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Original article

The feasibility of transcatheter aortic valve implantation using the Edwards SAPIEN 3 for patients with severe bicuspid aortic stenosis

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ABSTRACT

Background: There are currently only limited data focusing on transcatheter aortic valve implantation (TAVI) for bicuspid aortic valves (BAV) patients using the Edwards SAPIEN (Irvine, CA, USA) 3 (S3) valve. The aim of this study was to evaluate the feasibility and efficacy of TAVI using the S3 in patients with BAV.

Methods: A total of 153 TAVI cases performed with the S3 were included. BAV was detected by multidetector computed tomography (MDCT) in 10 (7%) patients. The other patients had tricuspid aortic valves (TAV). The BAV and TAV groups were compared.

Results: Patient age and logistic EuroSCORE were similar in the BAV and TAV groups. The calculated annulus average diameter (CAAD) by MDCT was significantly larger in the BAV group (26.5 mm vs 23.7 mm, $p = 0.036$) as was the annular area by MDCT (562 mm^2 vs 446 mm^2, $p = 0.033$). On the other hand, the valve diameter/CAAD ratio was significantly lower in the BAV group (1.01 vs 1.06, $p = 0.010$) as was the annular area oversizing percentage (3% vs 11%, $p = 0.033$). There were no significant differences between the two groups regarding the frequency of paravalvular aortic leakage (PVL) $\geq$2 (0% vs 6%, $p = 0.492$) and the 30-day mortality rate (0% vs 1%, $p = 0.799$).

Conclusions: Although TAVI for BAV tended to be carried out with a less oversized valve compared to TAVI for TAV, the frequency of post-procedural PVL $\geq$2 was similarly low in the two groups. TAVI using the S3 in patients with BAV seems to be feasible.

Introduction

Transcatheter aortic valve implantation (TAVI) has gained increasing acceptance as a treatment option for patients with severe symptomatic aortic stenosis (AS) who are considered high risk for surgical aortic valve replacement [1–6]. Despite its minimally invasive nature, TAVI is invariably associated with complications such as paravalvular aortic leak (PVL) and access site complications which remain limiting factors potentially affecting the outcome of this treatment strategy [2,7–9]. Although sutureless aortic valve replacement (AVR) may be a potential therapeutic option to reduce PVL as an alternative to TAVI [10], the structure of TAVI devices has been improved in order to overcome these problems. The balloon-expandable SAPIEN 3 (S3) prosthesis (Edwards Lifescience, Irvine, CA, USA) was designed to reduce post-procedural PVL by adding an outer skirt at the distal part of the prosthesis.

Bicuspid aortic valve (BAV) is a common cardiac anomaly with a prevalence of 0.5–2.0% in the general population [11,12]. Although TAVI for BAV had been formerly excluded from most clinical trials because of potential difficulties in expanding correctly the valve frame, several studies have recently reported the feasibility and safety of TAVI for BAV [13,14]. However, TAVI for patients with BAV is still challenging because of the potential risk of residual PVL or annulus rupture. Furthermore, there are currently only limited data focusing on TAVI for BAV patients using the Edwards S3 valve.

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The aim of this study was, therefore, to investigate the feasibility and safety of TAVI for BAV using S3.

Materials and methods

Study design

From October 2006, all consecutive high-risk patients with severe symptomatic AS treated with TAVI were prospectively included in our dedicated TAVI database. Patients with severe AS were considered candidates for TAVI if they were deemed ineligible or high risk for sutureless AVR. The decision to proceed with TAVI was made by a dedicated heart team composed of experienced clinical and interventional cardiologists, imaging specialists, cardiovascular surgeons, and anesthesiologists. The analysis reported here included 153 TAVI procedures using the S3, which were performed between June 2013 and April 2015. The S3 valve has been approved for social security reimbursement in France since September 2014. Written informed consent was obtained from all patients.

Vascular access and valve selection

Patients were selected for TAVI via the transfemoral approach (TF) or alternative approaches depending on the size, calcification and tortuosity of the ilio-femoral arterial access. The valve size was selected according to the assessment of the aortic root by multidetector computed tomography (MDCT). Appropriate sealing can be obtained at the inter-commissural level of the biscupid valve, as this inter-commissural space is usually smaller than the area-derived mean diameter. Therefore, the valve size was selected after taking into consideration not only the mean diameter calculated from the annulus area, but also the inter-commissural distance (Fig. 1).

MDCT image acquisition

MDCT images were obtained as previously described [13,15]. All examinations were performed using a Philips Brilliance 64-slice MDCT scanner (Philips Medical, Amsterdam, The Netherlands). Standard technical parameters were used: gantry rotation time 300 m, axial coverage 40 mm (64 mm × 0.625 mm), 120-kV tube voltage, 850–900 mAs intensity with no modulation and temporal resolution 165 ms. Retrospective electrocardiographic (ECG) gating was performed. Contrast enhancement was achieved with 50–90 ml of iomeprol 400 mg/ml (Iomeron®, Bracco, Milan, Italy). To achieve optimal synchronization, a bolus-tracking method was used in the descending aorta. Additional β-blockade was not administered in any case because of potential hemodynamic instability in patients with severe AS. The thickness of the reconstructed images was 0.67 mm. All data were transferred to an offline postprocessing dedicated workstation (Extended Brilliance Workspace; Philips Medical). The midsystolic phase of the cardiac cycle was selected (20% or 30% of R-R interval of the ECG spikes).

MDCT analysis

The measurement of the aortic annulus diameter was performed as described previously [16]. In short, the oblique plane that includes the nadirs of all three aortic cusps and which is perpendicular to the aortic root axis was identified. In this plane, the virtual annulus ring appears oval, allowing two orthogonal diameters (long-axis and short-axis) to be measured. The annulus surface area was then traced with a caliper. The MDCT-measured mean geometric annulus diameter was derived as follows: calculated annulus diameter (CAAD) = $2\sqrt{(\text{annulus surface area}/\pi)}$ as previously described [17]. The nominal external valve area of an expanded S3 prosthesis is 409 mm (23 mm), 519 mm (26 mm), and 649 mm (29 mm) as previously described [18]. The percentage of oversizing or undersizing was calculated using the following formula: % oversizing = (prosthesis nominal area/MDCT annular area − 1) × 100. The degree of calcification of the aortic valve was evaluated in mid-diastole using a simple linear regression method between calcification and blood densities and was described precisely [19]. An experienced level-3 cardiac CT reader performed the measurements twice, and the data represent the average of the two measurements. The CT-reader was blinded toward all outcome measurements and clinical outcomes of this study population. The intercommisural distance was measured 5 mm above the annulus plane.

Definition of BAV

BAV was defined as a deformed aortic valve with two functional cusps forming a valve mechanism with <3 zones of parallel apposition between cusps according to a previous report [20]. The classification into types depends on the number of raphes that are classified into 3 types: type 0, valves with no raphes; type 1, valves with 1 raphe; and type 2, valves with 2 raphes.

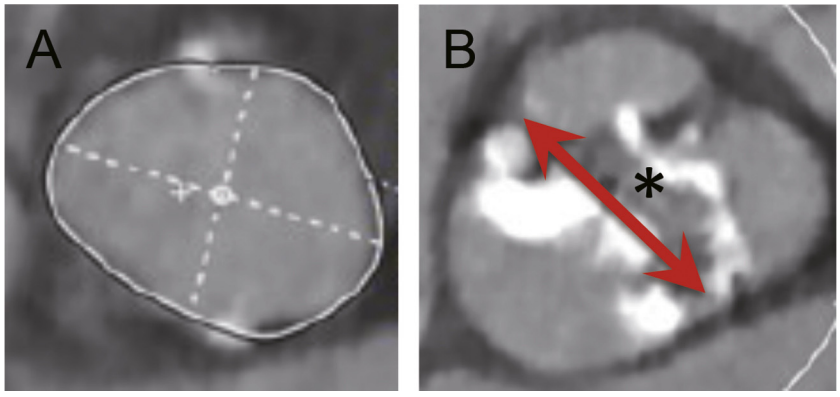

Fig. 1. (A) Multidetector computed tomography showed that the aortic annulus size was 21.5 × 24.5 mm with an area-derived mean diameter of 22.7 mm (annulus area 407 mm^2). The percentage of oversizing was 1%. (B) The inter-commissural maximal diameter was 21.8 mm. According to the percentage of oversizing of the annulus area, a 23-mm S3 valve was implanted with nominal or 1 ml over-filling of contrast. However, in this case, according to the inter-commissural diameter, 23-mm S3 valve was successfully implanted with 1 ml under-filling.

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