SURGICAL TECHNIQUE AND CLINICAL IMPLICATIONS OF TRANSCATHETER AORTIC VALVE BIOPROSTHESIS EXPLANTATION

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Abstract

There has been a worldwide rapid adoption of transcatheter aortic valve replacement (TAVR) as an alternative to surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis. Currently, more TAVR explants with SAVRs are performed than TAVR-in TAV. TAVR explantation is a technically hazardous procedure mainly due to significant aortic neo-endothelialization which incorporates the TAVR valve. Surgical techniques for TAVR explantation are not well established and surgeon experience at present is limited. In this manuscript, we describe our technique for surgical explantation of transcatheter aortic bioprosthesis. Familiarity with the procedure and its clinical implications is essential for all cardiac surgeons.

INTRODUCTION

Over the past decade, there has been a worldwide rapid adoption of transcatheter aortic valve replacement (TAVR) as an alternative to surgical aortic valve replacement (SAVR) for patients with severe aortic stenosis[1-2]. TAVR outcomes have considerable improved with advances in device technology and implantation techniques. From its originally role as a less invasive alternative for high risk surgical candidates, TAVR is now performed on intermediate and even low-risk patients[3-4]. Furthermore, SAVR indications have expanded to younger patients with bicuspid aortic valves and patients with aortic insufficiency[5]. Despite this global paradigm shift in the treatment of aortic valve pathology, there are very few studies that describe surgical techniques for TAVR explantation and what the clinical implications of such procedures are.

Currently, patients undergoing TAVR procedures are advised that they will likely require a TAVR-in-TAV in the future. This is certainly true for younger, low risk patients receiving transcatheter therapies for aortic valve stenosis, given that TAVR valves will degenerate in a similar fashion, if not earlier, compared to surgical aortic bioprostheses. The issue here is that the long term outcomes of TAVR-in-TAV are unknown and the feasibility of the procedure is also uncertain. As a result, we are expecting an expeditious increase in the number of patients needing surgical explants of TAVR valves, as these valves start to fail and TAVR implants continue to increase.

There is a significant learning curve for surgically explanting TAVRs, with limited published information in regards to surgical techniques for this entity. Our surgical community has only recently started to recognize the technical hazards associated with device explants mainly due to significant aortic neoendotheliazation which incorporates the TAVR valve[6-7]. In this manuscript, we describe our technique for surgical explantation of transcatheter aortic bioprosthesis.

PREOPERATIVE WORKUP

Obtaining a computed tomography scan and reviewing the procedure notes and fluoroscopic images of the index TAVR implant are critical when planning for a TAVR explant. There are several factors that need to be taken into consideration during the preoperative workup. The type of the valve, balloon-

expandable vs self-expanding, usually determines the anatomic location of calcification, which is more prominent in the root for balloon-expandable prosthesis and at the sinotubular junction for self-expandable devices[7]. The size of the annulus and the aortic root, in relation to the size of the valve may also reflect the difficulty of the surgical explantation. For example, an oversized valve in a smaller root will most likely be associated with more neoendothelialization and adhesions. The height of the coronary ostia and the position of the valve will determine the location of the aortotomy and the potential existence of subvalvular adhesions which will require careful dissection to avoid trauma to the interventricular septum and mitral valve apparatus. The percentage of the TAVR valve skirt below the aortic annulus during the initial TAVR deployment also predicts the expected technical challenges during the explant. Finally, the age of the valve is of significant importance, as newer valves are readily explanted whereas TAVRs performed over a year ago are more challenging to remove.

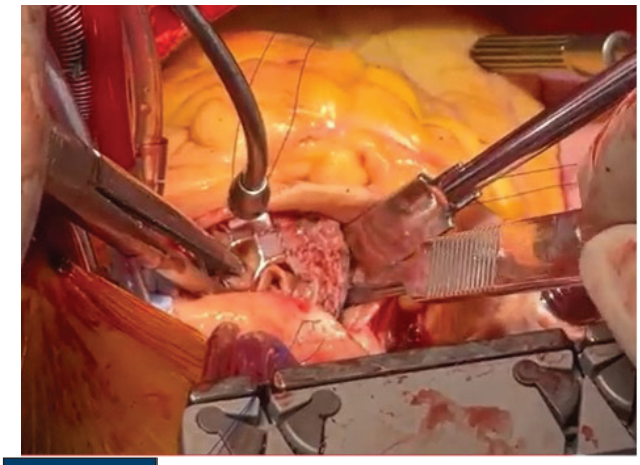

Figure 1 *Circumferential dissection of the TAVR valve using a sympathectomy dissector. The aortic root tissue is pushed off the skirt of the TAVR valve.*

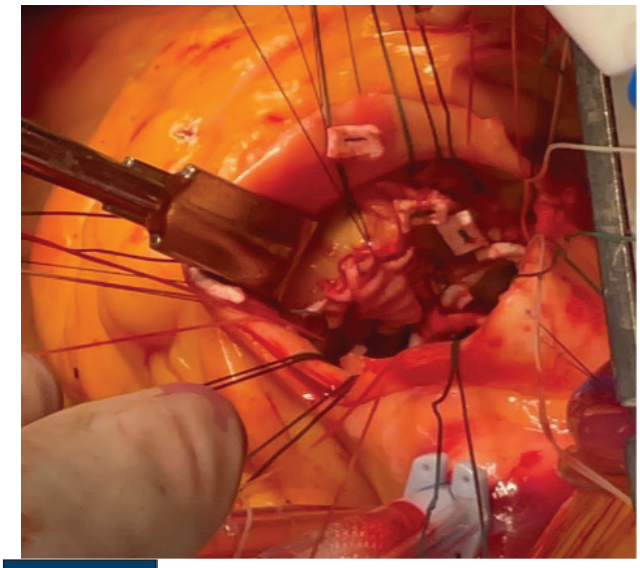

Figure 2 *Repair of iatrogenic VSD caused by TAVR explant.*

SURGICAL TECHNIQUE

The procedure is done through a standard sternotomy. When redo sternotomy is performed, we focus our dissection on the right heart and the superior mediastinum, which frees up the right atrium and ascending aorta for cannulation and placement of a retrograde cardioplegia cannula. Aortic cannulation and aortic cross clamping should be as high as possible, to allow for more working space. An LV vent through the right superior pulmonary vein is also recommended, which keeps the surgical field free of blood. The heart is arrested and myocardial protection is achieved, with delivery of antegrade and /or retrograde cold blood cardioplegia. Direct ostial cardioplegia deliver can sometimes be challenging, owing to the limited space in the aortic root, which is caused by the stent cage, the native leaflets pushed up against the aortic wall and the associated extensive aortic calcification. For patients with severe aortic regurgitation, when direct ostial delivery of cardioplegia is not possible, placing a coronary sinus catheter for retrograde cardioplegia is essential. When indirect insertion of a retrograde catheter is not possible (large Thebesian valve, small sinus, pacemaker leads), an open direct placement should be performed. For patients with severe AI and small aortic roots with or without severe calcifications, we recommend to preemptively perform bicaval cannulation, in anticipation for needing a right atriotomy for direct access to the coronary sinus.

For balloon-expandable valves, a standard transverse or oblique aortotomy is performed. For self-expanding devices, the aortotomy should made at the edge of the stent frame, which is easily palpable. Attempting to force a lower aortotomy through the stent cage, especially in older valves, may denude the aortic tissue along the aortotomy. The myth of pouring ice cold saline on the TAVR valve frame to make it easily retrievable is usually busted in almost all cases immediately. Once the valve is exposed, a Kocher clamp is used to grab the body of the valve and crush the stent cage. This will alleviate the radial force that secures the valve in place and once this is performed, the valve should come out easily, especially for implants that have been in for less than 6-12 months. For valves that are 12 months or older, explantation is more challenging owing to aortic neoendothelialization which extends into stent cage. We initially create an endarterectomy plane between the aortic intima and the valve using a #15 scalpel blade. A Kocher clamp is used as a handle to maneuver the valve and apply counter-tension. Utilizing two clamps can be more advantageous. Once the plane is circumferentially created, a sympathectomy dissector is used to push aortic root tissue off the skirt of the TAVR valve (figure 1). Careful dissection around the coronary ostia is necessary when adhesions are present, although the ostia are usually spared from the neoendotheliazation process, probably because of the presence of the native aortic valve leaflets sandwiched between the TAVR valve and the sinuses during the initial implantation. The same maneuver is performed deeper at the ventricular septum, membranous septum and aortomitral curtain, thus avoiding structural trauma. In some instances, valve adhesions are extremely severe and injury to subvalvular structures and / or

the annulus is inevitable. Any structural defects created during valve explantation are repaired with bovine pericardial or dacron patches (figure 2).

Once the valve is resected, the site is irrigated copiously to remove debris. Our technique for the surgical aortic valve replacement is slightly different in terms of suture selection. We use a combination of longer 23mm mitral suture needles on the thicker side of the annulus, particularly along the aortomitral curtain and the shorter 17mm aortic needles on the thinner side of the annulus along the membranous septum to avoid injury to the AV node. The rest of the aortic valve replacement proceeds in the usual fashion.

For valve-in-valve explants, a Kocher clamp is used to grab the valve sutures of the outer surgical valve and retract the entire valve-in-valve apparatus away from the annulus. This exposes the skirt of the inner TAVR valve with its attachments to the annulus and left ventricular outflow tract which are carefully dissected as described above. Once the surgical valve sutures are cut, the majority of the inner TAVR valve is usually freed. We feel that the valve-in-valve TAVR explantation is more forgiving than the older TAVR valve explants.

When significant damage to the aortic root has occurred, mainly in cases with dense root adhesions and severe neoendothelialization invading the TAVR valve, surgeons should be prepared to perform a root replacement.

INSTITUTIONAL TAVR EXPLANT OUTCOMES

Since June 2021, at our institution, we have performed 6 TAVR explants. Mean age was 74 (range 59-79), 67% were males (4/6), mean BMI was 31 (range 25-39), 67% were in NYHA class IV and the mean STS predicted risk was 11.42 at the time of surgery. The median age of the TAVR valve was 202 days (range 28-625 days). Explanted TAVR valves were balloon expandable in 67% (Sapien 3) and self expandable in 33% (one CoreValve and one Evolut). One TAVR explant was a redo sternotomy (previous CABG). Mortality at 30 days was 0%. Average length of hospital stay was 10 days (range 6-45 days). Prolonged hospital stay (45 days) was required for a 79 year old male patient who had a postoperative stroke and acute renal failure requiring dialysis. He had severe carotid artery disease, chronic renal failure and severe Ejection Fraction dysfunction (EF 25%). Survival at 180 days was 100%. Postoperative complications included: acute renal failure (50%, 3/6), stroke (17%,1/6), ventilator dependent respiratory failure (vent support >48hr) (33%, 2/6), infection (33%, 2/6). Permanent pacemaker was required in 20%, 1/5 and one patient already had a permanent pacing device prior to TAVR explant. Three patients (50%) required a concomitant procedure which consisted of aortic root replacement (17%), ascending aortic replacement (17%) and VSD repair (17%). Ascending aortic replacement was performed after removing a self expandable valve, whereas root replacement and VSR repair were required for self-expanding valves. The most common cause for TAVR explant was bioprosthetic endocarditis (67%, 4/6), followed by severe symptomatic PVL (33%). Coronary heights prevented the two PVL cases from undergoing TAV-in-TAVR.

DISCUSSION

Our aim here is to describe a reproducible and safe surgical technique for early and late explantation of the two main types of utilized TAVR valves and to provide an insight into the clinical implications associated with the procedure. Clearly, late explants are more technically challenging than rescue procedures for early device failures. Familiarity with TAVR explants, which are expected to become more frequent, will certainly improve postoperative outcomes and make it a less daunting procedure for surgeons. The importance of applied surgical anatomy and the critical surgical insight during these technically challenging procedures cannot be overemphasized.

Only a limited number of studies have reported outcomes of post TAVR explants with subsequent SAVR, with mortality appearing to be very high. Yokoyama et al [9] published a meta-analysis of observational studies and case series and identified 1690 patients that underwent TAVR explant. They reported that the TAVR explant rate among TAVR recipients was 0.4% (95% CI 0.2-0.6%), with a mean age of 73.7 years and a 30 day mortality of 16.7% (95% CI 12.2-21.1%). Balloon-expandable valves were more frequently explanted compared to self-expandable (59.8% vs 40.2% respectively). The etiologies of TAVR explant were not reported in this study. Fukuhara et al[6], published the University of Michigan experience with 15 TAVR explants performed over an 8 year period. They reported that 100% of patients ($p=0.004$) with valves older than a year old developed postoperative renal failure, 67% of all patients required permanent pacemaker placement and the operative mortality was 11%. The clinical indications for surgical TAVR explant were: paravalvular leak (41.2%), SVD (23.5%), intraprocedural coronary obstruction (11.8%), intraprocedural valve migration (11.8%) and endocarditis (5.9%). The same group recently published TAVR explant data from 2016-2019, comparing balloon expandable with self expandable, using the STS database[10]. During TAVR explant, they found that 63% of patients required a concomitant procedure, most commonly an aortic repair (27%). Self-expandable underwent more ascending aortic replacements (22% vs 9%, $p<0.001$), whereas root replacement was similar between the two cohorts (19% vs 24%, $p=0.22$). The overall 30 day mortality rate was 18%, without differences in mortality or morbidity between the groups.

Taking into account the technical demands of a TAVR explant and the subsequent high mortality associated with the procedure, we feel that the expansion of TAVR indications to low risk patients and furthermore to younger patients should be reconsidered. Currently when assessing potential TAVR candidates, nobody is discussing the potential need for a future complex surgical explant, but are rather focusing on the option of TAVR-in-TAV, although the feasibility of TAVR-in-TAV is not well established. Tang *et al*[11] studied the feasibility of TAVR-in TAV based on the coronary height from coplanar views obtained during 551 TAVR implants. They reported that 21.4% of patients would not be candidates for a TAVR-TAV procedure in the future, owing to left main obstruction risk.

The unfeasibility of TAVR-in-TAV is certainly much higher when taking into consideration all etiologies for exclusion from a TAVR re-intervention.

In conclusion, surgical explantation of TAVR valves older than 12 months is a complex and challenging procedure, whereas newer valves are removed easier. Surgical techniques for TAVR explantation are not well established and surgeon experience at present is limited. In addition, reported outcomes are dismal, with mortality rates as high as 20%. Current published data demonstrate an explant rate of <1%, however we anticipate a rapid increase in this number in the near future. Familiarity with the procedure and its clinical implications is essential for all cardiac surgeons.

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