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ORIGINAL ARTICLE

Use of Transcatheter Valves for Open Surgical Mitral Valve Replacement. Australian Experience

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Background Mitral valve procedures remain a surgical challenge in the presence of extensive annular calcification, which presents a formidable technical challenge. Aggressive debridement is limited by risk of serious complications and the technical complexity of pericardial patch reconstruction of the debrided area.

Methods An open surgical approach with a transcatheter valve allows the valve to be placed under direct visualisation to facilitate positioning and to evaluate the likelihood of both perivalvular leakage and atrioventricular disruption. The open approach has the additional advantage of performing concomitant surgeries like other valve procedures, arrhythmias surgeries and coronary bypass.

Results We present our experience with open surgical mitral valve replacement (MVR) using transcatheter valve in different patients requiring varied procedures. These patients were not suitable for MVR using standard prosthetic valve and techniques. They were also not suitable for percutaneous MVR because of heavily calcified anterior mitral leaflet and the other concomitant procedures required.

Conclusions Open MVR with a transcatheter balloon-expandable valve can avoid the need for technically challenging and high-risk decalcification of mitral annulus. These novel techniques using transcatheter valves can be successful in complex cases where standard prosthetic valves are impossible to implant in a heavily calcified mitral annulus.

Keywords Extensive mitral annular calcification • Open mitral valve replacement • Transcatheter aortic valve • Edwards Sapien valve

Introduction

Mitral valve procedures remain a surgical challenge in the presence of extensive mitral annular calcification (MAC) which presents a formidable technical challenge. It is a degenerative process affecting mostly elderly patients. Aggressive debridement is limited by risk of serious complications and the technical complexity of pericardial patch reconstruction of the debrided area. A small, hypertrophied ventricular cavity in severe mitral stenosis adds to the potential problems.

We present our experience with open surgical mitral valve replacement (MVR) using transcatheter valves in different patients who required varied procedures.

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Methods

We used transcatheter valves to replace heavily calcified mitral valve with extensive MAC by open surgery in three patients who had varied diagnoses.

Patient 1

A 68-year-old obese (110 kgs) woman presented with worsening exertional dyspnoea for last 5 years. She had decreased exercise tolerance to 15 metres at the time of presentation. She had a background of chemotherapy and radiotherapy for Hodgkin's lymphoma 12 years before and was a type-2 diabetic on oral hypoglycaemic medications. Transthoracic (TTE) and transoesophageal echocardiograms (TOE) showed a heavily calcified mitral valve (especially anterior mitral leaflet, anterior mitral valve leaflet (AML)) with extensive mitral annular calcification (MAC) with extension of calcification in the subvalvular apparatus (SVA), significant leaflet restriction (mean gradient, MG = 20 mmHg and peak gradient, PG = 40 mmHg) and moderate tricuspid valve (TV) regurgitation. Coronary angiogram showed mild coronary artery disease with extensive circumferential MAC (doughnut appearance) and left circumflex coronary artery (LCX) running very close to the posterior annulus. (Figure 1). Cardiac computed tomography (CT) confirmed severe circumferential MAC, particularly thick along the posterior leaflet attachment, measuring up to 1.6 cm and LCX in close proximity to the heavily calcified posterior mitral annulus (Figure 2). The antero-posterior diameter of the annulus on CT-chest imaging was used to decide on the optimum size and position of the valve.

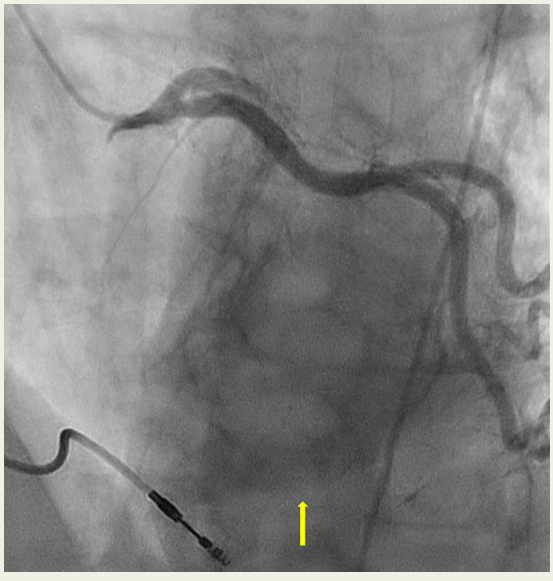

Figure 1 Coronary angiogram image showing extensive circumferential calcification of mitral annulus (doughnut appearance, yellow arrow) and left circumflex artery running very close to the posterior annulus.

The patient was discussed in a combined multidisciplinary meeting and it was decided that she was not safe for MVR with standard prosthetic valve and techniques in view of the dense and extensive calcification of mitral annulus and subvalvular apparatus considering the risks of atrioventricular dehiscence and injury to LCX artery. She was also not suitable for percutaneous implantation of a transcatheter valve into the mitral annulus in view of the heavily calcified anterior mitral leaflet which could cause left ventricular outflow tract (LVOT) obstruction from systolic anterior motion (SAM). An open surgical MVR via the left atrium with a transcatheter valve and TV repair was planned.

Approval was obtained from Australian Government Department of Health under the Special Access Scheme (SAS) Category B to use the transcatheter Edwards Sapien valve for MVR.

The patient underwent successful MVR using a 29 mm Edwards Sapien-XT valve (Edwards Lifesciences, Irvine, CA, USA) and TV repair with 32 mm Edwards Physio-II ring. Standard cardiopulmonary bypass (CPB) techniques using aorto-bicaval cannulation, antegrade aortic-root and retrograde cardioplegia, left atrium (LA) and right atrium (RA) approaches were used. A 30° thoracoscope was used for better visualisation. There was a large calcified mass in AML which was excised to avoid LVOT obstruction (Figure 3). The heavily calcified mitral annulus with a markedly reduced valvular orifice area that was unable to accommodate a 19-mm valve sizer (Perimount; Edwards Lifesciences). But after the excision of the calcified mass in AML and careful annular debridement, the annulus could accommodate a 25-mm Perimount sizer. A 29 mm sized Edwards Sapien-XT valve was chosen because the mitral commissure-to-commissure dimension was measured to be around 28 mm on preoperative cardiac CT imaging.

The Sapien valve was deployed into the mitral annulus under direct vision and without using its Ascendra delivery sheath, with enough balloon inflation used to achieve adequate coaptation with the annulus (Figure 3). The metal strut positions were inspected to avoid LVOT obstruction. Cardiopulmonary bypass time was 147 minutes, and cross-clamp time was 116 minutes. Post-bypass TOE showed the prosthetic Sapien valve implanted in mitral annulus functioning well with trivial regurgitation and mean gradient of 3 mmHg. The mean LVOT gradient was 20 mmHg.

The patient had an uneventful postoperative recovery and was discharged on postoperative day 8 on a regimen of low-dose aspirin for anticoagulation.

The patient is doing well since then and is in New York Heart Association (NYHA) functional class I in her latest follow-up. Transthoracic echocardiocardiograph (after 1 year and 3 months of operation) has shown well-functioning aortic prosthetic valve in mitral position, with a mean gradient of 2 mmHg and trivial regurgitation. The mean LVOT gradient was 15 mmHg.

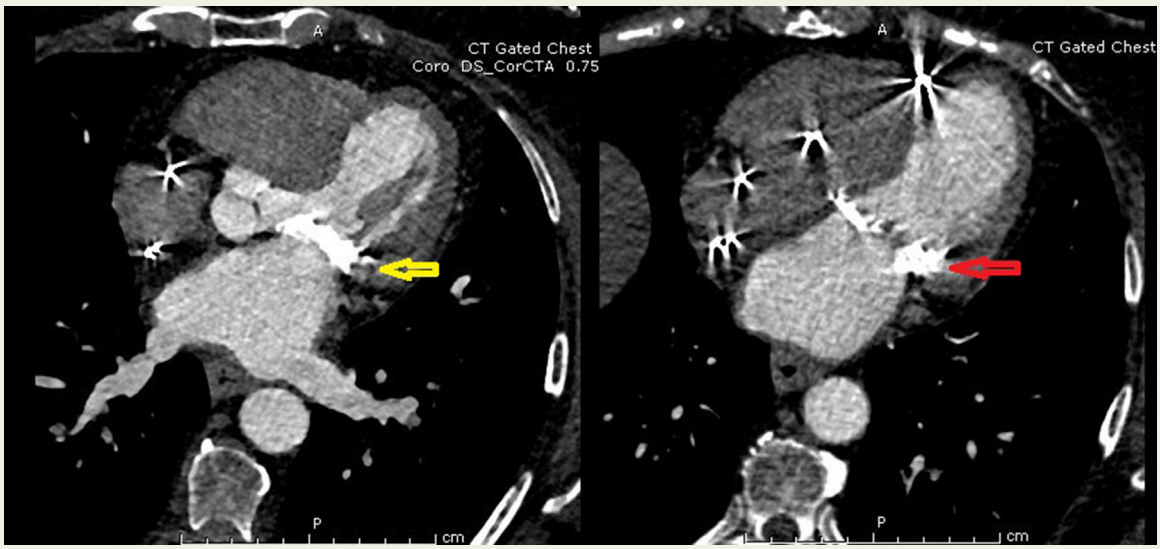

Figure 2 Cardiac computed tomography images showing severe circumferential mitral annular calcification, particularly thick along the posterior leaflet attachment.

Patient 2

A 67-year-old man presented with worsening dyspnoea on exertion for last 3 years. He was in NYHA functional class III at the time of presentation. He had a background of radiotherapy for Hodgkin's lymphoma at the age of 22 years, TTE and TOE showed a heavily calcified MV (especially AML) with severe MAC and significant leaflet restriction of both leaflets (MG = 15 mmHg, PG = 26 mmHg), moderate mitral regurgitation, moderate calcific aortic stenosis (AS) and severe focal atheroma in aortic root with diffuse mild thickening of ascending aorta consistent with radiation-induced heart disease (RIHD). Full heart study showed severe two-vessel coronary artery disease [involving second obtuse-marginal (OM2) and right coronary arteries (RCA)] with severe MAC and moderate-severe pulmonary arterial hypertension (PAH).

He underwent successful MVR using a 29 mm Edwards Sapien-XT valve, aortic valve replacement (AVR) with 23 mm Edwards Magna Ease valve with aortic endarterectomy and coronary artery bypass grafting (CABG) X 2 [left radial artery to posterior descending branch of RCA and saphenous vein graft to OM2]. Standard CPB techniques using aorto-bicaval cannulation, antegrade aortic-root and retrograde cardioplegia, left atrium (LA) and transverse anterior aortotomy approaches were used. A 30° thoracoscope was used for better visualisation. The MV was heavily calcified with both leaflets and surrounding annulus calcified around its entire circumference (Figure 4). This extended into the aorto-mitral curtain. The AV was similarly heavily calcified as was the aortic root. The heavily calcified AML was excised to avoid LVOT obstruction and the annulus was sized to approximately 26 mm in diameter. A 29 mm sized Edwards Sapien-XT valve was crimped onto the balloon and deployed into the mitral annulus under direct vision, with enough balloon inflation used to achieve adequate coaptation with the annulus (Figures 5 and 6). The metal strut positions

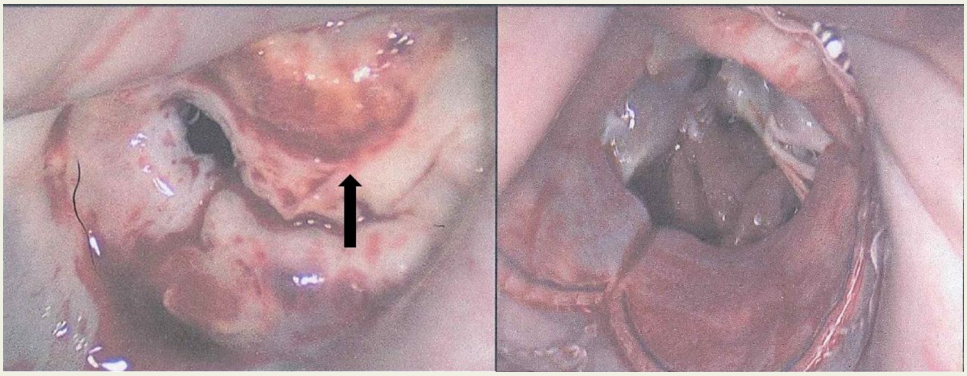

Figure 3 Intraoperative image using a 30° thoracoscope, **Left:** showing a large calcified mass in anterior mitral leaflet (AML); **Right:** showing the transcatheter Sapien valve implanted in mitral annulus.

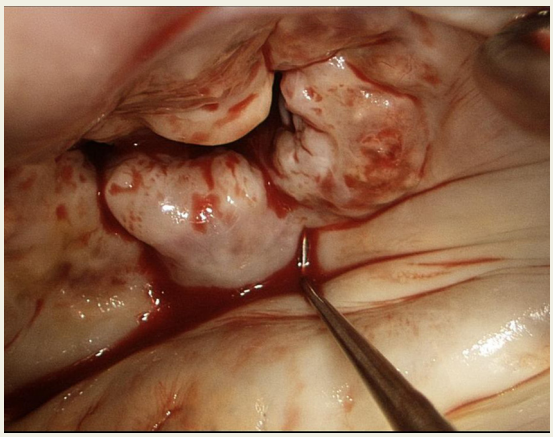

Figure 4 Intraoperative image showing the extensive mitral annular calcification (MAC) and leaflets calcification.

were inspected to avoid LVOT obstruction. Through transverse aortotomy, AV leaflets were excised and the annulus was partially debrided. Aortic endarterectomy was done in the non-coronary sinus to facilitate both seating the valve and subsequent aortic closure. A 23 mm Magna Ease valve was then seated well in a supra-annular position with a mixture of pledgetted and non-pledgetted 2/0 polyester sutures. The two aorto-coronary top ends of the grafts were then constructed.

Cardiopulmonary bypass time was 122 minutes, and cross-clamp time was 93 minutes. Post-bypass TOE showed the prosthetic Sapien valve implanted in mitral annulus and the aortic valves functioning well with trivial regurgitation with mean gradient across the Sapien valve was 9 mmHg. There was dynamic LVOT obstruction noted with mean gradient of 70 mmHg. The mechanism could be related to the struts of the Sapien valve in MV position.

The patient recovered well from surgery and was discharged with low-dose aspirin on postoperative day 12.

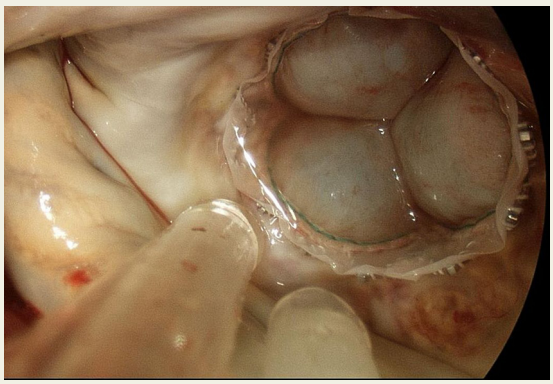

Figure 6 Intraoperative image showing the well-positioned transcatheter valve.

Predischarge TTE revealed a mean gradient of 8 mmHg across MV and 65 mmHg across LVOT.

The patient is in NYHA functional class I in latest follow-up after 1 1/2 years of operation. His TTE showed well-functioning prosthetic mitral and aortic valves with trivial regurgitation and mean gradients of 7 mmHg across MV and 55 mmHg across the LVOT.

Patient 3

An 83-year-old woman presented with worsening exertional dyspnoea for last 3 years. She was in NYHA functional class III–IV at the time of presentation and had a recent history of multiple admissions for congestive cardiac failure and acute pulmonary oedema, the last one being 2 months ago. She had a background of type-2 diabetes (on insulin), hypertension, asthma, chronic kidney disease (baseline creatinine = 113) and hypercholesterolaemia. Transthoracic echocardiogram and TOE (Figure 7) showed a heavily calcified mitral valve with extensive MAC and extension of calcification in the SVA (MG = 17 mmHg), severe calcific AS (MG = 87 mmHg, valve area = 0.5 cm^2) and severe PAH (pulmonary artery

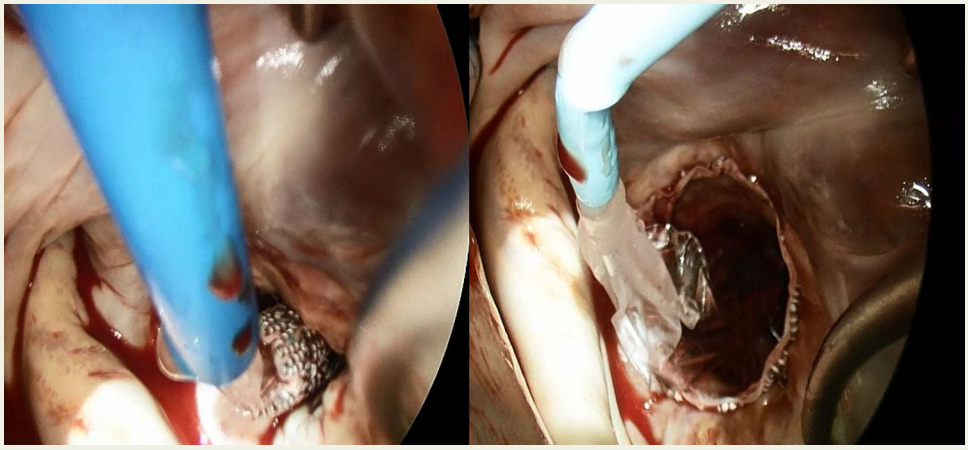

Figure 5 Intraoperative images, **Left:** showing the transcatheter valve crimped onto the balloon and being deployed; **Right:** showing the transcatheter Sapien valve implanted in mitral annulus.

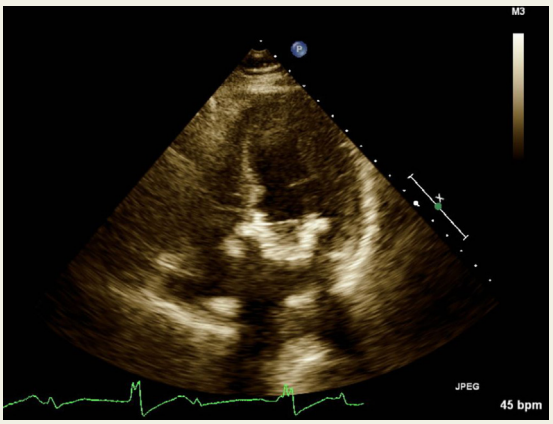

Figure 7 Preoperative transthoracic echocardiograph image showing a heavily calcified mitral valve with extensive annular calcification.

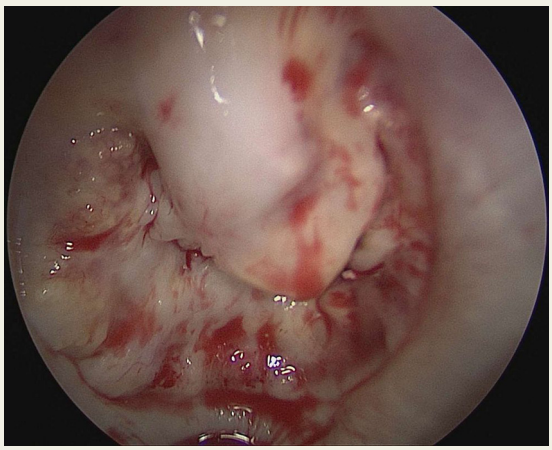

Figure 9 Intraoperative image showing the extensive mitral annular calcification, especially in anterior mitral valve leaflet (AML).

pressure = 75/40 mmHg). Coronary angiogram showed mild coronary artery disease with extensive circumferential MAC. Cardiac computed tomography (CT) revealed severe circumferential MAC extending into SVA and onto LV wall (Figure 8).

The patient was discussed in a combined multidisciplinary meeting and it was decided that she needed the double-valve replacement which was high-risk considering its complicated nature, co-morbidities and poor baseline function (mainly housebound and often bed-bound).

Standard CPB techniques using aorto-bicaval cannulation, antegrade aortic-root and retrograde cardioplegia, left atrium (LA) and transverse anterior aortotomy approaches were used. A 30° thoracoscope was used for better visualisation. The LV was small with severe concentric hypertrophy. The MV was heavily calcified (especially the AML) and surrounding annulus calcified around the entire circumference extending into the base of left ventricle (Figure 9). The AV was similarly heavily calcified and severely stenotic. A 29 mm sized Edwards Sapien-XT valve was deployed into the mitral annulus under direct vision and the balloon was inflated to achieve adequate coaptation with the annulus. The metal strut positions were inspected to avoid LVOT obstruction. There was a paravalvular leak anterolaterally on static saline-test. This was sutured closed with a pledgetted 4/0 prolene stitch. A 19 mm Magna Ease valve was then implanted through transverse aortotomy, using a mixture of pledgetted and non-pledgetted 2/0 polyester sutures.

Cardiopulmonary bypass time was 125 minutes, and cross-clamp time was 102 minutes. Post-bypass TOE showed both the prosthetic Sapien valve implanted in mitral annulus and the aortic valves functioning well with trivial

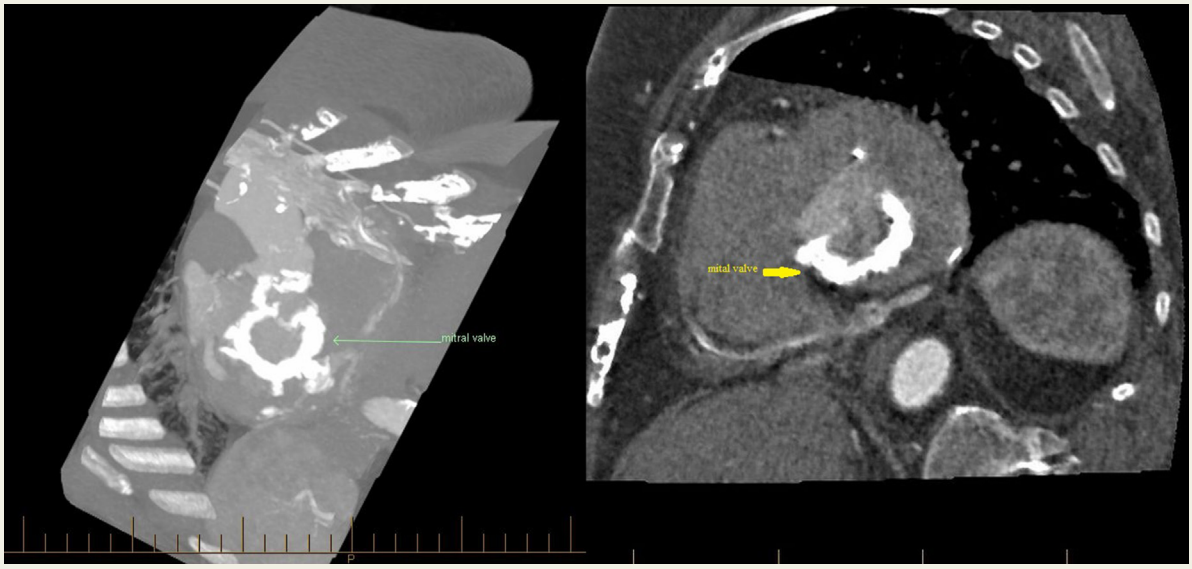

Figure 8 Cardiac computed tomography images showing severe circumferential mitral annular calcification.

regurgitation with mean gradient of 4 mmHg across the Sapien valve and 5 mmHg across AV. But the Sapien valve was causing significant impingement into the LVOT with mean gradient of 60 mmHg. The RV also had significant systolic dysfunction and the patient didn't tolerate sternal closure. The patient was transferred to the intensive care unit in a stable condition with low-dose inotropic support and chest left open with a plastic membrane cover. Her chest was closed successfully on postoperative day 4. She developed acute-on-chronic renal failure needing daily haemodialysis. She remained haemodynamically stable for a week afterwards. Transthoracic echocardiogram showed improving RV function and LVOT gradient (mean 35 mmHg). Unfortunately, she developed multi-organ dysfunction and expired on postoperative day 16 following further deterioration.

Results

All three patients had Edwards Sapien-XT valve for MVR. The first patient had concomitant TV repair; the second patient had AVR and CABG X 2 in addition; while the third patient had AVR as concomitant procedure.

Discussion

Mitral valve procedures remain a surgical challenge in the presence of extensive annular calcification, which presents a formidable technical challenge, and are associated with significant surgical risk. It is a degenerative process affecting mostly elderly patients. Cammack et al. [1] used the term 'the bar of death' to describe the mitral annulus calcification as the mortality after such surgery was 30% during that period.

Survivors of Hodgkin's disease and other thoracic malignancies treated with mantle RT may develop RIHD which encompasses a range of deleterious effects on the heart, from subclinical histopathological findings to overt clinical disease [2,3]. The damaging cardiac effects may be manifested in the pericardium, myocardium, valves, conduction system or coronary arteries. Severe calcification of the fibrous skeleton of the heart including valve annuli can be seen in such patients and valve disease is common following cardiac irradiation. Valvular pathologies due to radiation therapy may range from mild asymptomatic valvular thickening to severe, haemodynamically significant valvular thickening, and may manifest as stenosis or insufficiency. Valvular disease appears to progress with time following irradiation and diagnosis often occurs more than a decade following irradiation and pathology of severely diseased valves demonstrate thickened, fibrotic leaflets [4]. The left-sided valves are more often involved than the right side; a higher pressure load on the left ventricle could play a role in the stenotic evolution [5]. Valvular calcification was seen among those with moderate/severe valvular regurgitation/stenosis whereas leaflet thickening and reduced movements without calcification were seen among those with no or only mild valvular stenosis/regurgitation.

Two types of approaches [6] are proposed for patients with extensive mitral annular calcification requiring mitral valve procedures. Decalcification is avoided in one of the approaches and it includes prosthesis placement—intra-atrial, semi-intra-atrial, or intra-annular. In the other approach, the calcified annulus is excised and the annulus is reconstructed usually with a pericardial patch. Decalcification of the annulus can lead to serious complications such as left ventricular rupture, atrioventricular disruption bleeding, atrioseptal defect, atrioventricular fistula, coronary artery injuries, and periprosthetic valve leakage [1]. Improved management of these complications during this complex surgery has led to decreased mortality. The other approach is technically complex and demanding.

In our experience, two patients had prior radiotherapy for Hodgkin's lymphoma and had severe RIHD. Intra-annular insertion of a standard prosthetic valve was not safe in our patients due to the heavily calcified annulus and extension of calcification in SVA onto the LV wall, considering the risks of atrio-ventricular dehiscence and injury to LCX artery. An open surgical approach with a transcatheter valve allows the valve to be placed under direct visualisation to facilitate positioning and to evaluate the likelihood of both perivalvular leakage and atrioventricular disruption. The open approach has the additional advantage of performing concomitant surgeries like other valve procedures, arrhythmias surgeries and coronary bypass.

There are reports of percutaneous implantation of a transcatheter valve into a heavily calcified mitral annulus. In the largest series of 64 patients published by Mayra Guerrero et al. [7] six patients had LVOT obstruction.

Current large-sized transcatheter devices in the left ventricle can compromise the LVOT and cause obstruction either by the device itself or by the native mitral valve that's left in place. The risk of LVOT obstruction is even higher if AML is heavily calcified. We excised the AML in all cases.

Astarci P [8] et al. reported the first case of transcatheter valve used during a complicated open mitral valve surgery in 2013, where the transcatheter valve was used as a bailout procedure to reduce the operative mortality associated with complete mitral annulus decalcification during a long procedure requiring double valve replacement and double bypass grafting.

There are reports of implantation of these transcatheter valves using a minimally invasive approach. Ferrari and colleagues [9] approached the mitral valve by means of a right thoracotomy and left atriotomy, using an on-pump, fibrillating heart technique. While Koeckert et al. [10] reported the use of a Sapien XT for native mitral valve replacement with valve preparation and delivery via a totally endoscopic robotic approach.

Conclusion

Extensive mitral annular calcification presents a formidable surgical challenge during mitral valve procedures. Although

experts recommend extensive decalcification with annular reconstruction, it may be impossible to implant a standard prosthetic valve in some mitral valves and novel techniques using transcatheter valves can be successful in complex cases. Open MVR with a transcatheter balloon-expandable valve can avoid the need for technically challenging and high-risk decalcification of mitral annulus.

Conflict of Interest

None declared.

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