ORIGINAL ARTICLE

Transcatheter mitral valve-in-valve implantation for failed bioprosthesis

Başarısız biyoprotez hastalarında transkateter mitral kapak-içi-kapak implantasyonu

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ABSTRACT

Objective: This study is a report of clinical and echocardiographic outcomes of experience with transapical mitral valve-in-valve (VIV) replacement.

Methods: Eleven patients with a mean age of 63.7±13.0 years who underwent transapical mitral VIV implantation for a failed bioprosthesis at a single institution were enrolled. All of the patients were considered high-risk for surgical intervention, with a Society of Thoracic Surgery predicted risk of mortality of 14.2±17.6%, and a mean European System for Cardiac Operative Risk Evaluation (EuroSCORE II) of 10.5±6.1%.

Results: Transapical mitral VIV implantation was successful in all of the patients. Edwards, Sapien XT and Sapien 3 valves (Edwards Lifesciences Corp., Irvine, CA, USA) were used in 8 (73%), 2 (18%), and 1 (9%) patients, respectively. Size 26 valves were used in 6 (55%) patients while size 29 valves were used in 5 (45%) patients. All of the patients (11, 100%) had no or only trace mitral regurgitation at the end of the procedure. The mean length of hospital stay was 19±8.0 days. The survival was 100% at 14 days, and 90% at 30 days and at 4 years. One patient died as a result of multiorgan failure on day 16 of intensive care unit stay. The mean mitral valve gradient across the percutaneous valve was 2.26±1.047 mmHg, and the mean valve area was 2.20±0.14 cm^2. Through the 4 years follow up, the New York Heart Association class of the 10 patients remaining improved to class II with no readmission for heart failure. All of the patients were on coumadin with a target international normalized ratio of 2–3.

Conclusion: In high-risk patients, transapical mitral VIV implantation can be performed with a high success rate and considerable improvement in clinical status.

ÖZET

Amaç: Bu çalışma, transapikal mitral kapak-içi-kapak (VIV) replasman operasyonunun klinik ve ekokardiyografik sonuçlarını paylaşmayı amaçlamaktadır.

Yöntemler: Başarısız biyoprotez nedeniyle aynı kurumda transapikal mitral VIV implantasyonu yapılan ve ortalama yaşları 63.7±13.0 olan 11 hasta bu çalışmaya dahil edilmiştir. Göğüs Cerrahisi Derneği'nin ortalama %14.2±%17.6 ve Avrupa Kardiyak Operatif Risk Değerlendirme Sistemi (EuroSCORE II)'nin ortalama %10.5±6.1 olarak belirlediği mortalite riski uyarınca tüm hastalar cerrahi müdahale açısından yüksek riskli hasta grubunda değerlendirilmiştir.

Bulgular: Transapikal mitral VIV implantasyonu tüm hastalarda başarıyla gerçekleşti. Edwards, Sapien XT ve Sapien 3 kapakları (Edwards Lifesciences Corp., Irvine, CA, ABD) sırasıyla 8 (%73), 2 (%18) ve 1 (%9) hastada kullanıldı. Altı (%55) hastada 26 numara ve 5'inde de (%45) 29 numara kapak kullanıldı İşlemin sonunda hastaların tamamında (11, %100) mitral regürjitasyon (MR) ya da buna ilişkin bir bulgu kalmadı. Hastanede kalış süresi ortalama 19±8.0 gündü. Sağkalım 14. günde sağ kalım oranı %100 ve 30 gün ve 4 yılda %90 olarak gerçekleşti. Çoklu organ yetersizliğinden dolayı bir hasta 16. günde yoğun bakım ünitesinde hayatını kaybetti. Perkütan kapak boyunca ortalama mitral kapak gradiyanı 2.26±1.047 mmHg ve ortalama kapak alanı 2.20±0.14 cm^2 idi. Dört yıllık takip süresince geriye kalan 10 hasta kalp yetersizliğinden dolayı yeni başvuru olmaksızın New York Kalp Derneği Kalp Yetmezliği sınıflandırmasında Sınıf II'ye yükseldi. Tüm hastalar, 2–3 uluslararası normalleştirilmiş oran hedefiyle coumadin kullanmaktaydı.

Sonuç: Yüksek riskli hastalarda, transapikal mitral VIV implantasyonu yüksek başarı oranıyla gerçekleştirilebilir ve klinik sonuçlarda önemli bir iyileşme sağlanabilir.

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Transcatheter valve-in-valve (VIV) is gaining interest as an important option for high-risk patients with structural valve deterioration after bioprosthetic valve replacement. Since the report of the first experience with transcatheter VIV in the aortic position,[1] the majority of reported VIV procedures have also been in the aortic position, although a number of case series have demonstrated favorable results in the mitral position.[2,3]

Most VIV transcatheter mitral valve replacement (TMVR) has been performed through the transapical approach, which permits a shorter, direct, coaxial route rather than an antegrade approach.[4] However, the transapical approach has several potential deficiencies; it requires a thoracotomy, which can be prohibitive in patients with pulmonary disease. Postoperative pain can be significant after thoracotomy, and there is a risk of ventricular disruption in the context of apical manipulation. Retrograde insertion of the valve has the danger of capturing or disrupting the chordae while placing the valve. In the PARTNER trial (Placement of Aortic Transcatheter Valve) quality-of-life assessment, the transapical approach demonstrated no improved benefit compared with a surgical approach, whereas the transfemoral approach did.[5]

Additional alternative access routes include transatrial[6] or transfemoral-transseptal approaches.[7] Disadvantages of a transatrial approach are that it requires a thoracotomy and it is often difficult to obtain a coaxial delivery plane view because of the angle of access. The transfemoral-transseptal approach has been described,[7] but this approach requires a long sheath to shield the valve passed in an upward direction and traversing the atrial septum to the mitral valve, which is in a left and downward direction, which could result in insertion of the valve without the ability to either deploy or remove it.[8–10]

Transcatheter mitral VIV implantation into failing surgical bioprosthetic valves has been previously reported and has evolved in recent years as a promising complementary therapy to avoid repeat cardiac surgery in patients affected by multiple comorbidities and those who are considered at high risk for surgical reoperation. Though several approaches to access a mitral bioprosthesis or ring have been described, including transseptal and transatrial techniques, most experience has been gained using transapical access.

The current standard when treating degenerated mitral bioprostheses with transcatheter valves is the use of Edwards balloon-expandable devices (Edwards Lifesciences, Irvine, CA, USA). This technique is good overall, but it is limited by a lack of repositionability and retrievability and issues associated with residual regurgitation and malpositioning.[10–12]

Abbreviations:

3D	*Three-dimensional*
CT	*Computed tomography*
EF	*Ejection fraction*
INR	*International normalized ratio*
IV	*Intravenous*
LVEF	*Left ventricular ejection fraction*
LVOT	*Left ventricular outflow tract*
MR	*Mitral regurgitation*
MVA	*Mitral valve area*
MVG	*Mitral valve gradient*
NYHA	*New York Heart Association*
TEE	*Transesophageal echocardiography*
TIA	*Transient ischemic attack*
TMVR	*Transcatheter mitral valve replacement*
TTE	*Transthoracic echocardiography*
VIV	*Valve-in-valve*

This study examined clinical and echocardiographic outcomes of experience with transapical mitral VIV replacement.

METHODS

This retrospective single-center study included 11 patients who underwent transcatheter mitral VIV implantation for a failed bioprosthesis. The study was approved by the King Faisal Specialist Hospital & Research Centre Ethics Committee (RAC #2181015).

Patient selection

All of the patients were discussed in multidisciplinary heart team meetings and deemed to be at high risk for surgical intervention due to comorbidities and frailty. The indication for valve replacement was considered according to the current guidelines.[13] Preoperative transthoracic echocardiography (TTE) and transesophageal echocardiography (TEE) were performed to assess valve pathology and valve sizing with the inner diameter of the failed bioprosthesis used as reference.

All of the patients underwent either a preoperative computed tomography (CT) angiogram or a coronary angiogram to evaluate the presence of significant coronary artery disease requiring intervention. Three-dimensional (3D) printing was used to avoid significant tilting and obstruction of the left ventricular outflow tract (LVOT). Patients with a significant perivalvular leak, bioprosthesis infective endocarditis, or with life expectancy of less than 1 year were excluded from the analysis.

Transapical valve-in-valve implantation technique

The procedure was performed under general anesthesia in a hybrid operating suite with cardiac surgery capabilities available as back-up. Briefly, a transvenous pacemaker was advanced through the right common femoral vein into the right ventricular apex. After a left lateral minithoracotomy at the fifth or sixth intercostal space, an apical puncture was performed. A 6-F, 12-cm sheath was advanced over a soft wire into the left ventricular cavity. A Glidewire (Terumo Corp., Tokyo, Japan) was advanced across the mitral bioprosthesis into the pulmonary vein using a Judkins right 4 catheter as a conduit.

The Glidewire was then exchanged for a stiff wire, after which an Edwards sheath (Edwards Lifesciences, Irvine, CA, USA) was advanced over the stiff wire across the mitral bioprosthesis into the left atrium for anchoring. The valve was advanced to the tip of the sheath and then the valve was deployed using the unsheathing technique to ensure proper location under the guidance of TEE and fluoroscopy using rapid pacing. All of the procedures were performed using heparin as an anticoagulant to achieve activated clotting time of 250-300 seconds.

Statistical analysis

The statistical analysis was performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean±SD, where appropriate, and categorical data were expressed as percentages. All p values refer to 2-tailed tests of significance, and a p value of ≤0.05 was considered significant.

RESULTS

Baseline characteristics

The mean age of the study patients was 63.7±13.0 years, and 8 of the 11 (81%) patients were females (81%). It is worth noting that most of the patients were female and relatively young in age, mainly due to a high prevalence of rheumatic heart disease.

In the group, there was 1 patient (9%) classified as New York Heart Association (NYHA) Class II, 5 patients (45%) categorized as NYHA Class III, and 5 patients (45%) with a NYHA Class IV assessment. The reported comorbidities included 5 patients (45%) with diabetes, 3 (27%) with atrial fibrillation, 3 (27%) with chronic renal failure, and 3 (27%) with prior transient ischemic attack (TIA) or stroke. Three (27%) patients had hospitalizations due to heart failure during the prior 12 months and 1 patient (9%) had a prior myocardial infarction.

The mean predicted risk of mortality estimated by the Society of Thoracic Surgery score was 14.2±17.6%, and the mean European System for Cardiac Operative Risk Evaluation (EuroSCORE II) was 10.5±6.1%, which is consistent with a high-risk patient group. Our patients had undergone the following cardiac surgeries: 1 patient (9%) had tricuspid valve surgery, 11 underwent (100%) mitral valve surgery, 1 (9%) underwent aortic valve surgery, 2 (18%) underwent coronary artery bypass grafting, and 1 patient had a prior implantable cardioverter-defibrillator/biventricular pacemaker inserted. All of the patients who had undergone mitral valve surgery had received a bioprosthetic valve replacement. The primary indication for mitral valve replacement during the first surgery was rheumatic valve disease. Table 1 summarizes the baseline characteristics and surgical history.

All 11 patients had intravalvular MR due to malfunction of the bioprosthesis resulting in severe MR. Eight patients had 4+ grade MR and the remaining 3 patients had 3+ grade MR. The left ventricular ejection fraction (LVEF) was >50% in 9 of the 11 patients, and 30–50% in the remaining 2 patients prior to transcatheter valve implantation (Fig. 1).

Procedural characteristics

Transcatheter mitral VIV implantation was successful in all of the study patients. Edwards, Sapien XT and

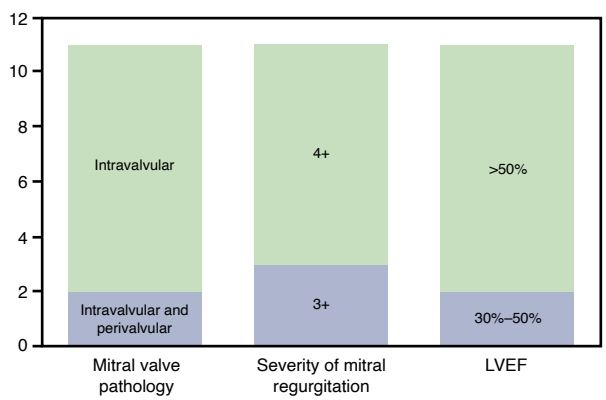

Figure 1. Mitral valve pathology, severity, and left ventricular ejection fraction (LVEF).

Table 1. Baseline characteristics

	n	%	Mean±SD
Demographics			
Mean age (years)			63.7±13.0
Gender, female	9	81	
Mean weight (kg)			64.3±18.2
Mean height (cm)			151.7±8.9
Medical history			
Diabetes	5	45	
Atrial fibrillation	3	27	
Chronic renal failure	3	27	
Prior TIA or stroke	3	27	
Hospitalization due to HF during prior 12 months	3	27	
Prior CABG	2	18	
Prior myocardial infarction	1	9	
NYHA class			
II	1	9	
III	5	45	
IV	5	45	
Surgical risk			
Mean STS predicted risk of mortality			14.2±17.6
Mean EuroSCORE II			10.5±6.1
Mean LV end-diastolic diameter (cm)			4.67±0.83
Previous cardiac surgery			
CABG	2	18	
Prior ICD/BiV PPM	1	9	
Tricuspid surgery	1	9	
Mitral surgery	11	100	
MVR bioprosthetic	11	100	
Aortic valve surgery	1	9	

BiV PPM: Biventricular permanent pacemaker; CABG: Coronary bypass graft; HF: Heart failure; ICD: Implantable cardiac defibrillator; LV: Left ventricle; MVR: Mitral valve regurgitation; NYHA: New York Heart Association; STS: Society of Thoracic Surgery; TIA: Transient ischemic attack. SD: Standard deviation.

Sapien 3 valves were used in 8 (73%), 2 (18%), and 1 (9%) patients , respectively. A size 26 valve was used in 6 (55%) patients, while a size 29 valve was used in 5 (45%) patients. The transapical approach was used in all cases and 100% technical success was achieved. Pre-implantation valvuloplasty was performed in 1 patient (9%) to determine the valve size. The mean mitral valve gradient (MVG) across the percutaneous valve was 2.26±1.047, while the mean valve area (MVA) was 2.20±0.141 cm^2. In all of the patients (11, 100%), trace or no residual MR was seen at the end of the procedure.

Of the 9 patients with a pre-procedure ejection fraction (EF) of >50%, it dropped to 45% in 5 patients and 30% in 1 patient, while the remaining 3 maintained an EF of >50%. Of the 2 patients with a pre-procedure EF of 30-50%, it 1 case it was reduced to 30%, while the other patient maintained an EF of 45%. However, all patients were in a good clinical condition.

The mean length of hospital stay was 19±8.0 days (Table 2) The survival was 100% at 14 days and 90% at 30 days. One patient died due to multiorgan failure at 16 th day of stay in the intensive care unit.

In-hospital complications

Post procedure, the study patients developed the following in-hospital complications: Stroke (1, 9%, mainly TIA and the patient recovered completely before discharge), major bleeding (3, 27%), endocarditis (1, 9%, which resolved completely after 1 week of intravenous [IV] antibiotics, and as of the time of writing, the patient continues to have a properly functioning mitral valve), hemolytic anemia (1, 9%, hemoglobin eventually stabilized and no blood transfusion required), valve thrombosis (1, 9%, which was treated with IV thrombolytic, which resulted in completely functioning valve with no gradient). A mitral valve re-intervention (second balloon inflation to seal the perivalvular leak) was required in 1 (9%) and a new permanent pacemaker were required in 1 (9%) patient. A 30-day echocardiography assessment showed trace to no MR in 10 (91%) patients (Table 2).

The first patient of the series was started on dual platelet therapy postoperatively. On day 3, he developed high gradients across the percutaneous valve and thrombus formation on 1 leaflet. He was treated successfully with IV streptokinase and coumadin therapy was initiated to achieve a target INR of 2–3 with no further events. Subsequently, the protocol was changed to fully anticoagulate the patients with coumadin and heparin bridging.

Clinical and echocardiographic follow-up

TTE was performed at 1 day, 30 days, and 6 months post procedure and annually thereafter for the next 4 years.

The mean MVG across the percutaneous valve was 2.26±1.047, and the MVA was 2.20±0.14 cm^2. There was no evidence of percutaneous valve degeneration, stenosis dehiscence, or thrombus formation during 4 years of follow-up in the remaining 10 patients.

Five patients (45%) with a NYHA Class III grade and 5 patients (45%) with NYHA Class IV status improved to NYHA class II with no readmissions for heart failure. No significant bleeding requiring hospitalization occurred throughout the follow-up period.

The 5 patients with an LVEF of 45% post procedure improved to more than 50%, while the 2 patients with an LVEF of about 30% post valve implantation

Table 2. Procedural results and in-hospital complications

Procedural results	
Access transapical	11 (100%)
Technical success	11 (100%)
Post-implantation valvuloplasty	1 (9%)
Mean MVG	2.26±1.047
Mean MVA	2.20±0.141
Residual MR at end of procedure	Trace or none 11 (100%)
Mean length of stay (days)	19±8.0
In-hospital complications	
Stroke	1 (9%)
Mitral valve re-intervention	1 (9%)
Major bleeding	3 (27%)
New permanent pacemaker requirement	1 (9%)
Endocarditis	1 (9%)
Hemolytic anemia	1 (9%)
Valve thrombosis	1 (9%)
30 days echo MR	None to trace 10 (91%)
30 days LVEF	<30% 2 (18%), 30%–50% 6 (55%), >50% 3 (27%)

MVG: Mean mitral valve gradient; MVA: Mitral valve area; MR: Mitral regurgitation; LVEF: Left ventricular ejection fraction.

remained the same. The 3 remaining patients maintained an LVEF of more than 50%.

All of the patients were discharged home on coumadin to achieve a target INR of 2–3 and continued coumadin maintenance.

DISCUSSION

Advancements in transcatheter valve replacement technologies have revolutionized the management of patients with valvular disease. As illustrated in several previous studies, transcatheter valve replacement may provide better clinical outcomes when compared with surgical replacement in a well-chosen high-risk patient group.[2,3,14,15] Transcatheter mitral VIV replacement through the transapical access, which allows a shorter, direct, and coaxial route, was successful in all 11 of our patients. There was a significant improvement in MR in all cases, with residual MR after the procedure reduced from severe to trace or none. Eight patients had a 4+ grade MR and the remaining 3 had a 3+ grade MR.

Proper planning using preoperative TTE/TEE to delineate valve pathology and valve sizing, as well as using 3D printing to avoid LVOT obstruction during valve deployment are crucial steps to limit major complications and improve outcomes. It is imperative to exclude ischemic mitral valve pathology by using preoperative CT or coronary angiography imaging, and to revascularize when necessary.

A decline in LVEF following MR correction has been reported in previous studies.[16,17] Seven of our 11 patients had a decline in their LVEF post procedure, indicating that the left ventricular ejection may have appeared to be better than it actually was. This finding is consistent with current published data, which supports detection and intervention of MR as early as possible. However, in most patients, the EF returned to normal over time and all of the patients continued to improve symptomatically, even the one who continued to have a low EF. Balloon valvuloplasty was performed in 1 patient to assess valve size and ensure the balloon was very well-opposed, given that the patient had significant calcification. Overall, the patients displayed improved short-term clinical outcomes after the procedure, although the information available is insufficient to determine long-term outcomes. Despite the fact that the group consisted of high-risk patients, the adverse event rate was low and the majority of patients were discharged directly home.

It is worth noting that 1 patient developed thrombosis in the newly inserted valve while on dual antiplatelet therapy. This could be because the mitral valve is a low-flow area. These patients may benefit from anticoagulation with therapeutic INR even for a short period of time. Furthermore, 1 patient developed hemolytic anemia after the valve insertion. Although the patient did not need a blood transfusion, the reason may be worth investigating further since the valve was not close to the LVOT or stenosed.

The length of the hospital stay for these patients was longer than average because these patients had been referred to our institution from smaller Saudi cities that lacked the appropriate infrastructure to follow the patients in local hospitals. We believe that the experience reflected in this study adds a valuable perspective on this procedure and we hope it is a useful contribution to the scientific and medical community. The primary limitations of this research are the small number of patients and its retrospective nature.

Conclusion

This study is an examination of a group of 11 patients who underwent transcatheter mitral VIV implantation at a single institution. There was 100% technical success and a low adverse clinical event rate. This treatment modality has the potential to become an established therapy for selected patients with additional studies describing management of mitral valve dysfunction through TMVR and patient outcomes.

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Ethical statement: The study was approved by the King Faisal Specialist Hospital & Research Centre Ethics Committee (RAC #2181015).

Peer-review: Externally peer-reviewed.

Conflict-of-interest: None.

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Anahtar sözcükler: Mitral; sonuç; transapikal; kapak-içi-kapak; kapak cerrahisi.