

Hybrid approach of percutaneous coronary intervention followed by minimally invasive mitral valve surgery: a 5-year single-center experience

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Background: The current study evaluated the safety and feasibility of staged (“hybrid”) percutaneous coronary intervention (PCI) followed by isolated minimally invasive mitral valve (MV) surgery [PCI + minimally invasive mitral valve surgery (MIMVS)], for patients with concomitant coronary artery and MV disease.

Methods: A total of 93 patients who underwent PCI + MIMVS for coronary artery and MV disease between February 2009 and April 2014 were retrospectively analyzed.

Results: There were 54 (58.1%) men and 39 (41.9%) women. The mean age was 73±8 years, and all patients had severe mitral regurgitation. PCI was performed for single-vessel coronary artery disease in 40 (43%) patients, two-vessel in 49 (52.7%), and three-vessel in 4 (4.3%). Within a median of 48 days (IQR, 18–71) after PCI, 78 (83.9%) patients underwent primary valve surgery, and 15 (16.1%) underwent re-operative valve surgery, with 56 (60.2%) having MV replacement, and 37 (39.8%) having MV repair. Sixty-five (69.9%) patients were being treated with dual anti-platelet therapy at the time of surgery. The median number of transfused intra-operative red blood cell units was 1 (IQR, 0–2), and the intensive care unit and hospital lengths of stay were 46 hours (IQR, 27–76) and 8 days (IQR, 5–11), respectively. Post-operatively, there was 1 (1.1%) cerebrovascular accident, 2 (2.2%) patients developed acute kidney injury, and 4 (4.3%) required a re-operation for bleeding. Thirty-day mortality occurred in 4 (4.3%) patients. At a mean follow-up of 15.3±13.2 months, 3 (3.4%) patients required target-vessel revascularization. The survival rate was 89% and 85% at 1 and 3 years, respectively.

Conclusions: In patients with concomitant coronary artery and MV disease, PCI + MIMVS can be safely performed and is associated with good short-term and follow-up outcomes.

Keywords: Minimally invasive valve surgery; mitral regurgitation; mitral valve (MV) surgery; percutaneous coronary intervention (PCI); right thoracotomy

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Introduction

In patients with concomitant coronary artery and mitral valve (MV) disease, performing combined coronary artery bypass grafting (CABG) with MV surgery confers a higher risk of mortality when compared with isolated MV repair or replacement (1,2). In these patients, one may attempt to reduce the operative risk by performing two smaller, lower risk procedures. This “hybrid” staged approach consists of percutaneous coronary intervention (PCI) to treat the coronary artery disease, and a minimally invasive approach for the MV surgery. The use of PCI in treating the coronary artery disease permits the use of minimally invasive surgical techniques, obviating the need for a median sternotomy and CABG (3).

The benefits of minimally invasive mitral valve surgery (MIMVS) include improved cosmesis, fewer blood transfusions, less pain, less wound infections, shorter ventilation time, shorter hospital length of stay, an enhanced post-operative recovery, and lower costs, when compared with a conventional sternotomy approach (4-8). In the setting of coronary artery and valvular disease, the less invasive approach of PCI plus minimally invasive valve surgery has demonstrated excellent early and mid-term outcomes (9-17). However, the data evaluating the use of PCI for coronary artery disease prior to isolated MV surgery (PCI + MIMVS) are limited. We report our 5-year single center experience utilizing this technique.

Methods

The Mount Sinai Medical Center (Miami Beach, FL, USA) Institutional Review Board approved the study, and patients were enrolled in our institutional Society of Thoracic Surgeons (STS) Database after written informed consent was obtained. The study was a retrospective review of all patients with combined coronary artery and MV disease who underwent hybrid PCI + MIMVS between February 2009 and April 2014. Baseline variables, operative characteristics and outcomes, and major adverse cardiovascular events during the follow-up period were analyzed using our institutional electronic medical records, outpatient surgical and cardiology office visits, and a follow-up survey at 6-month intervals.

Excluded were patients with endocarditis, those who underwent a procedure on another valve, or had a procedure on the aorta. A hybrid approach for intervention was selected after a comprehensive Heart Valve Team

evaluation, which included calculation of the STS predicted risk of morbidity and mortality or EuroSCORE II (European System for Cardiac Operative Risk Evaluation), incorporation of the SYNTAX (Synergy Between PCI With Taxus and Cardiac Surgery) score to determine the suitability of PCI for the coronary disease, and individual patient co-morbidity and preference (18,19). Dual antiplatelet therapy with clopidogrel (600 mg) and aspirin (325 mg) was commenced after coronary stenting in all patients, followed by clopidogrel 75 mg and aspirin 81 mg daily thereafter. All patients resumed their antiplatelet regimen within 24 to 48 hours after surgery.

The technique for MIMVS performed at our institutions has been previously described (20). In summary, a right thoracotomy was performed via a 5–6 cm skin incision made in the 4–5th intercostal space lateral to the anterior axillary line and, subsequently, the MV was accessed via a standard left atriotomy. A chordal-sparing technique was utilized for MV replacement, with preservation of the posterior leaflet and chords with anterior leaflet excision, or preservation of both leaflets when feasible. The MV repairs were performed with reconstructive techniques tailored to the specific MV lesion, and sizing of the annuloplasty ring was based on the height or surface area of the anterior mitral leaflet.

Statistical analysis

The variables are reported as the mean \pm standard deviation (SD), median and interquartile range (IQR, 25–75%), or number (N) and percentage. Follow-up survival was estimated with a Kaplan-Meier analysis. The Statistical Package for Social Sciences, version 21 (SPSS Inc., Chicago, IL) was used for all statistical analyses.

Results

There were 93 patients identified who underwent PCI + MIMVS, of which there were 54 men (58.1%) and 39 women (41.9%), with a mean age of 73 ± 8 years. All patients had severe mitral regurgitation, and the median left ventricular ejection fraction was 55% (IQR, 40–62%). There were 15 (16.1%) patients with a history of previous cardiac surgery. The etiology of mitral regurgitation was primary in 59 (63.4%), secondary (ischemic) in 29 (31.2%), and 5 (5.4%) patients had prosthetic MV regurgitation. The majority of patients (84%) had their PCI and valve surgery performed in two separate hospital admissions, while the remaining 16% had both procedures done within the same hospital

Table 1 Patient baseline characteristics

Variable	Data (n=93)
Age, mean \pm SD (years)	73 \pm 8
Males (%)	54 (58.1)
Hypertension (%)	87 (93.5)
Diabetes mellitus (%)	34 (36.6)
Dyslipidemia (%)	75 (80.6)
Cerebrovascular disease (%)	17 (18.3)
Peripheral vascular disease (%)	12 (12.9)
Congestive heart failure (%)	30 (32.3)
Left ventricular ejection fraction, median [IQR] (%)	55 [40–62]
Preoperative creatinine, median (IQR) (mg/dL)	0.98 (0.85–1.18)
Body mass index, mean \pm SD (kg/m ²)	27 \pm 5
Prior coronary artery bypass graft surgery (%)	9 (9.7)
Prior isolated valve surgery (%)	1 (1.1)
Prior combined coronary artery bypass and valve surgery (%)	5 (5.4)
Pre-operative angiotensin converting enzyme inhibitor (%)	28 (30.1)
Pre-operative beta blocker (%)	67 (72)
Pre-operative statins (%)	62 (66.7)
Pre-operative dual antiplatelet therapy (%)	65 (69.9)

SD, standard deviation; IQR, interquartile range.

stay. The median time interval between PCI and surgery was 48 days (IQR, 18–71) (*Table 1*). Single-, two-, and three-vessel PCI was performed in 40 (43%), 49 (52.7%), and 4 (4.3%) patients, respectively. The most commonly treated coronary arteries were the mid-left anterior descending in 64 (68.8%) patients, the proximal left anterior descending in 22 (23.7%), the right coronary in 24 (25.8%), and the left circumflex in 31 (33.3%), with the majority of patients receiving drug-eluting stents (77.4%) (*Table 2*).

At surgery, 65 (69.9%) patients were on dual anti-platelet therapy. There were 78 (83.9%) who underwent primary surgery, and 15 (16.1%) who underwent re-operative valve surgery, which consisted of 56 (60.2%) MV replacements, and 37 (39.8%) MV repairs. The median aortic cross-clamp and cardiopulmonary bypass times were 71 minutes (IQR, 55–85) and 104 minutes (IQR, 84–126), respectively. Intra-operatively, a median of 1 unit of packed red blood cells was transfused (IQR, 0–2). There were 2 (2.2%) patients that required conversion to median sternotomy due

Table 2 Coronary artery anatomy and percutaneous coronary intervention procedural characteristics

Variable	Data (n=93)
Coronary intervention (%)	
Drug eluting stent	72 (77.4)
Bare metal stent	18 (19.4)
Balloon angioplasty	3 (3.3)
Coronary lesions (%)	
Mid left anterior descending coronary artery	64 (68.8)
Proximal left anterior descending coronary artery	22 (23.7)
Left circumflex coronary artery	31 (33.3)
Right coronary artery	24 (25.8)
Ramus intermedius coronary artery	2 (2.2)
Protected left main coronary artery	1 (1.1)
Saphenous vein graft	2 (2.2)
Number of coronary vessels treated (%)	
Single vessel percutaneous coronary intervention	40 (43.0)
Two vessel percutaneous coronary intervention	49 (52.7)
Three vessel percutaneous coronary intervention	4 (4.3)
Time from percutaneous coronary intervention to valve surgery, median [IQR] (days)	48 [18–71]

IQR, interquartile range.

Table 3 Operative characteristics

Variable	Data (n=93)
Aortic cross-clamp time, median [IQR] (min)	71 [55–85]
Cardiopulmonary bypass time, median [IQR] (min)	104 [84–126]
Intra-operative packed red blood cells, median [IQR] (units)	1 [0–2]
Mitral valve replacement (%)	56 (60.2)
Mitral valve repair (%)	37 (39.8)
Primary valve surgery (%)	78 (83.9)
Re-operative valve surgery (%)	15 (16.1)

IQR, interquartile range.

to poor surgical field exposure (*Table 3*).

The median intensive care unit and hospital length of stay, which included the time frame for the PCI, was 46 hours (IQR, 27–76) and 8 days (IQR, 5–11), respectively.

Table 4 Post-operative and follow-up outcomes

Variable	Data (n=93)
Post-operative outcomes	
Intensive care unit length of stay, median [IQR] (h)	46 [27–76]
Prolonged mechanical ventilation (>24 h) (%)	17 (18.3)
Re-intubation (%)	4 (4.4)
New-onset atrial fibrillation (%)	15 (16.1)
Deep wound infection (%)	0
Cerebrovascular accident (%)	1 (1.1)
Re-operation for bleeding (%)	4 (4.3)
Acute kidney injury (%)	2 (2.2)
Q-wave myocardial infarction	0
Hospital length of stay, median [IQR] (days)	8 [5–11]
30-day mortality (%)	4 (4.3)
Follow-up outcomes	
Time to follow-up, mean \pm SD (months)	15.3 \pm 13.2
Acute coronary syndrome (%)	5 (5.6)
Target vessel revascularization (%)	3 (3.4)
Cerebrovascular accident (%)	2 (2.3)
All-cause mortality (%)	12 (12.9)

IQR, interquartile range; SD, standard deviation.

The post-operative complications included 17 (18.3%) prolonged mechanical ventilation (>24 h), 15 (16.1%) post-operative atrial fibrillation, 1 (1.1%) cerebrovascular accident, 4 (4.4%) re-operations for bleeding, and 2 (2.2%) patients with acute kidney injury. Thirty-day mortality occurred in 4 (4.3%) patients, as a result of: 1 cerebrovascular accident, 1 cardiogenic shock, 1 sepsis, and 1 multi-organ failure (*Table 4*).

Follow-up was 100% complete. At a mean of 15.3 \pm 13.2 months post-operatively, 5 (5.7%) patients had an acute coronary syndrome, of which 3 (3.4%) required target-vessel revascularization. Cerebrovascular accidents and renal insufficiency occurred in 2 (2.3%) patients each (*Table 4*). There were 8 more deaths that occurred during the time frame of the study, and the actuarial survival was 89% and 85% at 1 and 3 years, respectively.

Discussion

The STS adult cardiac surgery database cites the operative

mortality of isolated MV repair at 1.1%, and MV replacement at 4.7% (1). When performing concomitant CABG, the operative mortality increases to 4.1% for repair and 9.8% for replacement, with a significantly greater occurrence of post-operative complications. Thus, it is hypothesized that the operative risk of combined CABG and MV surgery may be reduced by partitioning the operation into the two lower-risk procedures of PCI + MIMVS. The present study demonstrated a low morbidity and mortality with hybrid PCI + MIMVS for significant coronary artery and MV disease, with the majority of patients having multi-vessel PCI and subsequently undergoing primary or re-operative surgery.

Although one needs to be cautious when making direct comparison with other studies, reductions in the parameters of morbidity were noted when compared with data from the most recent STS adult cardiac surgery database outcomes. In patients undergoing CABG plus MV repair or replacement, the most common complication is new-onset atrial fibrillation, which occurs in 42.6% and 44.2%, respectively, and increases peri-operative morbidity and hospital length of stay (21,22). This figure is higher than the 16.1% noted in present cohort of PCI + MIMVS, and is consistent with prior studies suggesting a reduced incidence of post-operative atrial fibrillation when utilizing a minimally invasive approach for valve surgery (23,24). Similarly, prolonged mechanical ventilation occurred in 18.3% of the PCI + MIMVS cohort, with a reported incidence of 19.8% in CABG plus MV repair, and 29% in CABG plus MV replacement. By virtue of avoiding a sternotomy, minimally invasive surgery results in less thoracic surgical trauma and alterations in pulmonary physiology and biomechanics, which contributes to an enhanced post-operative recovery and faster extubation (8,12,25). The prevalence of additional parameters of peri-operative morbidity is outlined in *Table 5*.

Attempting to reduce the operative risk of combined CABG and valve surgery by performing PCI and valve surgery has been evaluated in different clinical scenarios, which have included the use of a median sternotomy or minimally invasive approach, as well as application in primary or re-operative single or double valve surgery (17). Leacche *et al.* reported the outcomes of 39 high-risk patients who underwent PCI + MIMVS via a right thoracotomy (26). Of the 39 patients, 5 (13%) presented with acute coronary syndrome, 19 (49%) were in congestive heart failure, 16 (41%) underwent urgent or emergent surgery, and 16 (41%) were re-operations. Thirty (77%) patients

Table 5 Post-operative outcomes compared with cardiac surgical procedures from the sSociety of Thoracic Surgeons database in calendar year 2015

Variable	Present study	Society of Thoracic Surgeons 2015 database outcomes	
	PCI + MIMVS (n=93)	CABG + MVR (n=2,681)	CABG + MVrep (n=3,862)
Operative mortality (%)	4.3	9.8	4.1
Re-operation for bleeding (%)	4.3	11.6	7.0
Deep wound infection (%)	0	0.4	0.3
Permanent stroke (%)	1.1	3.3	2.6
Prolonged ventilation (%)	18.3	29.0	19.8
Acute kidney injury (%)	2.2	8.2	5.2
New-onset atrial fibrillation (%)	16.1	44.2	42.6

CABG, coronary artery bypass grafting; MIMVS, minimally invasive mitral valve surgery; MVR, mitral valve replacement; MVrep, mitral valve repair; PCI, percutaneous coronary intervention (1).

underwent a single staged procedure of PCI + MIMVS in a hybrid operating room, while the remaining 9 (23%) had a two-staged procedure of PCI 1 to 4 days prior to MIMVS. Operative mortality occurred in 1 (2.6%) patient, which was lower than the STS predicted mortality of 14%. A subsequent study by our group evaluated the outcomes of 31 patients treated with hybrid PCI + MIMVS via a right thoracotomy for coronary artery disease and severe ischemic mitral regurgitation (15). Of note, 29 of these patients underwent isolated MV surgery, and are included in the current analysis. The mean left ventricular ejection fraction was $35\% \pm 11\%$, all patients were in New York Heart Association functional class III or IV, and 4 (13%) were re-operations. Single and two-vessel PCI was performed in 22 (77%) and 9 (29%) patients, respectively. There were 18 (58%) MV repairs and 13 (42%) replacements performed, with concomitant tricuspid valve repair in 2 (6%) patients, and papillary muscle approximation in 5 (16%). The 30-day mortality was 3%. At a mean follow-up of 2.4 ± 1.6 years, 2 (6%) patients required PCI for target-vessel revascularization. Survival was 84% and 80% at 1 and 5 years, respectively, demonstrating excellent short and mid-term outcomes.

The most recent data from STS demonstrate that in those undergoing isolated MV surgery, the rate of MV repair was 57.4%, and MV replacement was 42.6% (2). In the cases where MV pathology and etiology were documented, 56.6% were identified as having mitral regurgitation due to annular or degenerative disease, without stenosis, of which repair was performed in 75.0% of patients. In the present study, the repair rate was 39.8%, with the MV being replaced in 60.2% of the cases. While

the reason for the lower repair rate cannot be clearly deduced, it should be noted that the etiology of mitral regurgitation was mixed. Primary mitral regurgitation consisted of patients with degenerative, calcific, or rheumatic disease and the reparability of these pathologies varies markedly. Additionally, one-third of population consisted of secondary (ischemic) mitral regurgitation, and 5.4% had prosthetic MV insufficiency, in whom the only option was MV re-replacement.

The primary limitation of the present study is its retrospective nature, and the associated potential for treatment selection bias. This includes the selection process for PCI + MIMVS, which was dependent upon a suitable coronary anatomy for PCI. Importantly, the study was clinically driven and did not follow a protocol, which may be more representative of the practice patterns of community interventional cardiologists. All procedures were elective and the operation consisted of isolated MV surgery, and as such, the outcomes presented herein cannot be extrapolated to other clinical scenarios. Finally, given the observational nature of the analyses and lack of a comparison group undergoing CABG plus MV surgery, the data are best interpreted as providing evidence for the safety and feasibility of hybrid PCI + MIMVS for select patients with combined coronary artery and isolated MV disease requiring surgical intervention.

In conclusion, a hybrid approach of PCI + MIMVS can be performed safely in the setting of coronary artery and MV disease, and is associated with good short and follow-up outcomes. This includes patients with single or multi-vessel coronary artery disease, and those undergoing primary or re-operative MV surgery.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Ethical Statement: This retrospective study was approved by the Institutional Review Board at the Mount Sinai Medical Center, Miami Beach, Florida, USA.

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