Transcatheter valve-in-ring implantation after failure of surgical mitral repair

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Abstract

OBJECTIVES: Redo surgery after failed mitral valve repair may be high risk, or contraindicated in patients with comorbidities. Because of this high risk, other interventional possibilities like transcatheter valve implantation might be of benefit. We report our experience with transcatheter mitral valve-in-ring implantation (TVIR) in high-risk patients after failure of surgical ring annuloplasty.

METHODS: From January 2010 to February 2012, following a multidisciplinary discussion, 17 high-risk patients underwent TVIR using Edwards SAPIEN XT prostheses, via either a transvenous transseptal (n = 8), or a transapical approach (n = 9).

RESULTS: Patients were aged 70 ± 16 years, in New York Association classes III/IV. Their mean logistic EuroSCORE was 36 ± 17% and mean Society of Thoracic Surgeons risk score 13 ± 9%. The mean time interval between surgery and repair failure was 7 ± 3 years. Annuloplasty rings were semi-rigid in 14 cases, flexible in 2, and rigid in 1. Manufacturers ring diameters were 26 mm in 4 patients, 27 mm in 1, 28 mm in 9, 30 mm, 31 mm and 34 mm in 1. The predominant failure mode was regurgitation in 12 cases and stenosis in 5. SAPIEN XT diameters were 26 mm in 15 patients, 23 mm and 29 mm in 1. Procedural success rate was 88% (15/17). Emergency surgery was needed in 1 patient due to acute dislodgement of the ring. The degree of mitral regurgitation was reduced to none or mild in all but 2 patients; final mean gradient was 7 ± 3 mmHg. Thirty-day survival was 82% (14/17 patients). At last follow-up (13 ± 5 months), survival rate was 71% (12/17).

CONCLUSIONS: These preliminary results suggest that TVIR is feasible, with low operative risk, and may provide short-term clinical and haemodynamic improvement in selected high-risk patients with failure of mitral ring annuloplasty.

Keywords: Transseptal · Transapical · Valve-in-ring implantation · Mitral repair · High risk

INTRODUCTION

Mitral valve disease, particularly mitral regurgitation (MR), is the second-most-frequent valvular disease [1, 2]. Mitral valve repair, which includes ring annuloplasty in most cases, is the preferred intervention when feasible [3]. Failure of the repair with recurrence of significant MR may, however, occur [4, 5]. Reoperation is the standard of care for these patients, but may carry a high or even prohibitive risk, particularly in elderly patients with comorbidities. This high risk is an incentive for the use of less-invasive techniques.

In parallel, the rapidly growing experience with transcatheter aortic valve implantation (TAVI) leads to the consideration of the potential use of the transcatheter valve-in-valve replacement after the failure of the surgical implanted valve in either the aortic or mitral positions [6, 7]. A few experimental series, isolated case reports and one short monocentre series have suggested the feasibility of transcatheter mitral valve replacement after failure of mitral valve surgery with ring annuloplasty [8–13].

The aim of the present study was to report our preliminary multicentre experience with transcatheter mitral valve-in-ring...
implantation (TVIR), in order to better assess the feasibility and early results of this technique.

METHODS

Patients

The study population consisted of patients who had severe symptomatic surgical mitral repair failure and were treated with TVIR via either the transseptal or the transapical approach, using the Edwards SAPIEN XT transcatheter heart valve (Edwards Lifesciences, Inc., Irvine, CA, USA). Preoperative screening included clinical evaluation and careful analysis of the characteristics of the mitral rings. In addition, comprehensive echocardiography allowed the assessment of mitral valve morphology and function, location and severity of MR and/or mitral stenosis (MS) and confirmation of the absence of left atrial thrombus. Then, a team of cardiologists, cardiac surgeons and anaesthesiologists evaluated the risk profile of the patients and reached a consensus for treatment decision.

Procedure

Procedures were performed under general anaesthesia and 2-D and 3-D transoesophageal echocardiography (TEE) guidance.

In patients who underwent a transapical approach, the procedure obeyed the general principles of transapical TAVI. The J preshaped stiff wire was placed in the left atrium or upper right pulmonary artery after retrograde crossing of the mitral valve. The SAPIEN XT prosthesis was mounted upside down (in comparison with a transfemoral position) on the catheter in the retrograde orientation.

In patients who underwent a transseptal approach, transseptal puncture was done at the high and posterior part of the fossa ovalis. Then, an Inoue wire (Toray Medical Co., Chiba, Japan) was placed in the left atrium and septal dilatation was performed using peripheral Wanda balloons with diameters of 12–14 mm (Boston Scientific, Galway, Ireland). Then, the mitral valve was crossed using either a Critikon balloon wedge pressure catheter (Arrow Int., Inc., Reading, PA, USA), or a JR 4 5Fr catheter advanced on a 0.035 J wire. After placing a J preshaped 0.035 Amplatz ExtraStiff wire (Cook Medical, Bloomington, IN, USA) at the apex of the left ventricle, a predilatation of the mitral valve was performed in 2 patients with severe MS, using a 20-mm Z-MED balloon (NuMED, Cornwall, ON, USA) in 1 case and a 20-mm Bonhoeffer balloon (NuMED) in the other. Then, the 23- or 26-mm SAPIEN XT valve was mounted, upside down, on a standard 18 Fr or 19 Fr Novaflex catheter (Edwards Lifesciences) normally used for the transfemoral procedures and advanced to the mitral ring. Valve alignment and fine adjustment were achieved in the inferior vena cava. The prosthesis was directed towards the mitral valve by full flexion of the Novaflex catheter, in a projection perpendicular to the plane of the ring (Fig. 1).

Balloon expandable valves of 23 mm were considered suitable for Physio ring sizes up to 26 mm, the 26-mm SAPIEN for ring sizes from 26 to 31 mm and the 29-mm SAPIEN for the 34-mm ring. In all but 1 patient, 26-mm SAPIEN XT prostheses were implanted. In the remaining patient, the prosthesis was undersized according to the experiments [8] (23 mm for an annuloplasty ring of 28 mm), but was considered adequate because the tight MS was predilated by a 20-mm balloon with a residual waist on the balloon at full inflation. Then, the SAPIEN XT valve was placed within the mitral ring, its correct position carefully checked by fluoroscopy and TEE and deployed by slow balloon inflation under rapid pacing (160–200 bpm).

Follow-up

Clinical follow-up, transthoracic echocardiography (TTE), TEE and if possible multislice computed tomography (CT), were performed before discharge (Fig. 2). All adverse events were recorded prospectively. The 30-day medical visit and TTE were performed in our institutions or by the patients’ own cardiologist and data were collected by phone calls.

Definitions

Procedural success was defined by delivery of the prosthesis in the correct position, without procedural complications. Clinical endpoint definitions were the standardized definitions of the consensus report from the Valve Academic Research Consortium [14], Prosthetic function was assessed according to American Society of Echocardiography/American College of Cardiology recommendations for evaluation of prosthetic valves with echocardiography and Doppler ultrasound, using the integration of several qualitative and quantitative parameters obtained by both TTE and TEE [15]. MR was graded as none, mild, moderate or severe.

Statistical analysis

Data were expressed as mean ± SD. Statistical analysis was performed using JMP 7.0.1 Statistical Discovery statistical software from SAS Institute Inc. (SAS Campus Drive, Cary, NC, USA).

RESULTS

Patients

From January 2010 to February 2012, in 6 European high-volume centres, 17 patients underwent TVIR because of a failed mitral repair. The aetiology of mitral valve disease was functional in 9 cases, rheumatic in 3, degenerative in 2, postendocarditis in 1, postirradiation in 1 and iatrogenic in 1. The predominant mode of failure was regurgitation in 12 patients and stenosis in 5. The mean time between mitral repair and index hospitalization was 7 ± 3 years [2–10, 16].

Patients were aged 70 ± 16 years. All were severely symptomatic, in New York Heart Association (NYHA) functional classes III or IV, and at high risk or with contraindications to redo surgery. Their mean logistic EuroSCORE was 36 ± 17% and Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score 13 ± 9%. Three patients (1, 5 and 6) had a Logistic EuroSCORE < 20% and a STS score < 10%; the reasons for preferring TVIR to conventional redo surgery in those patients were as follows: (i) in Patient 1, previous Hodgkin lymphoma and breast cancer treated by chest radiation, previous tricuspid valve replacement and moderate aortic stenosis; (ii) Patient 5, the youngest patient of the series was a 17-year-old girl who underwent surgical mitral valve repair in 2007, with implantation of a Physio semi-rigid 28 mm ring. Due to
postoperative recurrence of rheumatic fever, early symptomatic mitral restenosis occurred, with severe pulmonary hypertension and severe right ventricular failure. Percutaneous mitral commissurotomy was attempted, but was unsuccessful, with severe residual MS. The medico-surgical team decided to perform TVIR because mechanical valve replacement was not possible. (iii) In Patient 6, morbid obesity, respiratory insufficiency and previous aortic valve replacement with septal myectomy. Patients’ baseline clinical characteristics and risk factor or contraindications to surgery are presented in Table 1.

Mitral repair

As shown in Table 2, annuloplasty rings were semi-rigid in 14 cases, flexible in 2 and rigid in 1. The manufacturers’ ring
diameters ranged from 26 to 34 mm. On baseline TTE, the five stenosed mitral valves had a mean area measured at 1.1 ± 0.3 cm² and a mean gradient at 13 ± 4 mmHg. MR was severe in 1 of the other 12 patients.

**Procedure and immediate outcome**

In patients who underwent a transapical approach, procedural success was 89% (8/9 patients). In 1 case, emergency surgery was needed because of an acute detachment of the ring following an appropriate SAPIEN XT prosthesis deployment in a patient with a partial ring dehiscence (considered trivial at pre procedural TEE). The patient underwent successful removal of the completely detached ring and inserted SAPIEN prostheses, followed by implantation of a surgical mechanical valve prosthesis. In patients who underwent a transseptal approach, crossing of the valve by the prosthesis was easy in all but 1 case with severe MS. Procedural success was 87% (7/8 patients). In 1 case, the SAPIEN XT prosthesis was implanted in a too-atrial position, and a second valve was implanted within the first, with a good result. All other prostheses were implanted in an adequate position with no major complication. In 1 patient with a very fibrous interatrial septum, a significant left-to-right shunt was observed at the end of the procedure, which led to the placement of an Amplatzer closure device.

In all but 1 patient, 26-mm SAPIEN XT prostheses were implanted, and only one 29-mm prosthesis was used in the largest 34-mm ring.

Mean hospital stay duration after valve implantation was 10 ± 4 days (range: 3–26). No patient had more than mild paravalvular regurgitation, consisting of small paraprosthetic jets without circumferential extension. The intraprosthetic gradients at discharge could be classified as ‘significant residual stenosis’ in 1, as ‘possible stenosis’ in 2, according to the recommendations for the evaluation of surgical prosthetic valves [13]. In 3 cases, a dynamic gradient was observed in the left ventricular outflow tract, due to the displacement of the subvalvular apparatus toward the outflow tract. In all but 1 patient who underwent a transseptal approach, no significant interatrial shunt was observed. Although the rings became more circular after prosthesis implantation, the application of the prosthesis was not complete all around their circumference. There were 2 early postoperative deaths due to refractory congestive heart failure. One patient had a cardiac arrest due to ventricular tachycardia a few days after a straightforward procedure, after which an intractable heart failure occurred, leading to death on Day 26 post-procedure. The other patient died on Day 14, in the context of refractory hypotension, abdominal pain and acute renal failure. At discharge, all of the survivors were in NYHA class II.

The mean follow-up duration was 13 ± 5 months. One patient, who lived abroad, was lost to follow-up. Survival rate at last follow-up was 72% (12/17 patients). The 3 post-discharge deaths were caused by sepsis at 1 month in 1 case, sudden unexplained death at 5 months in another, and refractory heart failure at 7 months in the last. Functional status in survivors is shown in the Fig. 3. One patient successfully underwent TAVI due to progression of aortic stenosis, which had become severe and symptomatic. One patient who remained in NYHA class III with persistent pulmonary hypertension underwent mitral valve replacement, with improvement of neither functional status nor pulmonary pressures. No haemolysis occurred.

**DISCUSSION**

The preliminary results in this series suggest that in selected high-risk patients after failure of surgical ring annuloplasty, TVIR is feasible and could be achieved safely and effectively. It may provide short-term clinical and haemodynamic improvement. TVIR may become an attractive option in this population, when the risk of reoperation is considered to be high by the Heart Team.
<table>
<thead>
<tr>
<th>Patients</th>
<th>Surgical ring</th>
<th>Failure mode</th>
<th>Delay to valve dysfunction (years)</th>
<th>Mean mitral gradient (mmHg)</th>
<th>MVA (cm²)</th>
<th>MR grade</th>
<th>SPAP (mmHg)</th>
<th>Approach</th>
<th>SAPIEN XT diameter (mm)</th>
<th>Mean mitral gradient (mmHg)</th>
<th>MVA (cm²)</th>
<th>MR grade</th>
<th>Intraventricular gradient (mmHg)</th>
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CE: Carpentier Edwards; NA: not available; MR: mitral regurgitation; MVA: mitral valve area; SPAP: systolic pulmonary artery pressure; TA: transapical; TS: transseptal.
*Indicates in-hospital death.
Background

There is limited experience of percutaneous treatment after failure of mitral valve repair. Percutaneous mitral commissurotomy (PMR) has been successfully performed in selected patients when restenosis is pure and associated with commissural fusion [17]. In patients with predominant MR, no experience is reported with the only available percutaneous technique, i.e. edge-to-edge repair, which does not seem to be well suited to the causal mechanism/anatomy [18]. TVIR is attractive because the presence of the annuloplasty ring may serve as an anchor zone, which is not the case in native valves. The experience of TVIR is limited to 2 experimental series, 3 isolated cases and one short monocentre series, reporting results that have suggested the feasibility of the technique [8-13]. The lessons learnt from TAVI apply at all steps of TVIR, i.e. patient selection and performance of the procedure [19-21].

Patient selection

In patients with failure of valve repair for ischaemic MR, TVIR may be even more attractive because the risk of reoperation is further increased by old age, the presence of patent coronary bypass and left ventricular dysfunction.

The available prosthesis sizes can be used for the treatment of a large number of patients with ischaemic MR where undersized rings are used and for certain patients with rheumatic valve disease without severe annular dilatation; however, they are not large enough in case of degenerative MR even if the 29-mm Edwards SAPIEN may allow implantation in rings at least up to 31 mm and was used in a 34-mm prosthesis in the present series. Incomplete rings, limited to the posterior aspect of the mitral annulus, may not provide the necessary support for implantation of the prosthesis. Most of our patients, as was the case in the other reports, had semi-rigid rings; however, the success of the procedure in our last patient suggests that TVIR might also be done in flexible rings.

Technique

The transapical approach was used in the initial experimental series [8], the transapical approach in one experimental series and 2 of 3 human cases [10, 12], and the transeptal approach in the other experimental series [9], and in one monocentre series [13]. Transseptal catheterization is becoming more common practice because of its large usage in PMR, and more importantly in Western countries in electrophysiology and new interventional techniques [22]. This approach was successful in all cases in this series; however, it is a demanding technique that requires specific training. TEE guidance is useful in choosing the location of the puncture site in the fossa ovalis, which may be similar to that used in the edge-to-edge technique, to facilitate the orientation and alignment of the prosthesis. In this aspect, the surgical transapical or direct transatrial approach provides a more straight entry and easier stabilization. This advantage should be balanced with the higher invasiveness of the latter.

At this point of time, only the balloon expandable Edwards Sapien XT prosthesis can be used for TAVI, because the design of the self-expanding Medtronic CoreValve is not suited for implantation in the mitral position and the Melody prosthesis is of too-small a diameter to accommodate most of the annuloplasty rings used in adults and would not be anticipated to be sufficiently durable in the systemic circulation [9].

Positioning of the valve prosthesis is challenging. Fluoroscopic guidance after careful selection of a view perpendicular to the mitral ring is crucial. 2-D and 3-D TEE guidance is also helpful. The aim is to cover the annuloplasty ring with the basal skirt of the prosthesis in order to avoid paraprosthetic regurgitation, without being ‘too ventricular’ to avoid intraventricular obstruction. To facilitate positioning, right ventricle pacing is necessary, as well as a staged and slow inflation.

The procedure is simpler in patients with radiopaque rings. In this case, the ring is visible using fluoroscopy alone, allowing the transseptal procedures to be performed using only sedation, without the use of contrast medium, which will further reduce the risk in this population.

RESULTS

The procedure was technically successful in all but 2 cases, and all, but one, prostheses were positioned at the level of the annuloplasty ring. The radial force of the balloon expandable prosthesis allows a solid fixation of the valve in the ring, as demonstrated experimentally [8]. All imaging modalities show that the ring becomes almost completely circular even if it is semi-rigid, which is important for valve function.

In 1 patient, ring detachment followed by recurrent severe MR occurred immediately after a correct SAPIEN implantation. In this particular case, in retrospect, the annular ring was found to be partially detached from the annulus by pre procedural CT scan evaluation. This finding was not evident at TEE examination. The presence of partial ring dehiscence may be considered a contraindication to valve-in-ring procedures both for the risk of residual MR and for the potential of ring dislodgement and need for surgery. According to our limited experience, CT scan should be used in addition to TEE to evaluate anatomy prior to the procedure. Paravalvular MR was mild or trace in all patients. This is probably the consequence of a good apposition of the prosthetic valve into the annulus, combined with the interrogation of some valvular tissue between the ring and the prosthesis. Severe paravalvular MR may occur in case of undersizing or if the prosthesis is ‘too atrial’ where the pericardial skirt of the prosthesis does not cover the ring. The potential consequences...
of paravalvular leaks should be carefully determined, with particular attention paid to the development of haemolysis [23]. New devices with an external cuff may reduce paravalvular leaks.

Taking into account the limitations in the estimation of prosthetic stenosis, the intraprosthesis gradients observed at discharge seem slightly higher than those observed with current bioprostheses [15]. These figures are similar to those observed after valve-in-valve implantation using the same type of transcatheter prosthesis [7]. After TVIR, the mean gradient was nevertheless reduced and functional improvement was obtained, leading us to expect a lower risk of subsequent surgery. The long-term consequences of the residual gradients on prosthesis degeneration should be further evaluated.

Careful echocardiographic assessment showed mild intraventricular gradient in 3 patients. After mitral valve replacement, particularly when using high-profile bioprostheses, intraventricular gradients may be due to complete preservation of the anterior leaflet and subvalvular apparatus, which is not avoidable in TVIR [24, 25], or a small ventricular cavity, or thickened intraventricular septum. These latter two conditions occurred in one of our patients with previous papillary muscle hooping and another with previous septal myectomy. In addition, dynamic obstruction may be worsened in a hypercontractile left ventricle, or preload reduction. In the future, it will be necessary to evaluate the risk-benefit ratio of lower profile prostheses, which will decrease this complication but may position making more difficult. This complication is unlikely when the left ventricle is enlarged, such as in MR secondary to ischaemic disease or cardiomyopathy, which will be particularly suitable for TVIR.

Although rare, significant left-to-right shunting can be observed after the transeptal approach. If needed, percutaneous closure of the interatrial septum tears can be used; however, the haemodynamic effect of closure of such shunts should be evaluated because it may be detrimental in patients in whom left atrial pressures remain high.

Follow-up

A large majority of patients in this series experienced immediate improvement in clinical condition and haemodynamics. Most cardiovascular events were due to the multifactorial nature of the disease, comorbidities, or progression of aortic stenosis. Only 2 patients who were in NYHA class IV did not experience any improvement and died postoperatively due to persistent refractory heart failure. These 2 patients were preoperatively in very critical condition, with both end-stage heart valve disease and severe extracardiac comorbidities. During follow-up, neither valve dysfunction nor haemolysis was observed. These findings are similar to those observed in the high-risk TAVI population, where the non-valvular factors account for most of the secondary clinical failures. The role of the Heart Team is crucial to identify those who will benefit from interventions, and those who will not.

Limitations

The main limitation of this preliminary series is the small number of patients included in the limited follow-up. It is, however, the largest series so far and allows homogenous and comprehensive clinical and echocardiographic evaluation.

CONCLUSION

Reoperation remains the reference treatment for patients with failure after mitral valve repair with ring annuloplasty. However, it may be high risk or even contraindicated for cardiac or non-cardiac reasons. This preliminary series suggests that, when performed by experienced medico-surgical teams, TVIR is feasible, safe, and provides short-term improvement in valve function and clinical condition in selected high-risk patients. It is expected that we will see larger series with a long-term follow-up to evaluate durability and safety. We have seen in this small group that this procedure can reduce MR significantly, but it is important to evaluate the long-term consequences of the residual gradients. The respective advantages of the transvenous vs the transapical or minimally invasive transatrial approaches should also be evaluated in order to assess the potential role of this technique. Technological improvement in valve design is likely to lead to refinements in the technique. Finally, the lessons learnt from TVIR will also be useful for developing transcatheter mitral valve replacement.


REFERENCES


