

Transcatheter resection of the native aortic valve prior to endo valve implantation - A rational approach to reduce TAVI-induced complications

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Introduction

Complications due to compression of diseased native aortic leaflets between the endo valve and the aortic wall after transcatheter aortic valve implantation (TAVI) have been well described.

Four factors have encouraged the evaluation of TAVI in lower-risk populations with aortic stenosis: rapid improvements in TAVI technology, increasing experience in recent years, the encouraging results obtained in multi-center registries and, most importantly, the results from the high-risk cohort of the PARTNER trial. Indeed, some preliminary results of TAVI in intermediate-risk patients with severe aortic stenosis have been promising (1).

There are already reports of TAVI in low-risk patient series. Lange (2) reported a series of 420 patients who underwent TAVI using the CoreValve (Medtronic, Inc., Minneapolis, Minnesota) or Edwards SAPIEN (Edwards Lifesciences, Irvine, California) valve. Patients undergoing TAVI in the first quartile had significantly higher logistic EuroSCORES than those in the second, third, or fourth quartiles (Q1: 25.4±16% *vs.* Q2: 18.8±10% *vs.* Q3: 18.3±11% *vs.* Q4: 17.8±12%, analysis of variance $P < 0.001$).

There were no significant differences in mortality rate observed between Q1 and Q4 after adjustment for baseline characteristics at 30-day and 6-month follow-up (30-day mortality rate adjusted HR: 0.29; 95% CI: 0.08 to 1.08; $P = 0.07$; 6-month adjusted mortality rate HR: 0.67; 95% CI: 0.25 to 1.77; $P = 0.42$).

They conclude that the results of the study demonstrate an important paradigm shift toward the selection of lower surgical risk patients for TAVI. Significantly better clinical outcomes can be expected in lower than in higher surgical risk patients undergoing TAVI. As TAVI becomes more routine widely available, operators may be tempted to implant the device in younger patients with fewer comorbidities.

In this paper we will demonstrate the necessity of resecting the native aortic valve prior to TAVI especially in young, low-risk patients. In particular, we will focus on known complications of TAVI and how native aortic valve resection may decrease the occurrence of these complications.

Potential Complications from TAVI

Paravalvular leak (PVL) post-TAVI

Percutaneous TAVI has extended our ability to treat patients with severe symptomatic aortic stenosis who would have been poor, if at all, candidates for open heart surgery (3). Today, two different major devices are available - one self-expandable and one balloon-expandable. Both devices have shown good performance once implanted, with lower transvalvular gradients and higher effective orifice areas than those observed in surgical valves (4-10). However, TAVI may result in severe complications: vascular injuries, cerebral embolisation, annulus rupture, conduction abnormalities, and paravalvular leak.

Regurgitation between the prosthetic sewing ring and the native valve annulus is a well-known phenomenon reported as paravalvular or paraprosthetic leak. In surgical series, the occurrence of paravalvular leak (PVL) has been reported in very few cases, being 2% and 8% after bioprosthesis and mechanical prosthesis respectively (11). Thus, it does not represent a major issue in the context of surgical aortic valve replacement and is not addressed in the current guidelines for valvular heart disease (12).

In contrast to surgical aortic valve replacement, during TAVI the native valve is not removed but crushed instead. Slight aortic insufficiency is not uncommon and has been reported in about 70% of patients for both available types of percutaneous valves (13-16). Moderate regurgitation has been observed in up to 40% of cases (14-16). In most cases, such aortic insufficiency is clinically acceptable, however, severe insufficiency can occur. The current reports only briefly mention the treatment of such severe insufficiency (5-9). The discrepancies in the prevalence of valve regurgitation after TAVI (17,18) are mainly due to the absence of standardized definitions and protocols to detect and score the leak. More recently, the Valve Academic Research Consortium provided a consensus aimed to standardise definitions on technical and clinical end-points in TAVI procedures (19). Nevertheless, in trying to estimate and quantify the valve regurgitation, they arbitrarily adopted a standard classification that is commonly used to describe regurgitation in native valve.

Mechanism of paravalvular leak

The aortic insufficiency after TAVI can be classified according to the type of regurgitation, its mechanism and its etiology. Paravalvular insufficiency may arise from patient-prosthesis mismatch due to under-sizing of the implanted device, incomplete expansion of the prosthesis stent frame or incorrect site of prosthesis implantation. Intravalvular insufficiency might be due to opening failure of the prosthesis' leaflets, leaflet damage occurring during the crimping maneuver or implantation phase, or again due to patient-prosthesis mismatch because of incorrect sizing of the valve.

In contrast to surgical series, direct sizing of the native aortic annulus is not possible during TAVI. The selection of the prosthesis that matches exactly with the native aortic annulus is paramount to the final procedural success, as the goal is to displace the native valve leaflets and deploy the device within the valve annulus. The native annulus should

be identified with the virtual basal ring below the nadir of the aortic cusps, which provides the right plane of the annulus that is not the anatomic ventriculo-aortic junction. Different methods are used to assess aortic annulus measurement: echocardiogram, angiography, and computed tomography. There is no gold standard for annulus measurement, and a multimodal assessment is strongly recommended (20), since the aortic annulus is not circular but might be ovoid in shape.

Tops *et al.* (21) reported that the annulus had an oval configuration in approximately 50% of patients evaluated for TAVI, with a mean difference between coronal and sagittal measurements of 3.0 ± 1.9 mm. Oval configuration of the annulus was also noted by Delgado *et al.* (22), who reported a significant difference between mean coronal (25.1 ± 2.4 mm) and sagittal (22.9 ± 2.0 mm) measurements in 53 patients with severe aortic stenosis. This oval geometry of the annulus has been previously underappreciated on imaging but has been well described in the surgical literature. Therefore multiple measurements in different planes are recommended. In this regard, the clinical use of 3D echocardiography assessing the aortic annulus in 3 planes may improve pre-TAVI evaluation over standard 2D echo. Moreover, a balloon-based annular measurement may be a useful adjunctive tool to select the proper valve size. It has been demonstrated that intraoperative evaluation of aortic regurgitation during balloon inflation for valvuloplasty increases the accuracy of the optimal device size selection (23).

Clinical impact of paravalvular leak

In most cases, aortic insufficiency is clinically acceptable and stable during follow-up (9-12), but severe insufficiency can occur. More recently, some authors have shown that even less-than-severe valvular leak might be related to higher 1-year mortality after TAVI (9). When severe regurgitation is present, multimodal imaging for an accurate assessment of the underlying pathophysiology of the regurgitation is of utmost importance in selecting adequate therapy.

Atrioventricular block (AVB)

The need for pacemaker implantation following TAVI ranges from 5.7% to 39% depending on the type of percutaneous prosthesis used (24,25). Studies assessing predictors of pacemaker implantation in the TAVI setting identified a number of candidate variables but were limited

by the small sample size.

This complication may significantly affect the outcome of the patient, increase hospital stay, overall cost of treatment and may be associated with an increased risk of sudden death. The left bundle branch exits 2 to 3 mm below the base of the triangle formed by the non-coronary and right coronary cusps of the aortic valve, close to the annulus and left ventricular outflow tract. Therefore, aortic valve surgery and any cardiac catheterization procedure requiring crossing of the aortic valve with guidewires and catheters carries the risk of trauma to the septal conduction pathways and particularly to the left bundle branch (LBB). Risk of AV block is subsequently higher in cases with pre-existing right bundle branch block (RBBB).

The reported incidence of AVB requiring a pacemaker after CoreValve implantation ranges from 18% to 39% while the incidence of LBBB is about 50%. New onset conduction disorders and requirement for pacemaker after implantation of an Edwards SAPIEN aortic bioprosthesis are infrequent (incidence of 4.3%). The Edwards SAPIEN prosthesis was specifically designed to respect nearby anatomic structures. For technical reasons, a deeper intraventricular insertion of the self-expanding CoreValve is generally observed. In the report by Piazza (25), the length of stent below the noncoronary cusp was calculated to be on average 10.3 mm (range, 6.7 to 14.6 mm) in a series of 40 patients; the cutting distance being 6.7 mm. Indeed, the lower limit of the Edwards valve should not reach the upper part of the interventricular septum and in contrast to the CoreValve's nitinol self-expandable frame, the stainless-steel stent used with the Edwards model does not keep expanding after valve deployment, thus decreasing the risk of delayed conduction abnormality and allowing safe retrieval of the temporary pacing lead at the end of the procedure (26).

Piazza *et al.* (25), in their series of CoreValve implantations, reported the occurrence of new-onset widening of the QRS complex in 30% of cases immediately after pre-implantation balloon valvotomy. Of note, in one of our patients who required permanent pacing, complete AV block occurred immediately after balloon valvotomy. The large valves used in TAVI can also result in compression of the upper interventricular septum and impair AV conduction. In their series of Edwards SAPIEN valve implantations, Sinhal *et al.* (26) reported that 10% of patients presenting with pre-existing RBBB needed pacemaker implantation. Godin *et al.* (27) reported similar outcome using similar Edwards SAPIEN valve.

Coronary ostial occlusion

A life-threatening complication is coronary artery stenosis or occlusion with a reported incidence of 0.6-7%. This data comes from the SOURCE registry (28) and large series like the Canadian experience (29). Rapid diagnosis and a staged management are mandatory to immediately save the life of the patient. Complete occlusion of the coronary ostium occurs at the time of valve deployment and is usually associated with hemodynamic collapse (30). Any hemodynamic instability of a patient after or during TAVI should raise the suspicion of coronary artery obstruction or occlusion. The only treatment option after diagnosis is immediate reestablishment of blood flow by percutaneous techniques or CABG. Crimi *et al.* (31) report a case of a transapical aortic valve implantation complicated by acute left main (LM) occlusion, cardiac arrest, and hemodynamic collapse, successfully treated by balloon angioplasty and stent implantation. In some cases, cardiopulmonary support of some sort is necessary. The need for the heart team's involvement not only in decision-making, but also throughout the procedure itself is hence obvious.

Several patient and procedure related factors potentially associated with this event have been proposed and should be considered during the selection of the patients, though their predictive value has to be confirmed by additional data. A low-lying coronary ostium, bulky native leaflets, a narrow root, an excessively enlarged valve leaflet or the new valve prosthesis itself might result in coronary occlusion. The anticipation of coronary occlusion can allow the operator to establish measures such as positioning of a protective wire in the coronary artery at risk.

In all prior reports, the coronary occlusion has not been due to the endo valve itself but rather due to the native leaflets' calcium or native leaflets' height. Webb described it clearly in his report about a single patient in whom coronary obstruction by a displaced native valve was observed (31). Until this is better understood, the presence of an unusually bulky left coronary leaflet appears to be a relative contraindication to percutaneous valve implantation.

The distance between coronary ostia and the aortic annulus is crucial. The team from Vancouver published this data in a paper by Tops in 2008 (21). Mean distance between the aortic annulus and the ostium of the right coronary artery was 17.2 ± 3.3 mm, and mean distance between the annulus and the ostium of the left coronary artery was 14.4 ± 2.9 mm. In 82 patients (49%), the length of the left coronary leaflet exceeded the distance between the

annulus and the ostium of the left coronary artery. There were no significant differences in the diameter of annulus, diameter of the sinuses of Valsalva, or the distance between the annulus, left coronary leaflet, and the ostium of the left coronary artery, between the patients with and without severe aortic stenosis.

Continuous embolisation of calcium debris

Neurological complication is a dramatic postoperative event, especially in this population with poor life expectancy. Indeed, cerebral event rates after conventional aortic valve replacement (AVR) range from 0.21% to 2.0% for neurological death and from 1.1% to 6.6% for clinical stroke (32). Magnetic resonance diffusion-weighted imaging (DWI) is a useful tool for diagnosing acute ischemic brain lesions, and has become a surrogate marker for clinical and sub-clinical brain embolism (33). We reported a rate of silent ischemic lesion of 90% after trans-femoral and 92% after trans-apical implantation of Edwards SAPIEN valve (34).

The rate of stroke reported in the TAVI literature is an important topic. In the PARTNER trial, Smith reported a rate of stroke that increases over the time (35). Rates of all neurologic events (i.e., all strokes and transient ischemic attacks) were higher in the transcatheter group than in the surgical group at 30 days (5.5% *vs.* 2.4%, $P=0.04$) and at 1 year (8.3% *vs.* 4.3%, $P=0.04$). Rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days ($P=0.20$) and 5.1% and 2.4%, respectively, at 1 year ($P=0.07$). Most strokes appeared to be procedure-related and embolic. Rates of stroke were similar whether the access was transfemoral or transapical. Despite a higher frequency of stroke with transcatheter replacement, the composite end point of death from any cause or major stroke was similar in the two study groups at both 30 days and 1 year.

Patient-prosthesis mismatch (PPM)

Aortic valve replacement in patients with severe aortic stenosis and a small aortic annulus has been associated with a high incidence of patient-prosthesis mismatch (36-39). Patient-prosthesis mismatch (PPM) has in turn been associated with diminished regression of left ventricular hypertrophy after valve replacement, reduced coronary flow reserve, increased incidence of congestive heart failure, diminished functional capacity, and increased risk of early and late mortality (40). In order to allow implantation of an appropriately sized

prosthetic valve and prevent mismatch in a patient with a small aortic annulus, an aortic annular enlargement procedure or a complete replacement of the aortic root may be necessary at the time of aortic valve replacement. These procedures significantly enhance the complexity of the operation, and may increase morbidity and mortality, especially in elderly patients (41,42).

Transcatheter aortic valve implantation has emerged as an alternative to AVR in high-risk patients with AS. However, no specific data exist on the results of TAVI in patients with a small aortic annulus. So far, only a few small series (43-47) have described the incidence of PPM after TAVI, and little is known about its impact on LV performance and clinical outcomes in these patients.

Incidence of PPM in patients undergoing TAVI

The present observation demonstrates that PPM is rather common and occurred in 18% to 20% of patients undergoing TAVI with balloon-expandable valves and between 30% to 40% using self-expandable valves. This difference can be partially explained by the fact that only one size of the device (26 mm, the smallest) was available at the time of TAVI in one-fourth of the patients (27%) in the reported series (45). In addition, the differences in prosthesis design may play a role. The Edwards SAPIEN valve is a trileaflet valve mounted on a balloon-expandable stainless stent frame that is 14.5 mm or 16 mm in height (for the 23- or 26-mm valve, respectively) and is implanted intra-annularly. Conversely, the CoreValve (designed for supra-annular implantation) has a longer frame of 53 or 55 mm (for the 26- or 29-mm device, respectively), with the lower third sitting within the LVOT.

Hemodynamic impact of PPM

Ewe in 2011 demonstrated that patients with PPM have less favorable changes post-TAVI compared with patients without PPM (45), displaying higher transvalvular gradients, limited LV mass regression and LA volume reduction, and persistently elevated LV filling pressures. The effective orifice area of the valve is higher in patients without PPM than in patients with PPM. Finally, more patients reported a lack of clinical improvement in the group with PPM.

Experimental work on resection

Our team has published experimental work on transapical

aortic valve resection in fresh cadavers (46). Resection was successful in 14/15 (93%) cadavers. The mean annulus diameter of aortic specimens measured by probe insertion was 24.2 ± 1.9 mm. The mean resected area diameter measured by probe insertion was 20.0 ± 0.5 mm.

We believe that this novel device will be very useful to decrease the amount of calcium before implantation of the endovalue by transapical approach. This will lead to a decrease in the rate of paravalvular leak, AV block, coronary occlusion and even the rate of late cerebral embolisation.

Conclusions

We believe that in the near future, all aortic valves will be replaced after careful resection of the native diseased leaflets using transcatheter-based technology. The adoption of TAVI or any other technology will be driven by the following factors: user-friendliness, teachability, validation of clinical benefit, patient preference, regulation and reimbursement. Regarding patient preference, patients almost always choose the less invasive approach even if it is less effective. If a less-invasive therapy is not inferior compared to a more invasive conventional procedure, then it is superior.

Cardiothoracic surgery is a fantastic specialty and cardiothoracic surgeons are uniquely qualified to be able to use multiple technologies to solve complex cardiac problems including percutaneous valve replacement technologies. We believe that endovalue resection before TAVI would improve already favorable outcomes in a group of some of the sickest patients and thus truly make differences in peoples lives.

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