

Tricuspid intervention for less-than-severe regurgitation simultaneously with minimally invasive mitral valve surgery in patients with atrial fibrillation

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ABSTRACT

Background: While tackling moderate tricuspid regurgitation (TR) simultaneously with left-side heart surgery is recommended by the guidelines, the procedure is still seldom performed, especially in the minimally invasive setting. Atrial fibrillation (AF) is a known marker of both mortality and TR progression after mitral valve surgery.

Aims: This study aimed to investigate the safety of performing tricuspid intervention and minimally invasive mitral valve surgery (MIMVS) in patients with preoperative AF.

Methods: We retrospectively analyzed data from the Polish National Registry of Cardiac Surgery Procedures collected between 2006 and 2021. We included all patients who underwent MIMVS (mini-thoracotomy, totally thoracoscopic, or robotic surgery) and had presented with moderate tricuspid regurgitation and AF preoperatively. The primary endpoint was death from any cause at 30 days and at the longest available follow-up after MIMVS with tricuspid intervention vs. MIMVS alone. We used propensity score (PS) matching to account for baseline differences between groups.

Results: We identified 1545 patients with AF undergoing MIMVS, 54.7% were men aged 66.7 (mean [standard deviation, SD], 9.2) years. Of those, 733 (47.4%) underwent concomitant tricuspid valve intervention. At 13 years of follow-up, the addition of tricuspid intervention was associated with 33% higher mortality as compared to MIMVS alone (hazard ratio [HR], 1.33; 95% confidence interval [CI], 1.05–1.69; $P = 0.02$). PS matching resulted in identifying 565 well-balanced pairs. Concomitant tricuspid intervention did not influence long-term follow-up (HR, 1.01; 95 CI, 0.74–1.38; $P = 0.94$).

Conclusions: After adjusting for baseline confounders, the addition of tricuspid intervention for moderate tricuspid regurgitation to MIMVS did not increase perioperative mortality nor influence long-term survival.

Key words: atrial fibrillation, minimally invasive surgery, mitral valve, tricuspid valve

WHAT'S NEW?

This study is the first to investigate long-term safety of performing tricuspid valve (TV) intervention for moderate tricuspid regurgitation (TR) in addition to minimally invasive mitral valve surgery (MIMVS) in patients with underlying atrial fibrillation (AF). There is a complex link between mitral valve disease, TR, and AF, with AF alone being associated with tricuspid annulus dilatation and TR linked to AF exacerbation. Besides, AF patients have a higher baseline risk, and thus benefits of adding TV intervention must be weighed against the risks of morbidity and mortality. Our analysis of a nationwide registry shows that after adjusting for baseline confounders, the addition of tricuspid intervention to MIMVS did not increase perioperative mortality or influence long-term survival.

INTRODUCTION

Tricuspid regurgitation (TR) is a common finding in patients undergoing mitral valve (MV) surgery [1–3]. The guideline recommendations for management of TR during MV surgery are based largely on observational data which are, however, inconclusive as to the safety and long-term durability of approaches involving concomitant TR intervention [4]. Nevertheless, there is a broad agreement that severe TR may not predictably improve after left-sided cardiac surgery, i.e. MV surgery, and, therefore, should be addressed during the index procedure. On the other hand, the surgical management of less-than-severe TR i.e. moderate tricuspid regurgitation is a subject of lively debate. There is also limited evidence on whether such a combined approach implemented during minimally invasive MV surgery (MIMVS) is as safe as MV alone [5, 6]. Recently published results of a randomized trial that assigned 401 patients undergoing mitral-valve surgery for degenerative mitral regurgitation (MR) to receive tricuspid annuloplasty (TA) for moderate TR or just MV have become available [7]. At 2 years, those who received TA had a lower incidence of the primary endpoint (worsening of TR, redo TA, or death) than those who underwent MV surgery alone. Tricuspid repair resulted in more frequent permanent pacemaker implantation (PPI). Over 50% of patients underwent respective surgeries with the conventional sternotomy approach [7].

There exists a direct link between MV disease (MVD) and both the development and progression of atrial fibrillation (AF) [3, 8]. The link between TR and AF, while less pronounced, only recently has been investigated by pivotal studies. One of them has shown that significant isolated TR was independently associated with lower rates of event-free survival in AF patients. Another study investigating concomitant MV and TV surgery found that progression to moderate or greater tricuspid regurgitation was associated with an increase in late mortality; with preoperative AF being the most important risk factor for late TR despite concomitant ablation surgery [9, 10]. Our analysis aimed to determine long-term survival of patients with underlying AF and moderate TR undergoing MIMVS.

METHODS

Data were collected retrospectively from the KROK registry (Polish National Registry of Cardiac Surgery Procedures,

available at: www.krok.csioz.gov.pl). The registry is an ongoing nationwide multi-institutional registry of heart surgery procedures in Poland; the details of the registry conception and design were described previously [11]. Due to anonymization of registry data and retrospective nature of the study, both patient consent and institutional review board approval respectively were waived.

Study population

The registry included all adult patients undergoing MIMVS for whatever reason between January 1, 2006 and December 31, 2021 and evidence of any type of preoperative AF. Post-operative AF was not recorded and, therefore, not considered. Minimally invasive mitral valve surgery was defined as mini-thoracotomy, totally thoracoscopic or robotic MV surgery [12]. Transcatheter replacement, transcatheter “edge-to-edge” repair, and mitral chordae transapical implantations were not considered. Patients undergoing surgery due to infective endocarditis were excluded. Choice of cannulation site, cross-clamp, cardioplegia, annuloplasty rings, valve prostheses, and repair techniques were recorded whenever possible. Similarly, the data regarding surgical ablation and/or left atrial appendage occlusion (LAAO) were collected. Patients were assigned to two groups: those undergoing MIMVS with concomitant TV replacement or repair (MIMVS plus TVR/r) and those who underwent MV alone (MIMVS alone).

Clinical variables and endpoints

For patients undergoing heart surgery, we considered and reported 3 categories of variables: (1) baseline demographics: age, sex, EuroSCORE II, and its single components; (2) extent of coronary artery disease (CAD) and/or valvular and/or aortic disease, and (3) surgical variables: urgency, operative technique [13]. The primary endpoint was death from any cause reported at 30 days and the longest available follow-up for the comparison of MIMVS plus TVR/r vs. MIMVS alone patients. In-hospital outcomes and lengths of stay in the intensive care unit (ICU) and hospital (HLoS) were compared and reported as well. Baseline clinical, procedural, and outcome data at follow-up were entered into prespecified electronic case report forms. Kidney Disease Improving Global Outcomes (KDIGO) definition of acute kidney injury was adopted. Follow-up status with

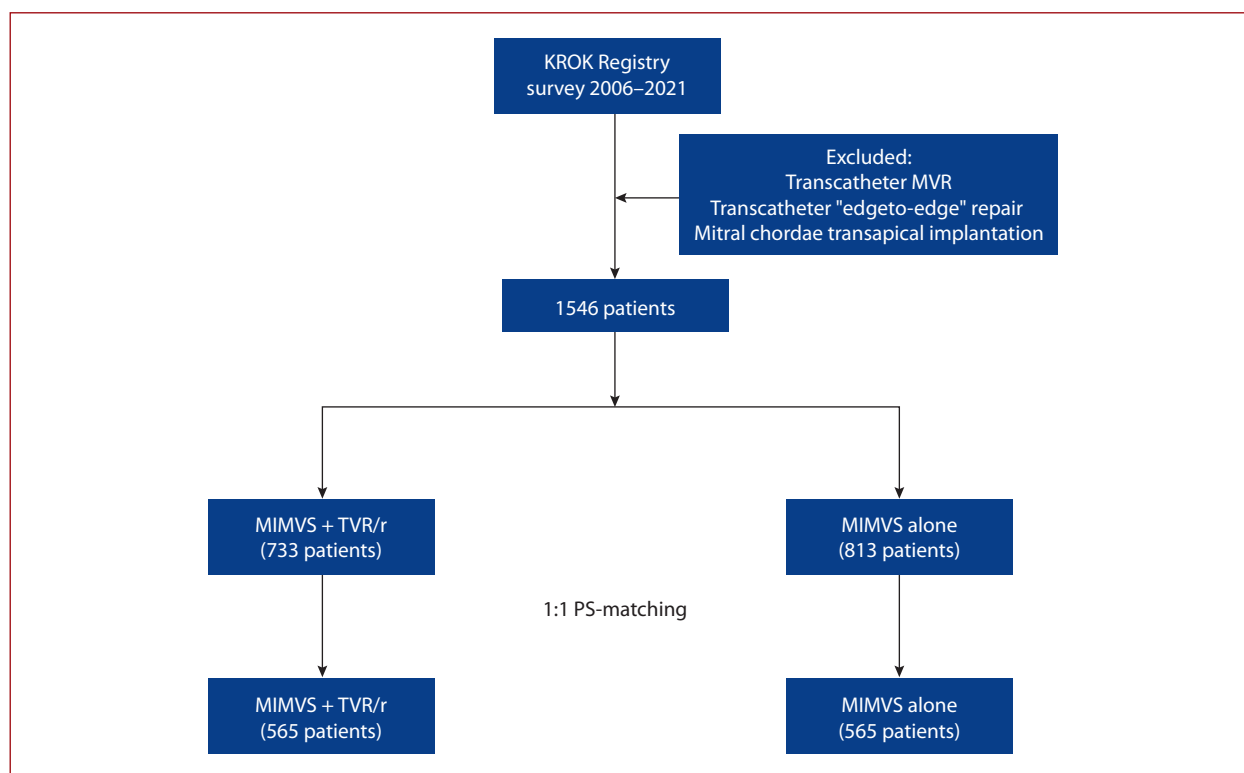


Figure 1. Study flowchart

Abbreviations: MVR, mitral valve replacement; MIMVS, minimally invasive mitral valve surgery; PS, propensity score; TVR/r, tricuspid valve replacement or repair

respect to all-cause mortality was validated in the Polish National Health Fund database and incorporated in the KROK registry.

Statistical analysis

Registry records with >5% of missing data were not considered; in those with <5%, missing data were input by artificial neural networks [14]. Continuous variables were summarized as mean (standard deviation [SD]) if normally distributed; non-normal distributions were summarized as medians and interquartile ranges (IQR) and compared with the Mann-Whitney U test or standard t-test as appropriate. Categorical variables (number [%]) were compared with the Fisher's exact test. Risk ratios (RRs) were used primarily for 30-day/in-hospital outcomes. Univariable and multivariable logistic regression analyses to determine predictors of mortality were conducted. Similarly, we carried out univariable and multivariable logistic regression analyses to identify the factors associated with performing concomitant TVR/r. We built a non-parsimonious model including variables identified in multivariable analyses for propensity score matching (PSM); a one-to-one nearest neighbor matching was performed with replacement (caliper 0.2); overall long-term mortality was assessed with Kaplan-Meier curves fitted before (unadjusted model) and after propensity score matching [15]. The quality of the matching was assessed by visual inspection [16]. Cox regression was used to determine the long-term hazard ratio (HR) for all-cause mortality as stratified by MIMVS plus

TVR/r and MIMVS alone patients. As sensitivity analysis to assess survival in MIMVS plus TVR/r and MIMVS alone subsets, we further stratified patients according to pre-defined subgroups. STATA MP v13.0 software (StataCorp, College Station, TX, US) and the packages "psmatch2", "rrobust", "optmatch", "matchIt", and "CRTgeeDR" in R Core Team 2013 were used.

RESULTS

Patient baseline characteristics

During the study, 1545 patients with AF undergoing MIMVS were identified. At baseline, 54.7% were men ($n = 846$), aged 66.7 (9.2) years, with a median of 4.4 (2.7%–6.1%) EuroSCORE II operative risk. Of those, 733 (47.4%) underwent concomitant tricuspid valve intervention (Figure 1) for moderate TR. Baseline and operative characteristics of the unadjusted population are available as Supplementary material, Tables S1, S2. Variables associated with TVR/r performance were identified in uni- and multivariable analyses and are available as Supplementary material, Table S3. Among these, higher age ($P < 0.001$), BSA ($P < 0.001$), and LAAO were associated with TVR/r, while previous PCI ($P < 0.001$), renal impairment ($P = 0.02$), urgency ($P < 0.001$), and mitral valve replacement (MVR) ($P = 0.03$) were predictive of not undertaking TVR/r.

Clinical outcomes are listed in Supplementary material, Table S4; 30-day mortality was 4.0% vs. 3.3% ($P = 0.59$) in the MIMVS plus TVR/r or MIMVS alone groups, respec-

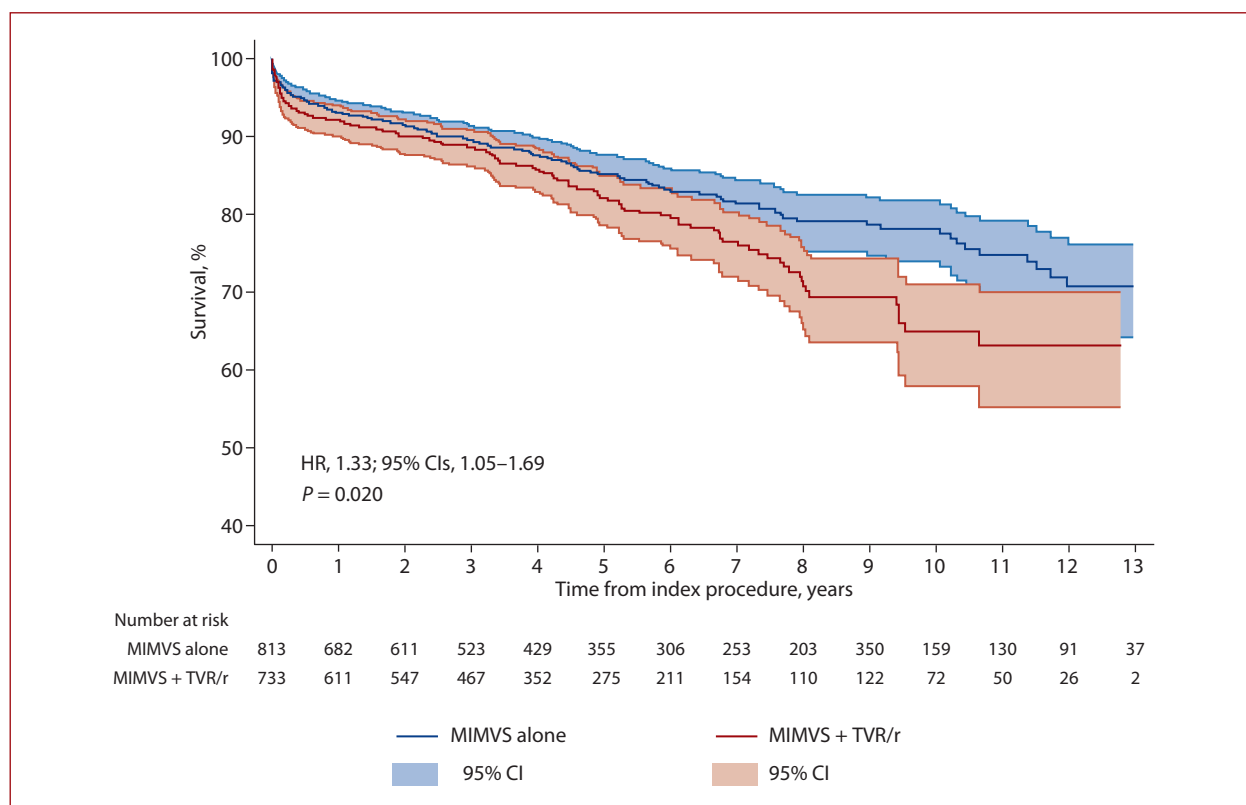


Figure 2. Long-term unadjusted survival analysis

Abbreviations: HR, hazard ratio; CI, confidence intervals; MIMVS, minimally invasive mitral valve surgery; TVR/r, tricuspid valve replacement or repair

tively. At 13 years, the addition of tricuspid intervention was associated with 33% higher mortality as compared to MIMVS alone (HR, 1.33; 95% CI, 1.05–1.69; $P = 0.02$) (Figure 2). Further predictors of mortality were NYHA class and surgical urgency. The uni- and multivariable analyses of mortality predictors are listed as Supplementary material, Table S5.

Propensity score matching

One-to-one PS matching resulted in 565 pairs assigned to the MIMVS plus TVR/r or MIMVS alone groups. Moreover, PS matching with the exclusion of urgent procedures and exact matching by age were performed. Quality of the matching with histogram distribution of PS scores along with propensity scores estimates are available for both models as Supplementary material, Figures S2, S3, and S6, respectively. Standardized mean differences between PS-matching variables in MIMVS plus TVR/r or MIMVS alone subgroups were assessed visually (Supplementary material, Figure S1). Table 1 lists the baseline characteristics of PS-matched patients. There were no marked differences between the patients except for the continuous variables of age (68 [61–73] years vs. 69 [63–74] years; $P = 0.003$) and EuroSCORE II (3.16 [2.09–4.95] vs. 2.34 [1.32–4.43]; $P < 0.001$). Operative characteristics are further available in Table 2. Most patients were elective (90.8%); 4.2% underwent redo surgery.

Table 3 lists perioperative complications; there were no major differences between MIMVS plus TVR/r or MIMVS except for the observed propensity for lower rates of re-thoracotomies for bleeding associated with MIMVS plus TVR/r. Median ICU and hospital length of stay were 12 days vs. 10 days ($P < 0.001$) and 45.1 hours vs. 44.9 hours ($P = 0.19$), respectively for MIMVS plus TVR/r vs. MIMVS.

In both of the PS-matched models, performing concomitant TVR/r did not influence the long-term follow-up: HR, 1.01; 95% CI, 0.74–1.38; $P = 0.94$ (Figure 3); HR, 1.08 (0.61–1.91); $P = 0.79$ (Supplementary material, Figure S7). The proportional hazard assumption was not violated ($P = 0.16$) as also graphically assessed by Schoenfeld residuals (Supplementary material, Figure S5).

DISCUSSION

To the best of our knowledge, our analysis is the first study that investigated the influence of the addition of TVR/r in patients with less-than-severe TR and preoperative AF undergoing MIMVS as compared to patients undergoing isolated MIMVS. The main finding of our analysis is that in the PS-matched model, despite the longer cardiopulmonary bypass (CPB) and X-clamp time, the concomitant tricuspid intervention is safe and does not increase perioperative, short-term, and remote mortality and has a limited impact on perioperative morbidity.

Table 1. Propensity matched patient baseline characteristics

Variable	Propensity matched pairs		
	MIMVS + TVR/r (n = 565)	MIMVS alone (n = 565)	P-value
Baseline characteristics			
Age, years, median (IQR)	68 (61–73)	69 (63–74)	0.003
Male sex, n (%)	280 (49.5)	284 (50.3)	0.81
EuroSCORE II, median (IQR)	3.16 (2.09–4.95)	2.34 (1.32–4.43)	<0.001
Diabetes, n (%)	119 (21.1)	140 (24.8)	0.14
Active smoking, n (%)	260 (46.0)	253 (44.8)	0.72
Hypertension, n (%)	409 (72.4)	428 (75.8)	0.20
Hyperlipidemia, n (%)	242 (42.8)	252 (44.6)	0.55
BMI, kg/m ² , median (IQR)	27.2 (24.1–30.1)	27.8 (24.9–29.9)	0.12
BSA, m ² , median (IQR)	2.7 (2.5–2.9)	2.7 (2.5–2.9)	0.73
Renal impairment, n (%)	105 (18.6)	113 (20.0)	0.55
PVD, n (%)	71 (12.5)	74 (13.1)	0.79
Carotid artery disease, n (%)	33 (5.8)	40 (7.1)	0.40
Previous stroke, n (%)	33 (5.8)	37 (6.5)	0.62
Asthma/COPD, n (%)	45 (8.0)	52 (9.2)	0.46
LVEF, %, median (IQR)	54 (45–60)	54 (45–60)	0.20
PHT, n (%)	175 (31.0)	161 (28.5)	0.36
CAD (any degree), n (%)	71 (12.5)	101 (17.9)	0.01
Previous MI, n (%)	35 (6.2)	45 (8.0)	0.25
Previous PCI, n (%)	50 (8.8)	62 (11.0)	0.23
NYHA class, n (%)			<0.001
I	41 (7.2)	69 (12.2)	0.005
II	184 (32.5)	136 (24.1)	0.002
III	303 (53.5)	306 (54.2)	0.86
IV	37 (6.5)	54 (9.6)	0.06

Abbreviations: BMI, body mass index; BSA, body surface area; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; EuroSCORE; European System for Cardiac Operative Risk Evaluation; IQR, interquartile range; LVEF, left ventricular ejection fraction; MI, myocardial infarction; MIMVS, minimally invasive mitral valve surgery; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; PHT; pulmonary hypertension; PVD, peripheral vascular disease; TVR/r, tricuspid valve replacement/repair

Table 2. Propensity matched patients' surgical details

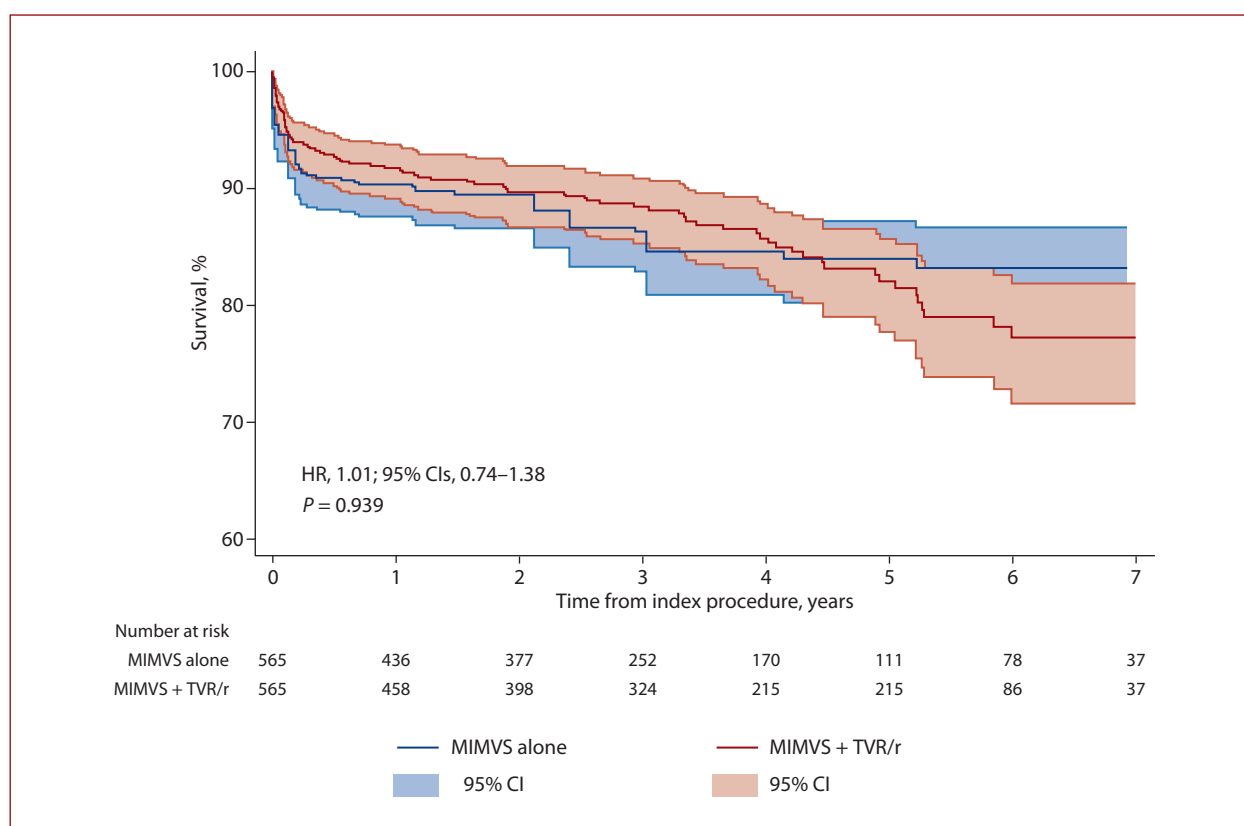
Variable	Propensity matched pairs		
	MIMVS + TVR/r (n = 565)	MIMVS alone (n = 565)	P-value
Surgical characteristics			
Redo surgery, n (%)	17 (3.0)	30 (5.3)	0.05
Non-elective, n (%)	42 (7.4)	62 (11.0)	0.04
Mitral valve disease, n (%)			
MV stenosis (any degree), n (%)	48 (8.5)	77 (13.6)	0.008
MR pathology, n (%)			
Primary	418 (73.9)	340 (60.2)	<0.001
Secondary	148 (26.1)	225 (39.8)	
MR, n (%)			
Mild	29 (5.2)	36 (6.4)	0.70
Moderate	115 (20.4)	104 (18.4)	0.11
Severe	419 (74.4)	424 (75.2)	0.05
MVR, n (%)			
Mechanical prosthesis, n (%)	30 (5.3)	13 (2.3)	0.008
Implanted valve size, mm median (IQR)	29 (27–29)	29 (25–30)	0.89
MVr			
Annuloplasty ring, n (%)	458 (81.1)	477 (84.4)	0.156
Implanted ring size, mm median (IQR)	30 (28–34)	30 (28–34)	0.38
Surgical ablation, n (%)			
LAAO, n (%)	206 (36.5)	190 (33.6)	0.35
CPB time, min median (IQR)	155 (123–185)	135 (106–162)	<0.001
X-clamp time, min median (IQR)	107 (86–128)	85 (65–110)	<0.001

Abbreviations: CPB, cardiopulmonary bypass; LAAO, left atrial appendage occlusion; MIMVS, minimally invasive mitral valve surgery; MR, mitral regurgitation; MV, mitral valve; MVr, mitral valve repair; MVR, mitral valve replacement; TVR/r, tricuspid valve replacement/repair

Table 3. Propensity matched patients' in-hospital complications

Variable	Propensity matched pairs		
	MIMVS + TVR/r (n = 565)	MIMVS alone (n = 565)	P-value
In-hospital complications			
24-hour mortality, n (%)	5 (0.9)	0 (0.0)	0.06
30-day mortality, n (%)	23 (4.1)	31 (5.5)	0.27
Cardiac tamponade and/or re-thoracotomy for bleeding, n (%)	62 (11.0)	29 (5.1)	<0.001
Respiratory failure, n (%)	38 (6.7)	38 (6.7)	>0.99
Neurologic complications, n (%)	15 (2.7)	13 (2.3)	0.85
Multiorgan failure, n (%)	10 (1.8)	15 (2.7)	0.42
Gastrointestinal complications, n (%)	9 (1.6)	7 (1.2)	0.80
Acute kidney failure and/or dialysis, n (%)	16 (2.8)	20 (3.5)	0.50
Wound infection, n (%)	12 (2.1)	11 (1.9)	>0.99
PPI, n (%)	8 (1.4)	9 (1.6)	0.81

Abbreviations: MIMVS, minimally invasive mitral valve surgery; PPI, permanent pacemaker implantation; TVR/r, tricuspid valve replacement/repair

**Figure 3.** Long-term propensity-matched survival analysis

Abbreviations: see Figure 2

AF and TR frequently accompany MVD and both have been shown to be risk factors for various adverse outcomes regardless of intervention [8]. The common perception that TR secondary to MVD resolves after surgical treatment has been questioned multiple times, especially in patients with preoperative AF [3]. Alarming evidence of poor outcomes in patients with variable degree or hemodynamically significant TR grew over the past years. The recent analysis of 33 305 patients demonstrated that the presence of any degree of TR was associated with adverse long-term clinical outcomes and, what is more important, at least moderate TR was independently associated with increased

mortality [17]. While surgical intervention in severe TR is currently well-established, researchers who focused on the natural history of less-than-severe TR in patients with MVD demonstrated that TV disease is likely to progress, particularly after durable repair of MV [1]. A pivotal study by Dreyfus et al. suggested that tricuspid annulus diameter (TAD), rather than a grade of regurgitation, should be taken into consideration in the decision-making process for TV correction [18]. Further research supported this hypothesis, as recent evidence advocates for the addition of TV annuloplasty to MV surgery in patients with less-than-severe TR and annulus dilatation over 40 mm. In such

cases, a surgical approach is not only safe but also results in less frequent progression to severe TR [7, 19]. On the other hand, the study by Bertrand et al. [20], that focused on TV function after ischemic MR surgery, did not confirm these findings, concluding that worsening of unrepaired non-severe TR is uncommon after MVS, and TAD alone is not a good predictor of its progression.

When it comes to TR and AF, there is a relationship between the two of them. On the one hand, AF is a well-established risk factor for progression of untreated TR, but, on the other, TR may contribute to AF recurrence after ablation [2, 9, 21]. Potential mechanisms of TR progression due to AF included right ventricular (RV) dilatation and dysfunction, leaflet tethering, right atrial enlargement, and, finally, TAD [22]. Ortiz-Leon et al. demonstrated that AF contributes to TA and right atrial remodeling in patients with non-severe TR regardless of left heart disease [23]. This finding is in line with previous reports suggesting that patients with functional TR associated with AF may be the most suitable candidates for annuloplasty due to its dilatation without leaflet tethering [24]. Clinical benefits of minimally invasive TVR/r were recently investigated by Sorajja et al. [25] in their randomized controlled trial comparing percutaneous transcatheter edge-to-edge repair (TEER) with medical treatment. Not only was the procedure successful in 98.3% but also it was related to a significant improvement in terms of primary composite endpoint, in regurgitation severity, and quality of life. Notably, 90% of the studied population had AF.

Careful analysis of our PS-matched model results in the context of previous studies supports the thesis that the addition of TVR/r to MIMVS is safe and does not result in increased mortality. It is an important finding, especially considering concerns linked with longer CPB and X-clamp times in minimally invasive techniques as compared with conventional sternotomy. These concerns may be reflected in the lower frequency of TVR/r in patients undergoing non-elective surgery, even after PS-matching. Urgency is a well-known risk factor related to poor prognosis, which is supported by our multivariable logistic regression results [26]. A higher rate of re-thoracotomies due to bleeding in patients undergoing double valve surgery was also reported in earlier works and explained by an additional incision and maneuvers involving the right atrium [6]. Importantly, multivariable logistic regression showed an almost 5-fold increase in mortality prediction in patients undergoing redo surgery (Supplementary material, *Table S5*). We also noted that HLoS in the TVR/r group were two days longer, which is consistent with observations from the recent study that investigated TVR addition in patients with moderate or less-than-moderate TR and annular dilatation over 40 mm who had undergone MVS due to degenerative MR [7]. However, contrary to the outcomes from the study based on the Netherlands Heart Registration data, in the unmatched model, the addition of TV intervention was associated with a 33% higher mortality than in the MIMVS-alone group [6].

Moreover, we found more discrepancies in terms of perioperative complications. The aforementioned study by Gammie et al. indicated that although double valve surgery resulted in a lower incidence of a primary endpoint event, there was over 5-fold higher rate of PPI in the TV intervention group [7]. In the analysis of the Society of Thoracic Surgeons database, the addition of TVR to MVS in patients with AF resulted in a doubling of unadjusted PPI rates [27]. In contrast to those reports, we found similar PPI rates between two groups, which is in line with Huang et al. study that demonstrated no difference in complete heart block incidence when TVR is added to MIMVS [28].

Limitations

Despite the multicenter design of the registry and relatively large group of patients included in the analysis, several limitations need to be addressed. Data on the exact type of AF and detailed information on the preoperative specific echocardiography results, such as right ventricular systolic pressure (RSVP), tricuspid annular plane systolic excursion (TAPSE), and/or TAD and right ventricular systolic pressure were not collected in the KROK registry. It prevented us from conducting further analyses, such as the possible predictive value of TAD. No details such as surgical technique in ablation, mitral and tricuspid valve surgery were included in the KROK registry. In order not to reduce the sample size, we did not include mitral regurgitation pathology in the PS-matching. It resulted in unequal distribution of primary and secondary MR. A higher percentage of secondary MR in the MIMVS alone could be a risk marker, and as such may have driven the null results in the current analysis. No information on the rate of preservation of subvalvular apparatus was provided, which might have influenced the long-term prognosis as well. Long-term results of this study are limited to all-cause mortality; therefore, no conclusion regarding clinical outcomes (e.g., progression of TR or NYHA classification) could be drawn. The KROK registry does not collect long-term echocardiography data either. The actual rate of PPI might be understated because this procedure is often performed outside surgery departments for reasons connected with reimbursement, and, therefore, some procedures may not be included in the registry.

CONCLUSIONS

In the unmatched population, at 13 years, performing tricuspid intervention in addition to MIMVS was associated with 33% higher mortality as compared to MIMVS alone. In the PS-matched model, concomitant TVR/r in patients with moderate TR and AF undergoing MIMVS was safe and did not increase perioperative risk but a higher rate of re-thoracotomies for bleeding and longer HLoS were noted in the double valve surgery group. Further studies are necessary to establish criteria that would help guide the decision about concomitant tricuspid intervention during minimally invasive mitral valve surgery, in particular, in patients with underlying AF.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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