Transcatheter aortic valve implantation of a CoreValve device using novel real-time imaging guidance

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Thorough imaging of the aortic valve and related structures is highly important before and during transcatheter aortic-valve implantation. However, conventional aortography is limited for guiding precise valve placement and depends on contrast injections. A real-time imaging system capable of guiding the operator during Edwards-SAPIEN valve procedures has been introduced (C-THV, Paieon Inc.). We describe the first application of the novel C-THV system during CoreValve implantation in a very challenging clinical scenario that required precise high implantation using minimal contrast.

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1. Introduction

Transcatheter aortic-valve implantation (TAVI) has become an alternative therapy for high-risk patients with severe symptomatic aortic stenosis [1,2]. Currently, the two leading technologies are the Medtronic CoreValve System (Medtronic, Minneapolis, MN, USA) and the Edwards-SAPIEN valve (Edwards Lifesciences, Irvine, CA, USA). Thorough imaging of the aortic valve and related structures is highly important before and during the procedure [3,4]. However, conventional aortography is limited for guiding the operator in precise valve placement in relation to the native valve and requires contrast injections. Our group and others have reported the development of an imaging modality capable of three-dimensional reconstruction of the aortic root during Edwards-valve TAVI procedures (C-THV, Paieon Inc., Israel) [5–7]. The present report describes the first application of a novel C-THV system in real time during CoreValve implantation in a challenging clinical case that required precise high implantation with minimal contrast.

2. Patient description

An 80-year-old woman was examined in our department for deteriorating functional capacity (NYHA Class III). She had undergone mechanical monoleaflet mitral-valve implantation 21 years previously. She also had many severe comorbid diseases, including chronic atrial fibrillation, diabetes mellitus, and renal failure (creatinine 1.5 mg/dl; estimated glomerular filtration rate, 28 ml/min). Echocardiography revealed severe tricuspid-valve regurgitation with an extremely enlarged right atrium of 67 mm in diameter, severe aortic-valve stenosis with measured valve gradients of 118/71 mmHg, and a calculated valve area of only 0.3 cm². There was mild aortic-valve regurgitation; the ascending aorta was not enlarged. The left ventricular ejection fraction was 45%, and right ventricular function was preserved. There was also asymmetric septal hypertrophy of 12 mm. The diagnosis was severe symptomatic aortic-valve stenosis.

The patient was considered a very poor candidate for conventional aortic valve replacement surgery owing to her relatively old age, significant frailty, previous cardiac surgery, and other comorbidities. The logistic EuroSCORE was 43.5, and the STS score was 11.4 for early mortality. Therefore, we evaluated her suitability for TAVI. On transesophageal echocardiography (TEE), the aortic valve annulus measured 20 mm. On angiography, the iliofemoral vessels were narrower than 5 mm and therefore unsuitable for valve delivery, but the diameter of the left axillary artery was 6 mm. The patient was therefore considered eligible for TAVI via the axillary approach. However, a very precise high implantation was required for two reasons: (1) to avoid incomplete CoreValve strut expansion secondary to the rigid mitral valve implant, and (2) to decrease the risk of a conduction abnormality and the need for long-term temporary pacemaker surveillance, because the severe tricuspid regurgitation could make the pacemaker lead position unsteady. Additionally, we needed to use as little contrast as possible owing to the patient’s severe renal impairment. Accordingly, we decided to implant a CoreValve device under real-time guidance of the C-THV system.

The patient underwent TAVI in May 2011. The procedure was performed under general anesthesia, continuous TEE monitoring, and surgical cut-down of the left axillary artery.

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3. Valve implantation

The optimal projection for valve implantation was selected according to the device’s color-coded map which displays the recommended angulation zones (Fig. 1A); this method was described previously [5–7]. The operator selected left anterior oblique 19° and caudal 5°. Conventional aortography confirmed that this projection was compatible with valve implantation (Fig. 1B). Balloon valvuloplasty was then performed using a 22-mm balloon (Nucleus, NuMED, Hopkinton, NY, USA) inflated under rapid ventricular pacing (200Hz) (Fig. 1C). A 26-mm CoreValve device and delivery system equipped with an AccuTrak Stability Layer were delivered through an 18-Fr sheath that was introduced directly into the left axillary artery. Fluoroscopy was used to guide the prosthetic valve into the diseased annulus (Fig. 1D). The technician marked the annulus target line on the program and circled an opaque object that was moving synchronically with the annulus. The software displayed a virtual depth ruler and a line 4mm below the sinus line; that measure was made at operator discretion. Thereafter, the operator carefully moved the prosthetic valve while the software tracked and displayed its position in real time by fluoroscopic images (Fig. 1E–I). The optimal location was indicated by the gap between the two lines (0 and 4mm below the sinus line). At the operator’s first attempt, the software indicated that the position was too deep (Fig. 1E). Thereafter, the operator started to implant the valve while pulling the device slightly and, on the next attempt, he successfully localized the valve exactly at the desired position, at a depth between 0 and 4mm (Fig. 1G–I). Aortographic contrast injection was used only once during valve positioning (Fig. 2A and B), for a total of 65ml of contrast for the whole procedure. After valve implantation, aortography and TEE

![Perpendicular Projection Selection](image.png)

**Fig. 1.** (A) Color-coded map for selection of optimal projection: left anterior oblique 19° and caudal 5°. (B) Conventional aortography shows that this projection is compatible with valve implantation. The arrow indicates the mitral valve implant. (C) Balloon valvuloplasty using a 22-mm balloon (Nucleus, NuMED, Hopkinton, NY, USA). (D) The 26-mm CoreValve device is delivered through the native aortic valve. (E–I) Valve localization is guided in real time by a virtual depth ruler and a line 4mm below the sinus line. The gap between the two lines is the target for the lower part of the device. At the first attempt, the valve was placed too deep (E). Thereafter, its position was corrected without contrast injections.

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evaluation revealed no acute complications and only a minimal paravalvular leak. C-THV analysis showed that the CoreValve struts were open (23.1–23.8 mm at the aortic root), and the device was deployed at the desired location (0.4 mm below the right sinus and 3 mm below the left sinus). (Fig. 2C and D).

4. Follow-up

The vascular access was closed surgically and extubation was performed. Because of continuous bleeding from the axillary artery, a covered stent was implanted. Echocardiography showed a decrease in aortic valve gradients to 20/7 mmHg and an increase in the valve area to 23.8 mm at the aortic root) and the depth of the implantation is as planned (0.4 mm below the right sinus and 3 mm below the left sinus; Fig. 2C and D).

5. Discussion

Although CoreValve deployment does not require rapid pacing, there are usually temporary hemodynamic instability and significant regurgitation; therefore, implantation needs to be performed as quickly and safely as possible. Optimal positioning of the prosthetic valve during TAVI is crucial in order to avoid complications. Studies have reported an association between the depth of CoreValve implantation and paravalvular leak [8], need for a pacemaker [9], and occurrence of ventricular tachycardia [10]. It may also affect mitral-valve regurgitation, but evidence so far is lacking [11,12]. Valve positioning is even more complex in the presence of an extremely irregular anatomy, and in these cases TAVI using current systems carries a significant risk. During valve implantation, the location of the device is analyzed by native valve calcification, positioning the pigtail catheter on the coronary sinus, and by contrast injections.

Another unresolved issue in TAVI is the manner in which to select the projection for deployment. An optimal fluoroscopic working-view projection, with all three aortic cusps depicted in one line, is essential. However, conventional two-dimensional angiography is limited and demands many contrast injections [13,14]. Measurements of root diameter vary markedly among echocardiography, contrast angiography, multislice computed tomography, and magnetic resonance imaging [15–18]. The gold-standard imaging modality for use prior to TAVI is still controversial, and studies are lacking. Therefore, an improved imaging technique could help to make the procedure safer and more efficient.

In summary, we describe the first deployment of a CoreValve device under real-time guidance of a novel C-THV system in a patient with severe symptomatic aortic stenosis. We were strictly bound by two requirements: a precise high implantation and a minimal amount of contrast. In this difficult clinical scenario, we found the novel C-THV system to be a great asset in guiding valve placement. In our medical center, eight CoreValve procedures were guided in real time by this novel imaging tool. From our initial experience, it seems that using this imaging tool during CoreValve implantation could be especially helpful in cases where very accurate implantation depth is required or in patients for whom contrast injection should be minimized, such as renal failure patients. In our limited series, no patient hazard appeared. Application of the system did not interfere with the procedural flow, and almost all phases were performed by a technician. Future studies should evaluate the C-THV system in a large group of patients undergoing CoreValve implantation.

References

