Surgical mitral valve replacement using direct implantation of Sapien 3 valve in patients with severe mitral annular calcification without adjunctive techniques, a case report

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Abstract

Background: Mitral annular calcification (MAC) occurs represents a challenge to surgeons during mitral valve (MV) surgery with increased perioperative risk.

Case presentation: We describe a challenging case of an elderly female patient with multiple comorbidities who presented with symptoms and signs of heart failure with a previous history of mechanical aortic valve replacement 15 years prior to presentation. Echocardiogram showed severe mitral stenosis and regurgitation with severe calcification of the mitral annulus. Given her high-risk profile and unavailability of suitable percutaneous therapeutic options we decided to replace her mitral valve with Sapien 3 valve under direct exposure. The case describes the technical details for the valve implantation and demonstrates the viability of this option in high risk surgical patients without the need for adjunct techniques like predilatation, additional supporting sutures or patches with a review of the literature on open surgical implantation of Sapien 3 valve.

Conclusion: Direct open surgical implantation of Sapien 3 valve can be implanted safely in patients with severe MAC, without predilatation and without the use of other adjunctive techniques like fixation sutures or patches.

Keywords: Mitral valve replacement, Sapien 3 valve, MAC, Direct implantation

Background

Mitral annular calcification (MAC) occurs in 10% of the population with increasing prevalence with advancing age (up to 40% above 80 years) [1, 2] and it is independently associated with all-cause mortality [3]. It represents a challenge to surgeons during mitral valve (MV) surgery with up to 6 folds increase in perioperative risk [4]. Unfortunately, percutaneous interventions in this high-risk group of patients still carry a higher risk than open surgery with 30-day mortality of 25% and 1-year mortality of 53.7% [5, 6].

We report in this paper a case of open surgery for mitral valve replacement (MVR) in a high-risk patient with severe MAC using the direct implantation of Sapien 3 valve that is designed for percutaneous use without the use of any adjunctive techniques and we reviewed the literature in this subject. This is the first case implanted directly without the use of fixation sutures or any other adjunctive techniques.

Case presentation

This is a case of a 75-year-old lady who is known to have diabetes mellitus, hypertension, hypothyroidism, adrenal suppression, previous history of stroke and a history of aortic valve replacement with mechanical prosthesis 15 years prior to presentation. She was admitted urgently to
the cardiac care unit with shortness of breath on exertion class III and lower limb edema. Chest X-Ray was compatible with pulmonary edema. Echocardiogram showed a well-functioning aortic prosthesis but severe mitral valve stenosis (MS) and mitral regurgitation (MR) with severe Mitral annular calcification (MAC) (video 1, 2).

The patient was stabilized medically then underwent Cardiac CT to characterize the MAC that appeared as a dense horseshoe calcification occupying most of the circumference of the mitral annulus (Video 3, 4). The case was discussed in the multidisciplinary rounds and she was deemed very high risk for surgical intervention with a calculated STS risk score of (19.5%). Given the patient age and frailty, it was not reasonable to decalcify the mitral annulus and reconstruct the annulus that may lead to high risk of Atrio-ventricular (AV) groove dissociation. So the decision was taken to implant the Sapien 3 valve in the mitral position under direct vision after redo sternotomy. To predict the risk of post procedure LVOT obstruction, the neo LVOT was assessed preoperatively during systole by measuring the distance from the inter-ventricular septum to the frame of the simulated transcatheter valve and then calculating the neo LVOT area which was 211 mm² in this case. However, there is no set threshold for LVOT obstruction when this procedure is done using transatrial approach and the anterior mitral leaflet is excised since the calculated neo LVOT is underestimated due to the fact that there is flow through the cells of the valve stent frame.

Intraoperatively, and after exposing the mitral valve, the anterior leaflet was excised and was thickened and fibrosed (Video 5). The posterior calcium bar was so prominent that made the MV orifice very small not even accommodating size 25 regular MV prosthesis sizer. We decided preoperatively to use the largest Sapien 3 valve (size 29) based on the mitral orifice size from CT scan with additional 20% oversizing. We loaded the valve on the balloon in a similar way to the transapical aortic approach and we advanced the balloon inside the ventricle until the end of the valve stents was just across the mitral annulus (Video 6). We elected not to perform a balloon predilatation to avoid fracture of the calcium body or to induce atrioventricular groove rupture. Subsequently one operator was responsible for inflating the balloon and another one was responsible for stabilizing the position of the valve across the annulus with fine tuning the direction of the valve during inflation of the balloon. The balloon was inflated until an atmospheric pressure of 4 and kept inflated for 15 s then deflated (Video 7). The valve was nicely deployed and stable in position with normal movement of the leaflets. We did not use supportive sutures to fix the valve nor utilized any patches or skirts around the valve. The patient was weaned smoothly from bypass and intraoperative transesophageal echo was performed and showed that the valve is well seated in position with no evidence of any paravalvular leak (Video 8, 9). The mean gradient across the valve was 4 mmHg.

Discussion

Surgery for MVR carries very high risk in patients with MAC and percutaneous MVR techniques did not result in lower risk in this group of patients given its limitations in implantation techniques and the risks of paravalvular leaks and Left ventricular outflow tract (LVOT) obstruction. Hence there is a great need for further development in this field.

The first world-wide case of open antegrade placement of transcatheter valve for MVR was reported by Thierry Carrel et al. in June, 2012. They used SAPIEN XT size 26 valve in an 81 years old woman with severe MR & moderate MS. They decided to use this innovative method to avoid debridement of severe MAC and also due to small annulus, only 19 mm sizer were able to pass after resection of the anterior and part of the posterior leaflet [7]. Since that time only 36 cases were reported in the literature using open antegrade placement of transcatheter valve for MVR (Table 1). All these cases were performed using additional adjunctive techniques for implantation including balloon pre-dilatation, suture fixation, Teflon skirts around the valve and patches around the valve and sutured to the left atrial wall.

The direct surgical implantation of the percutaneous valves has some potential benefits including better orientation of the valve with accurate control of the device depth that may results in lower risk of paravalvular leak. It also allows for excision of the native leaflets that eliminates the risk of LVOT obstruction and decreases the risk of embolization.

In our case, we elected not use balloon pre-dilatation of the annulus in order to avoid the risk of calcium disruption or annular tear. We also wanted to avoid oversizing of the MV orifice before the valve deployment that may lead to paravalvular leak. We also decided not to place any additional fixation sutures for the device neither to use any patch around the device in order to shorten the cross-clamp time as much as possible especially in our elderly lady. We used 20% valve oversizing as the only technique to fix the valve in place using the device radial force. This is the first report of direct catheter based mitral valves implantation without adjunctive techniques.

The SITRAL study (Surgical Implantation of TRAnscatheter vaLve in Native Mitral Annular Calcification Study) [21] was designed to establish the safety and feasibility of the SAPIEN 3 valve for severe MS/MR associated with severe calcification in high risk or inoperable
| Author Year | No. of Cases | Age/ Sex | Type of Valve | Valve Size | Redo Access | MAC Indication | Note |
|-------------|--------------|----------|---------------|------------|-------------|----------------|------|
| Carrel et al. [7] 2012 | 1 | 81/F | Sapien XT | 26 | Yes | Sternotomy | Severe MR/ Moderate MS | 1st case |
| Astarci et al. [8] 2013 | 1 | 62/F | Sapien XT | 26 | No | Sternotomy | Severe MS/ Moderate MR | AVR + MVR+ CABG |
| Ferrari et al. [9] 2014 | 1 | 60/M | Sapien XT | 29 | No | Rt Thoracotomy | Severe MS | Hx of chest radiation |
| Lee et al. [10] 2016 | 1 | 83/F | Sapien XT | 29 | No | Sternotomy | Severe MR | |
| Murashita et al. [11] 2016 | 1 | 71/F | Sapien XT | 29 | No | Sternotomy | Severe MS | |
| Baumgarten et al. [12] 2016 | 3 | 1. 89/F 2. 83/F 3. 85/F | Sapien XT 1. 26 2. 26 3. 29 | Yes No No Mini Thoracotomy | 1. Yes 2. No 3. No 1. Severe MS | |
| Langhammer et al. [13] 2017 | 4 | 1. 80/F 2. 60/M 3. 79/F 4. 74/F | Sapien XT 1. 26 2. 29 3. 29 4. 29 | Yes No No No Sternotomy | 1. Yes 2. No 3. Yes 4. No 1. Severe MR/ Moderate MS | |
| Alfonsi et al. [14] 2017 | 1 | 76/F | Sapien XT | 26 | No | Sternotomy | Severe MS | 5. Post op mild PVL |
| Koehle et al. [15] 2017 | 1 | 66/ F | Sapien XT | 26 | Yes | Sternotomy | No | Severe MS Inserted inside a mechanical prosthesis ring |
| Polomsky et al. [16] 2017 | 2 | 1. 81/ M 2. 69/ F | Sapien 3 1. 26 2. 26 | No | Sternotomy | Yes | 1. Mixed 2. Severe MS |
| Gallo et al. [17] 2018 | 1 | 73/F | Sapien 3 | 29 | No | Sternotomy | Severe MS | |
| Russell et al. [18] 2018 | 8 | 1. 65/M 2. 78/F 3. 74/M 4. 87/F 5. 80/M 6. 77/M 7. 75/F 8. 69/F | Sapien 3 1. 29 2. 29 3. 29 4. 29 5. 29 6. 29 7. 26 8. 26 | Yes Yes Yes Yes Yes Yes Yes | Sternotomy/ Thoracotomy | Yes | (all) | (all) | PVL immediately post-implantation was none or trace in 6 patients and mild in 1. There were no cases of moderate or severe PVL. One patient with mild PVL post-TMVR developed hemolysis 6 months post-TMVR that was successfully treated with percutaneous closure using a vascular plug. There were no procedural major complications, including clinically significant LVOT obstruction, annular rupture, valve embolization, or migration. The mean length of stay has been 7.9 days following surgery. There were no in-hospital or 30-day mortalities. No patient had a stroke. One patient (#5) died at home 7 months post-operatively; all other patients are alive. |
Table 1 Literature Summary of Open Antegrade Placement of Transcatheter Valve for Mitral Valve Replacement (Continued)

| Author et al. | Year | No. of cases | Age/ Sex | Type of valve | Valve size | Redo Access | MAC indication | Note |
|--------------|------|--------------|----------|---------------|------------|-------------|----------------|------|
| Tabachnick et al. [19] | 2018 | 10 | 1. 87/F | 1. Sapien XT | 1. 26 | NA | Mini | 1. Stenosis |
| | | | 2. 84/F | 2. Sapien 3 | 2. 26 | | | 2. Mixed |
| | | | 3. 86/F | 3. Sapien 3 | 3. 29 | | | 3. Mixed |
| | | | 4. 87/F | 4. Sapien 3 | 4. 29 | | | 4. Mixed |
| | | | 5. 77/F | 5. Sapien 3 | 5. 26 | | | 5. Stenosis |
| | | | 6. 71/F | 6. Sapien XT | 6. 26 | | | 6. Stenosis |
| | | | 7. 76/F | 7. Sapien XT | 7. 26 | | | 7. Mixed |
| | | | 8. 70/F | 8. Sapien XT | 8. 26 | | | 8. Stenosis |
| | | | 9. 83/F | 9. Sapien 3 | 9. 29 | | | 9. Mixed |
| | | | 10. 80/F | 10. Sapien XT | 10. | | | 10. Mixed |
| | | | 8 details | 80/F | | | | |
| Ahmad et al. [20] | 2019 | 1 | 68/F | Sapien XT | 26 | No | Sternotomy | Yes | Severe MS |

Conclusion
Direct open surgical implantation of Sapien 3 valve can be implanted safely in patients with severe MAC, who are at high risk of complications from calcification of the mitral annulus, without predilatation and without the use of other adjunctive techniques like fixation sutures or patches. Longer follow up for these valves are needed to show the long-term outcomes of these techniques.

Supplementary information
Supplementary information accompanies this paper at https://doi.org/10.1186/s13019-020-1083-8.

Additional file 1 Video 1: Preoperative 2D Echocardiogram.
Additional file 2 Video 2: Preoperative 3D Echocardiogram.
Additional file 3 Video 3: Sagittal Reconstruction of Cardiac CT.
Additional file 4 Video 4: 3D Reconstruction of Cardiac CT.
Additional file 5 Video 5: Excision of the Anterior Mitral Leaflet.
Additional file 6 Video 6: Valve Positioning Across the Mitral Annulus.
Additional file 7 Video 7: Valve Deployment over a Balloon.
Additional file 8 Video 8: Postoperative 2D Echocardiogram.
Additional file 9 Video 9: Postoperative 3D Echocardiogram.

Abbreviations
AV: Atrio-Ventricular; LVOT: Left Ventricular Outflow Tract; MAC: Mitral Annular Calcification; MR: Mitral Regurgitation; MS: Mitral Stenosis; MV: Mitral Valve; MVR: Mitral Valve Replacement

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Authors’ contributions
All authors have made substantial contributions to the conception of the work, interpretation of data, and have drafted the work. All authors have approved the submitted version and agreed both to be personally accountable for the author’s own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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