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Minimally invasive mitral valve surgery: a systematic safety analysis

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ABSTRACT

Objective Minimally invasive surgery is increasingly adopted as an alternative to conventional sternotomy for mitral valve pathology in many centres worldwide. A systematic safety analysis based on a comprehensive list of pre-specified 30-day complications defined by the Mitral Valve Academic Consortium (MVARC) criteria is lacking. The aim of the current study was to systematically analyse the safety of minimally invasive mitral valve surgery in our centre based on the MVARC definitions.

Methods All consecutive patients undergoing minimally invasive mitral valve surgery through right mini-thoracotomy in our institution within 10 years were studied retrospectively. The primary outcome was a composite of 30-day major complications based on MVARC definitions.

Results 745 patients underwent minimally invasive mitral valve surgery (507 repair, 238 replacement), with a mean age of 62.9±12.3 years. The repair was successful in 95.8%. Overall 30-day mortality was 1.2% and stroke rate 0.3%. Freedom from any 30-day major complications was 87.2%, and independent predictors were left ventricular ejection fraction <50% (OR 1.78; 95% CI 1.02 to 3.02) and estimated glomerular filtration rate <60 mL/min/1.73 m^2 (OR 1.98; 95% CI 1.17 to 3.26).

Conclusions Minimally invasive mitral valve surgery is a safe technique and is associated with low 30-day mortality and stroke rate.

Key questions

What is already known about this subject?

► The safety of minimally invasive mitral valve surgery (MIMVS) is reported in many retrospective studies with favourable and well-defined 30-day stroke and mortality rates. However, composite outcomes such as major complications, major adverse cardiac events and major adverse cardiac and cerebrovascular events are poorly defined and reported at a wide range of 6.5%–33.0%. A systematic safety analysis of MIMVS based on a comprehensive list of pre-specified 30-days major complications rate defined by the Mitral Valve Academic Consortium (MVARC) endpoint and safety criteria is lacking.

What does this study add?

► To the best of our knowledge, this is the first study reporting outcome of MIMVS according to MVARC definitions. The mitral valve repair was successful in 95.8%, with an overall 30-day mortality of 1.2% and stroke rate of 0.3%. Freedom from any 30-day major complications was 87.2%, independent predictors were a decreased left ventricular ejection fraction and renal function.

How might this impact on clinical practice?

► MIMVS is a safe technique with favourable 30-day outcome such as a low 30-day mortality and stroke rate.

INTRODUCTION

The feasibility of minimally invasive mitral valve surgery (MIMVS) has been proven extensively and numerous high-volume centres have adopted this technique as a standard approach.[1–4] There is currently much literature available, but without evidence of superiority or inferiority of MIMVS compared with sternotomy. Multiple studies reported similar or favourable perioperative outcomes of MIMVS compared with standard sternotomy, but only two of them are randomised controlled trials,[5 6] most of them are observational,[1–4] and some of them are propensity-matched cohorts.[7] There is currently one large trial running in the UK (UK Mini Mitral Trial), for which we are still awaiting the results.[8] Nonetheless, increasingly centres worldwide report promising results,[9 10] which suggests that MIMVS is reproducible in a safe way with results equal to sternotomy. Most clearly reported benefits of MIMVS over sternotomy are faster return to daily activities and higher patient's satisfaction of cosmetics.[11] To achieve these benefits related to the surgical access site, MIMVS should never compromise the quality of the procedure and safety endpoints of the standard surgical treatment. However, a systematic safety analysis based on a comprehensive list of pre-specified 30-day major complications rate is still lacking. In previously mentioned studies, there is no consistency in definitions for adverse events, serious adverse events, major adverse cardiac events and major adverse cardiac and cerebrovascular events (MACCEs), which is a known issue in surgical research.[12] The Mitral

Table 1 Baseline characteristics

		N=745	
Age mean±SD, years		62.9±12.3	
Female		327	43.9%
Body mass index mean±SD, kg/m^2		25.4±3.9	
Euroscore 1 mean±SD		4.5±2.2	
Euroscore 2 mean±SD		1.4±1.2	
Diabetes mellitus		39	5.2%
Atrial fibrillation		272	36.5%
Peripheral vascular disease		6	0.8%
eGFR <60 mL/min/1.73 m^2		119	16.0%
Stroke		37	5.0%
Transient ischaemic attack		31	4.2%
COPD	GOLD 1	21	2.8%
	GOLD 2	24	3.2%
	GOLD 3	7	0.9%
	GOLD 4	3	0.4%
Endocarditis	Active	2	0.3%
	Healed	22	3.0%
Good left ventricular function		640	86.0%
Good right ventricular function		731	98.2%
Pulmonary hypertension	Yes	264	37.4%
	No	441	62.6%
	Missing	40	

COPD, chronic obstructive pulmonary disease; eGFR, estimated glomerular filtration rate.

Valve Academic Consortium (MVARC) provided clear endpoint and safety definitions for treatment of mitral regurgitation, with emphasis on transcatheter therapies.[13] Nonetheless, these definitions should be used for surgical treatment for mitral regurgitation as well to provide uniform results for comparison purposes. The aim of this study is to assess the safety of MIMVS by reporting all the complications during a 30-day follow-up in a systematic fashion with an emphasis on major complications based on MVARC definitions.

MATERIALS AND METHODS

Patient and public involvement

Patients and/or the public were not involved in the setting of this research due to its retrospective design, nor were they burdened with additional investigations, treatment or questionnaires.

Preoperative decision-making process

All patients referred for mitral valve surgery were discussed in the heart team. Consecutive patients with an indication for mitral valve surgery with or without concomitant tricuspid valve and/or maze surgery and/or closure of atrial septal defect were scheduled for MIMVS. Exclusion criteria for MIMVS were previous right thoracotomy, concomitant procedures other than aforementioned (eg, bypass surgery, aortic valve replacement) or severe peripheral vascular disease. Patients with previous cardiac surgery were operated on through MIMVS in our institution, but were excluded for current analysis.

Repair decision-making process

Assessment to repair the mitral valve was based on preoperative echocardiographic mechanism of mitral valve disease, (expected) tissue quality and clinical characteristics (eg, age). Annular dilatation and functional mitral regurgitation were repaired with ring annuloplasty. Ischaemic mitral regurgitation was repaired with an undersized ring. Prolapse of leaflets was repaired with triangular/quadrangular resection and sliding plasty of the annulus in the earliest patients. Starting from the end of 2009, the vast majority of the isolated prolapsing leaflets was repaired with neochordae combined with annuloplasty ring. Barlow disease was standardly repaired with a large annuloplasty ring combined with edge-to-edge stitch of scallops A2/P2.[14] After every repair, a transesophageal echocardiography was made intraoperatively to assess valve function. In case of residual MR more than grade 1, and/or mean pressure gradient >5 mm Hg and/or systolic anterior motion, a second pump run was considered in order to restore.

Data collection and definitions

Medical charts and records were collected for all patients, including demographics, operation notes and postoperative data between 2005 and 2015 (consecutive series). If a patient was transferred to another hospital, we contacted the referral hospital to retrieve postoperative data to complete the 30-day follow-up. For mortality, the Dutch civil register was consulted. All data regarding 30-day complications were collected according a prespecified list of complications based on MVARC criteria.[13] Composite of 30-day major complications was based on MVARC criteria and consisted of 30-day mortality, conversion to sternotomy, myocardial infarction, stroke, renal injury AKIN class II–III, any surgical reintervention (eg, bleeding, empyema or failed repair), prolonged ventilation >48 hours, low cardiac output syndrome (LCOS) >48 hours or necessity for mechanical support.[13] Low cardiac output syndrome LCOS was defined as the necessity for inotropes>30 min after correcting for fluid state,[15] which we separated in three categories: requiring <48 hours of support, requiring >48 hours of support and requiring mechanical support.

Endpoints

Primary endpoint was freedom from 30-day major complications, and secondary endpoint was freedom from any 30-day complications.

Surgical technique

Our surgical technique is based on the Leipzig approach.[1] Cardiopulmonary bypass was instituted by

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Table 2 Mitral valve disease aetiology and indication for surgery (N=745)

	n	%
Regurgitation	695	93.3
Carpentier type 1	120	17.3
Carpentier type 2	535	77.0
Carpentier type 3a	25	3.6
Carpentier type 3b	15	2.2
Aetiology for regurgitation		
Degenerative	534	76.8
Annular dilatation	109	15.7
Ischaemic/dilated cardiomyopathy	16	2.3
Endocarditis	14	2.0
Rheumatic	16	2.3
Post-radiation	6	0.9
Stenosis	30	4.0
Rheumatic	27	90.0
Degenerative	3	10.0
Combined	20	2.7
Rheumatic	16	80.0
Degenerative	4	20.0

groin cannulation. In case of concomitant tricuspid valve surgery or atrial septal defect, a second venous cannula was inserted through the right jugular vein until 2012 to establish total bypass. After this period, a bicaval cannula of LivaNova PLC (London, UK) was used for all operations, and in case of tricuspid valve surgery and/or atrial septum closure with snares around the superior and inferior vena cava. Surgical access was obtained by a right anterolateral mini-thoracotomy of approximately 4–5 cm through the fourth intercostal space. Aortic occlusion was performed with a Chitwood clamp. In 2014 and 2015, the Edwards IntraClude Intra-Aortic Balloon Occlusion Device (Irvine, California, USA) was used in 10 random patients. Selection of these patients was independent of patient factors, but rather on logistics only. Concomitant left maze surgery was performed in patients with atrial fibrillation by creating a left atrial box lesion set by Atricure cryICE (Mason, Ohio, USA). In most patients, the left atrial appendage was left untreated.

Statistical analysis

Univariate and multivariate analysis for predictors for complications were performed in SPSS Statistics for Windows, V.24.0 (IBM. Released 2016). Univariate analysis was done and variables with a p value of less than 0.1 or clinically relevant predictors were selected for inclusion in a multivariate logistic regression model. First, all selected covariates were entered in a multivariate logistic regression model, followed by forward conditional selection to explore the statistically strongest predictors. Second, all selected covariates were entered again into a second logistic regression model, followed by manual backward elimination based on statistical significance and clinical relevance. Predictors with a p value of less than 0.05 in our final model after manual backward elimination were considered as independent predictors for complications. The maximum number of covariates for our prediction model was set at 10% of the number of the outcome event.

RESULTS

Baseline characteristics

Baseline characteristics are shown in table 1. All patients but two were operated on electively after routine check-up. The two emergency patients were in cardiac shock due to acute severe mitral regurgitation, in one patient caused by papillary muscle rupture after a myocardial infarction and needed extracorporeal membrane oxygenation (ECMO) for several days. Both patients survived.

Mitral valve repair, intraoperative characteristics and hospital/ICU admission

Table 2 shows aetiology of mitral valve disease and indications for surgery. The repair techniques used are described in table 3 and figure 1 shows a flowchart of repairability assessment.

An edge-to-edge repair was only standardly performed in patients with Barlow's disease[14] since it is our standard approach, except in eight patients. Of these patients, two were due to systolic anterior motion of the mitral valve and received an edge-to-edge repair during a second pump run, in two patients as a bail-out and in four patients to prevent systolic anterior motion of the mitral valve. Success rate of repair was 95.8% (502/524). Of the repairable valves, 9.3% (54/578) were intentionally replaced since a repair was expected to have limited durability and/or that the benefit of replacement by bioprosthetic valve outweighs the risk of redo for unsuccessful repair, mainly in octogenarians (mean age 79±4 years).[16] Other reasons for replacement in repairable valves are shown in figure 1. All patients at discharge had no more than trace or mild regurgitation. Median ventilation time was 470 min (IQR 355–630). Median intensive care admission was 1 day (IQR 1–2). Median hospital stay was 7 days (IQR 6–10). Median hospital stay for patients in our hospital was 7 days (IQR 6–9), and median hospital stay for patients from referral hospital was 9 days (IQR 7–13).

30-Day mortality

The overall 30-day mortality was 1.2% (9/745), 0.4% (2/507) for mitral valve repair and 2.9% (7/238) for mitral valve replacement. The overall 30-day cardiac-related mortality was 0.9% (7/745) of which one patient had cardiogenic shock due to cardiac amyloidosis (confirmed in postmortem pathological investigation), one patient had intraoperative aortic dissection, one patient had severe and uncontrollable bleeding from a

Table 3 Intraoperative characteristics (N=745)

	n	%
MV replacement	238	31.9
Biological prosthesis	154	64.7
Mechanical prosthesis	84	35.3
MV repair	507	68.1
Ring size, mean±SD	32	±3
Repairable valves*	578	
Attempted repair	524	90.7
Intentionally replaced	54	9.3
Successful repair of attempted repair	502	95.8
Successful repair of repairable valves	502	86.9
Technique used	n	% of 507
Ring+neochordae PMVL +Alfieri stitch	247 +40	48.7 +7.9
Ring annuloplasty +Alfieri stitch	127 +31	25.0 +6.1
Ring+neochordae AMVL +Alfieri stitch	25 +4	4.9 +0.8
Ring+resection PMVL	19	3.7
Ring+neochordae both leaflets +Alfieri stitch	5 +2	1.0 +0.4
Ring+neochordae PMVL+resection PMVL	4	0.8
Ring+resection AMVL	2	0.4
Ring+neochordae AMVL+resection PMVL	1	0.2
Tricuspid valve repair	56	7.5
Atrial fibrillation ablation	132	17.7
Atrial septum defect repair	30	4.0
Mean aortic closs-clamp time, min	82±14	
Mean cardiopulmonary bypass time, min	122±35	

*See figure 1 for more details.
AMVL, anterior mitral valve leaflet; MV, mitral valve; PMVL, posterior mitral valve leaflet.

left ventricular free wall rupture, one patient had a severe stroke, one patient had arrhythmia (sudden death due to asystole on ICU), one patient had obstructive shock due to tamponade (despite rescue surgery) and one patient had hypovolemic shock due to excessive bleeding. The overall 30-day non–cardiac-related death was 0.3% (2/745) both due to pneumosepsis.

Primary outcome: 30-day major complications

All complications that occurred within 30 days are shown in table 4.

Completeness of data was 98.0%. Thirty-day major complication rate was 12.8% and the most common major complication was early re-exploration (within 7 days) for excessive bleeding 6.6% and 0.7% for late bleeding. The 30-day stroke rate was 0.3%. Less frequent major complications were LCOS necessitating mechanical support (ECMO, n=4), of which two have successfully been weaned while the other two died. In one of the surviving patients, the operation was complicated by a free wall rupture with unknown cause that fortunately could be repaired, and one patient was preoperatively in cardiogenic shock due to papillary muscle rupture. The two patients who did not survive suffered respectively from obstructive shock due to tamponade (same patient as mentioned earlier) and cardiogenic shock due to cardiac amyloidosis (same patient as mentioned earlier). All baseline characteristics are used for univariate analysis and are shown in the addendum (online supplemental file 1). Multivariate analysis revealed left ventricular ejection fraction (LVEF) <50% (OR 1.78; 95% CI 1.02 to 3.02) and estimated glomerular filtration rate (eGFR) <60 mL/min/1.73 m^2 (OR 1.98; 95% CI 1.17 to 3.02) as independent predictors for major complications. Figure 2 shows a forest plot of the multivariate model. Age and mitral valve replacement were not significant in multivariate analysis and was left out of the model.

Secondary outcome: 30-day any complications

Any 30-day complication rate is shown in table 4. Some complications like delirium and infections were more often frequently present in the replacement group due to higher age (repair 60 years vs replacement 70 years, p<0.001). Univariate predictors are shown in the addendum (online supplemental file 1). Higher age (>70 years) (OR 2.24; 95% CI 1.55 to 3.26), female sex (OR 1.39; 95% CI 1.01 to 1.90), eGFR <60 mL/min/1.73 m^2 (OR 1.94; 95% CI 1.21 to 3.17) and mitral valve replacement (OR 1.51; 95% CI 1.05 to 2.17) were independent predictors for any complications (figure 3). Pulmonary hypertension was not significant in multivariate analysis and left out of the model. Independent predictors for minor complications were the same as found for any complications.

DISCUSSION

The current safety study provides a unique comprehensive overview of all 30-day complications based on MVARC definitions in a high-volume MIMVS centre showing a low mortality (1.2%) and stroke rate (0.3%). The major complication rate was 12.8% and left ventricular systolic function and renal function were both independent predictors.

As mentioned before, comparison of composite outcomes (eg, MACCE) is difficult due to inconsistency in definitions and is reported at 6.5%–33.0% for both MIMVS and sternotomy.[3 17–21] Despite the result of our study (12.8%) is within the range of literature, it is difficult to compare these outcomes due to multiple definitions. To the best of our knowledge, this is the first study reporting MIMVS outcomes based on MVARC definitions and we encourage others to report their postoperative outcomes as stated in the MVARC criteria. The MVARC is a collaboration between leading academic research organisations and physician-scientist specialising in mitral

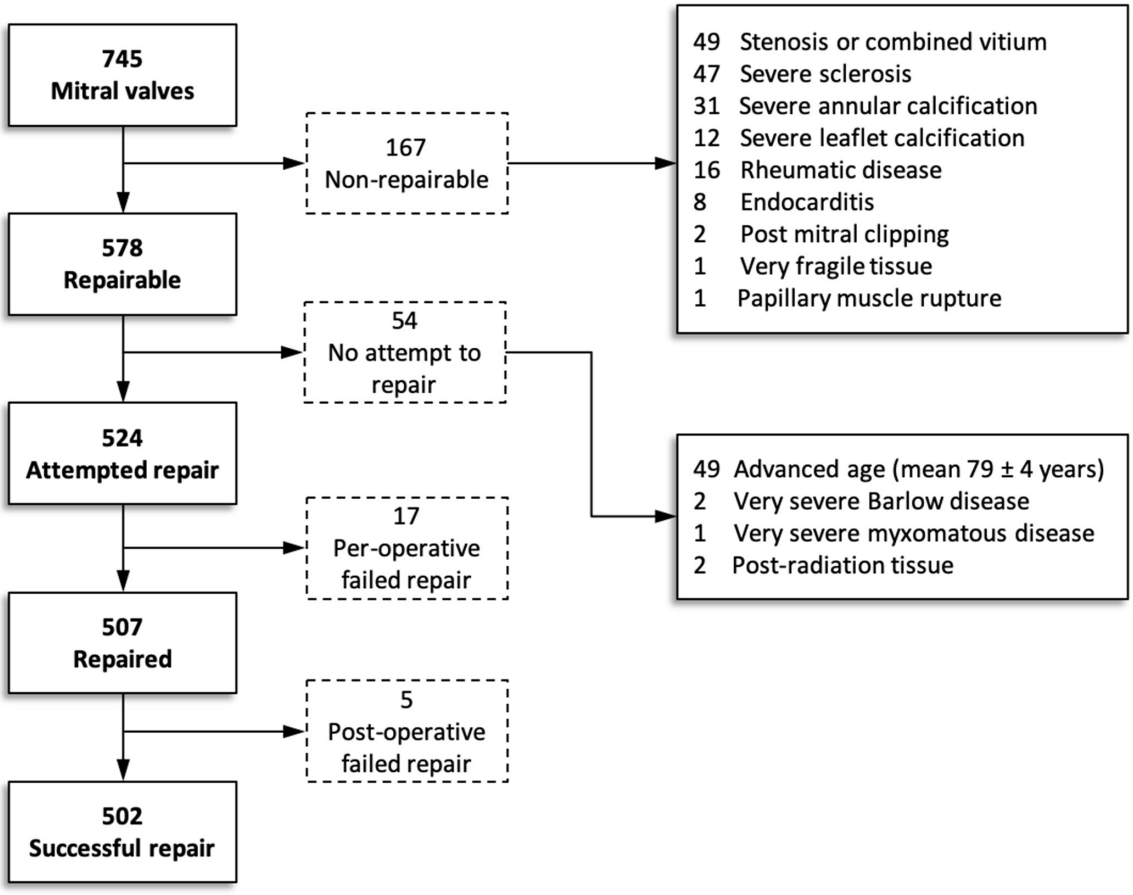

Figure 1 Flowchart of mitral valve repairability.

valve disease from the USA and Europe. The adoption of these recommendations will afford robustness and consistency in the comparative effectiveness evaluation of new devices, new approaches to treat mitral regurgitation and monitoring local and regional outcomes to guide quality improvement initiatives.[13]

MIMVS may be an alternative to conventional sternotomy approach with similar short-term and long-term mortality and in-hospital morbidity.[11] Although there were some initial concerns about aortic injuries and particularly stroke in MIMVS,[11] Sündermann *et al*[22] and more recently Al Otaibi *et al*[23] showed similar stroke rates and mortality in two meta-analyses. As shown in our study, 30-day mortality (1.2%) is comparable with other high-volume MIMVS centres (0.8%–4.2%) and stroke rate (0.3%) is in the lower spectrum (2.0%–2.9%).[1–4] Reported causes for higher stroke risk in MIMVS were retrograde arterial flow, use of endo-aortic balloon or reoperative cases.[24] Although retrograde arterial flow was applied in the current cohort, our stroke rate was lower compared with other literature. After a brief tryout in 2014–2015, we chose not to use the endo-aortic balloon routinely in our centre since the transthoracic clamp is in our experience the most simple, easy-to-handle and safe technique for aortic occlusion, which might explain the low stroke rate of 0.3%. However, a recent meta-analysis showed similar stroke and aortic dissection rates using the endo-aortic balloon, if performed under correct circumstances.[25] MIMVS requires significant dedication to overcome the steep learning curve which can be discouraging for adapting MIMVS in institutional routine surgical programme. Holzhey *et al* reported approximately 75–125 procedures to overcome the learning curve and ~50 procedures per year to maintain optimal results.[26] The key to a safe technique to overcome these learning curve–related risks are, in addition to sufficient volume, a standardised technique and approach, a dedicated surgeon and a well-instructed operation team.

Although Cheng *et al* reported no higher re-exploration for bleeding in a large meta-analysis (MIMVS 3.5% vs sternotomy 2.9%; OR 0.91, 95% CI 0.59 to 1.41),[27] early re-thoracotomy for excessive blood loss was the most frequent major complication (6.6%) and postoperative blood transfusion (30.9%) was the most frequent minor complication. The latter was most frequently observed in patients with re-thoracotomy for excessive blood loss. In the majority (57.1%), no active bleeding was found during re-exploration. In case of an active bleeding, the thoracic wall was the most common bleeding site. Our re-exploration rate is comparable with literature, which is reported at 4.9%–7.0%.[1–4] In our very early experience, the re-exploration rate was 10%; therefore, we decided to inspect the thoracic wall with the videoscope before

Table 4 30-day complications

	All (%)	Replacement (%)	Repair (%)	P value		All (%)	Replacement (%)	Repair (%)	P value
	N=745	N=238	N=507			N=745	N=238	N=507	
Any complications									
Patients with ≥1 minor or major complication	388 (52.1)	228 (45.0)	160 (67.2)	*<0.001*					
Minor complications					Major complications				
Patients with ≥1 minor complication	378 (50.7)	221 (43.6)	157 (66.0)	*<0.001*	Patients with ≥1 major complication	95 (12.8)	41 (17.2)	54 (10.7)	*0.001*
Transient ischaemic attack	16 (2.1)	6 (2.5)	10 (2.0)	0.631	30-day mortality	9 (1.2)	7 (2.9)	2 (0.4)	*0.012*
Delirium	28 (3.8)	21 (8.8)	7 (1.4)	*<0.001*	Conversion to sternotomy‡	6 (0.8)	3 (1.3)	3 (0.6)	0.352
New atrial fibrillation	111 (23.5)	44 (18.5)	67 (13.2)	0.061	Myocardial infarction <48 hours	9 (1.2)	2 (0.8)	7 (1.4)	0.533
New pacemaker	14 (1.9)	8 (3.4)	6 (1.2)	0.051	Myocardial infarction >48 hours	2 (0.3)	1 (0.4)	1 (0.2)	0.592
Pericardial effusion*	10 (1.3)	3 (1.3)	7 (1.4)	0.894	Stroke	2 (0.3)	1 (0.4)	1 (0.2	0.592
Pleural effusion*	26 (3.5)	12 (5.0)	14 (2.8)	0.119	Renal injury, AKIN class II–III	16 (2.1)	6 (2.5)	10 (2.0)	0.631
Pneumothorax*	9 (1.2)	5 (2.1)	4 (0.8)	0.142	Re-intervention for:				
Pneumonia	11 (1.5)	4 (1.7)	7 (1.4)	0.752	Early bleeding (<7 days)	49 (6.6)	21 (8.8)	28 (5.5)	0.093
Urinary tract infection	28 (3.8)	16 (6.7)	12 (2.4)	*0.005*	Late bleeding (>7 days)	5 (0.7)	3 (1.3)	2 (0.4)	0.201
Other infections	9 (1.6)	7 (2.9)	2 (0.4)	*0.012*	Pericardial effusion (>7 days)	3 (0.4)	1 (0.4)	2 (0.4)	0.959
Groin infection	2 (0.3)	2 (0.8)	0 (0.0)	0.970	Failed repair	5 (0.7)	0 (0.0)	5 (1.0)	0.972
Groin seroma*		1 (0.4)	5 (1.0)	0.434	Other§	6 (0.8)	3 (1.3)	3 (0.6)	0.352
Renal injury, AKIN class I	6 (0.8)	10 (4.2)	7 (1.4)	*0.022*	Prolonged ventilation >48 hours	5 (0.7)	2 (0.8)	3 (0.6)	0.700
Phrenic nerve palsy	17 (2.3)	2 (0.8)	9 (1.8)	0.335	LCOS with mechanical support	4 (0.5)	2 (0.8)	2 (0.4)	0.448
LCOS <48 hours	11 (1.5)	25 (10.5)	30 (5.9)	*0.028*	LCOS >48 hours	6 (0.8)	2 (0.8)	4 (0.8)	0.942
Blood transfusion†	55 (7.4)	104 (43.7)	126 (24.9)	*<0.001*					

LCOS: low cardiac output syndrome, requiring any inotropes for >30 min to maintain systolic blood pressure at greater than 90 mm Hg and cardiac output.
*Requiring drainage.
†Number of patients who needed 1 or more units of packet cells during admission on ICU or ward.
‡Unintended conversions: 2 iatrogenic aortic dissections, 3 perioperative bleeding and 1 right ventricular failure.
§Other re-interventions: 1 empyema, 1 left ventricular wall rupture, 1 endocarditis, 1 removal stuck epicardial pacemaker wire, 1 iatrogenic lung lesion, 1 pleural effusion.

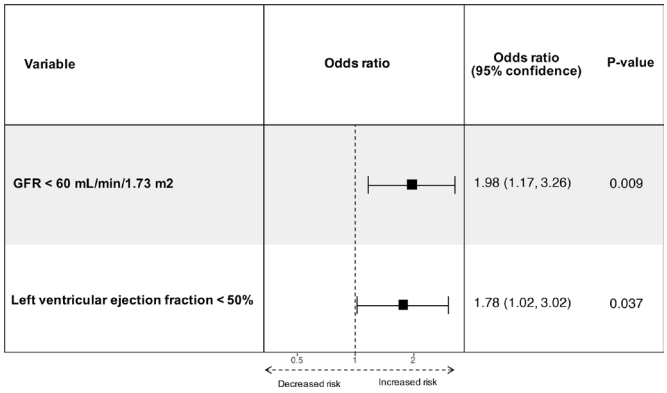

Figure 2 Forest plot of independent predictors for 30-day major complications. GFR, glomerular filtration rate.

closing the chest wall, leading to a decrease to 5% re-exploration rate in the last 3 years.

Surprisingly, an increased body mass index was not a predictor for any 30-day complications in this study, as we expected that they were at higher risk since the procedure is technically more challenging in these patients. We found excess 30-day major complications in patients with LVEF <50% and decreased eGFR, which is in line with literature.[28–30]

Limitations

There are few limitations in this study that needed to be addressed. First, all the data were collected retrospectively with all its known limitations. Furthermore, the data might have been biased by several time-dependent variables like operator experience. Three types of annuloplasty rings that were used in this time interval and different mitral valve repair techniques that were applied throughout the years. Ablation for atrial fibrillation was done in 17.7%, while baseline characteristics show 36.5% atrial fibrillation. Possible explanation is a strict definition used for preoperative atrial fibrillation since all patients with any reported atrial fibrillation is scored, while possibly not all of them are good candidates for ablation. Due to the retrospective character of this study, it is not possible to reconstruct the decision-making process to analyse whether it was long persisting, symptomatic and what the left atrial volume index was. However, the same effect was observed in other large series with preoperative atrial fibrillation in 33%–37% and an ablation rate of 9.8%–17.2%.[2 9]

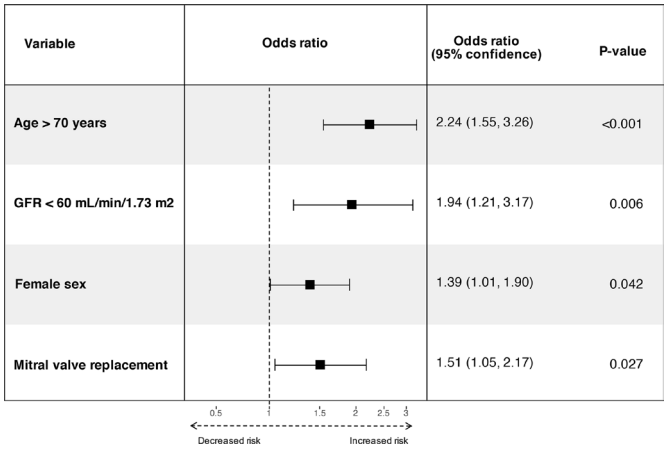

Figure 3 Forest plot of independent predictors for any 30-day complications. GFR, glomerular filtration rate.

CONCLUSIONS

The current study shows that MIMVS is a safe technique and is associated with low 30-day mortality and stroke rate.

Contributors All listed authors contributed substantial to the work, approved the final version and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. KK and TLdK contributed equally to this work. BPvP and NS contributed equally to this work. KK: drafting of the work and writing of manuscript. Acquisition, analysis and interpretation of data. TLdK: conceptualisation and critical revision of the work. KFS: acquisition of data and critical revision of the work. JCK: analysis of data and critical revision of the work. NS: conceptualisation and critical revision of the work. BPvP: conceptualisation and critical revision of the work.

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Competing interests None declared.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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