The extra working length provided by the longer sheath affords more room for two-person manipulation of the device. A long table is typically placed on the left side of the patient, which becomes the working area for the case, rather than attempting to manipulate the shorter Ascendra sheath closer to the patient.

Similar difficulty was encountered with the Ascendra sheath for TAo use: awkward working position owing to sheath length and rigidity, perisheath bleeding secondary to tension on the aortic entry site from sheath motion, and
unfavorable transitioning from dilator to sheath. With our method, the smaller loader cap (22/24F) sits within the chest, and the RF3 catheter and valve can be easily manipulated to the right of the patient, given its inherent flexibility. The extra working distance allows an operator to handle exchanges away from the field. Although care needs to be taken not to dislodge the loader cap, far less perisheath bleeding has been noticed. The Ascendra system is intended for antegrade crossing of the aortic valve and does not have a tapered end to facilitate retrograde valve crossing, which may cause additional problems for TAo access.

The limitations of the RF3 for transthoracic use have been minor and have not precluded its use in any of our cases but deserve mention. Proper attention to sterility must be made to prevent wire or sheath contamination with longer sheath size. With TAo procedures, the potential for a greater exposure to radiation exists.

In conclusion, we propose a number of advantages of RF3 delivery system use for transthoracic TAVR. These modifications can be adapted to next-generation valves, such as the Sapien XT.

Reference