




# High Efficacy and Low Early Mortality in High-Volume Center Tricuspid Valve Surgery

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Thorac Cardiovasc Surg

## Abstract

**Background** Isolated tricuspid valve surgery has been associated with early mortality rates of up to 10%. With rapidly emerging interventional catheter-based options, the question arises whether current technical and perioperative protocols in cardiac surgery translate into lower than previously expected mortality rates, especially when looking at data from high-volume centers.

**Methods** We performed a retrospective single-center analysis in 369 patients undergoing isolated tricuspid valve repair ( $n = 256$ ) or replacement ( $n = 113$ ) between 2009 and 2021. Surgical approaches included full sternotomy, as well as right-sided minithoracotomy. According to a recently introduced clinical risk score, patients were divided into scoring groups, and observed (O) versus expected (E) early mortality were compared. Pre- and postoperative tricuspid valve function was also analyzed.

**Results** Overall, 30-day mortality was 4.1%, ranging from 0% (scoring group 0–1 points) to 8.7% (scoring group  $\geq 10$  points), which was substantially lower than the expected early mortality (2% in the lowest to 34% in the highest scoring group). Preoperative tricuspid regurgitation was severe in 71.3% ( $n = 263$ ), moderate to severe in 14.9% ( $n = 55$ ), and mild or less in 6.5% ( $n = 24$ ). The corresponding postoperative values were 0% ( $n = 0$ ), 1.4% ( $n = 5$ ), and 81.6% ( $n = 301$ ).

**Conclusion** Our high-volume center data indicate substantially lower than predicted 30-day mortality in different cardiac surgical risk scoring groups. The majority of patients had zero to minimal residual tricuspid valve insufficiency postoperatively. Randomized controlled trials are needed to compare tricuspid valve functional results and long-term outcomes of surgical versus interventional procedures in patients undergoing isolated tricuspid valve procedures.

## Keywords

- ▶ tricuspid valve
- ▶ surgery
- ▶ complications
- ▶ outcomes
- ▶ heart valve surgery

## Introduction

Moderate-to-severe tricuspid regurgitation (TR) is observed in 0.55% of the general population and its prevalence

increases with age, affecting  $\sim 4\%$  of patients aged over 75 years.<sup>1</sup> According to various recent reports from numerous centers around the world, isolated tricuspid valve surgery is associated with high mortality rates, ranging from 7.9

received  
October 31, 2022  
accepted after revision  
February 9, 2023  
accepted manuscript online  
March 7, 2023

DOI <https://doi.org/10.1055/a-2048-8199>.  
ISSN 0171-6425.

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to 10.3%.<sup>2-8</sup> The study results so far appear to be compromised by either small sample sizes or rather inhomogeneous multicenter data acquisition. With the aim of facilitating preoperative decision-making and identifying appropriate patients for isolated tricuspid valve surgery, a clinical risk model based on data from 50 centers in the United States was introduced in 2018; predicted perioperative mortality (2–34%) grouped in risk scores ranging from 0 to 10 was reported.<sup>7</sup> In the present study of our own high-volume center, data analysis was performed to evaluate perioperative mortality risks in minimal-, low-, intermediate-, and high-risk patients in accordance with the aforementioned risk score and compared with German national data. In addition, we evaluated pre- and postoperative tricuspid valve function in our patients.

## Methods

### Patients

This retrospective report summarizes data obtained between August 2009 and December 2021 in patients with tricuspid valve surgery at our institution. The first inclusion criterion was an age of 19 years or over. In addition, we included only patients who underwent isolated valve replacement or repair. We also included patients with active endocarditis at the time of surgery, previous cardiac surgery, or patients requiring an emergent operation. After exclusion of 1,908 patients with combined cardiac surgical procedures, a total of 369 patients with isolated tricuspid valve surgery could be included in our data analysis. Approval for this investigation was obtained from the local ethics committee on April 27, 2022 (No. 2022–936). The requirement for written informed consent was waived.

### Anesthesia and Cardiac Surgical Techniques

Anesthesia was introduced with etomidate, rocuronium, and sufentanil, and maintained with a continuous infusion of remifentanyl (0.5–1 µg/kg/min) and vaporization of sevoflurane. Two surgical approaches were used: conventional sternotomy and minimally invasive surgery. In patients undergoing conventional sternotomy, aortic and bicaval cannula were placed for extracorporeal circulation (ECC). We administered antegrade warm Calafiore cardioplegic solution for cardiac arrest, which was repeated every 20 minutes. In patients undergoing minimally invasive surgery, cardiopulmonary bypass was established by cannulating the femoral vessels. The venous cannula was advanced into the superior vena cava (tubing system, Edwards Lifesciences Ltd, Irvine, California, United States). After commencing ECC, a right anterolateral minithoracotomy was performed. Additionally, three incisions were made for the camera port, the right atrial retractor, and the aortic cross-clamp (Chitwood clamp). Cardioplegic arrest was achieved by instilling warm blood cardioplegia (Calafiore) via the aortic root every 20 minutes.

For antibiotic prophylaxis, 2 g of cefazolin was given after the induction of anesthesia and thereafter at intervals of 3 hours. The target mean arterial pressure was 60 mm Hg,

and the target cardiac index (pump flow) was 2.5 L/m<sup>2</sup> body surface area. In patients with massively elevated potassium levels during cardiopulmonary bypass who did not respond to diuretic therapy, renal replacement therapy was performed.

Valve repair was performed by implanting an Edwards MC3 tricuspid device ( $n = 234$ ), an Edwards Physio tricuspid device ( $n = 4$ ) (both devices from Edwards Lifesciences Corp., Irvine, California, United States), or a Contour 3D Annuloplasty device ( $n = 13$ ) (Medtronic plc, Minneapolis, Minnesota, United States). Device size distribution was 28 mm ( $n = 2$ ), 30 mm ( $n = 68$ ), 32 mm ( $n = 84$ ), 34 mm ( $n = 54$ ), and 36 mm ( $n = 43$ ). Five patients underwent tricuspid repair without annuloplasty device implant.

For valve replacement, Edwards Perimount Magna ( $n = 37$ ), Edwards Perimount Magna Ease ( $n = 24$ ) (both valves from Edwards Lifesciences Corp., Irvine, California, United States), Medtronic Hancock II ( $n = 9$ ) (Medtronic plc, Minneapolis, Minnesota, United States), SJM Epic ( $n = 35$ ), and SJM Standard Masters valve ( $n = 8$ ) (both valves from St. Jude Medical Inc. Saint Paul, Minnesota, United States), respectively, were used. Device size distribution was 25 mm ( $n = 2$ ), 27 mm ( $n = 5$ ), 29 mm ( $n = 19$ ), 31 mm ( $n = 79$ ), and 33 mm ( $n = 8$ ).

### Data Collection

All preoperative, intraoperative, and postoperative data were prospectively recorded in a dedicated database on a routine basis. Biochemical parameters were analyzed and filed at our laboratory. For this report, we retrospectively collected the following preoperative parameters: age, sex, body mass index, stroke, hemofiltration, estimated glomerular filtration rate, diabetes mellitus, myocardial infarction, coronary artery disease, left ventricular ejection fraction (LVEF), chronic lung disease, EuroSCORE II, New York Heart Association (NYHA) functional class, endocarditis, severity of tricuspid insufficiency, pacemaker implant, defibrillator implant, and operation priority. Retrospectively collected perioperative and postoperative parameters until discharge were as follows: intra-aortic balloon pump implant, extracorporeal membrane oxygenation implant, hemofiltration, stroke, myocardial infarction, pneumonia, and deep sternal wound infection. In addition, the need for reoperation for bleeding and mortality were assessed. Pre- and postoperative TR were compared, and subgroup analysis with regard to tricuspid valve replacement versus repair was performed.

### End points

The main clinical end point was overall mortality, considered until discharge (designated in-hospital mortality) and until postoperative day 30. Mortality was assessed using the following sources of information: a review of our medical records; an annual, standardized form (postdischarge) completed by the patients themselves and by their family physician; and annual consultation of the respective registration office in case of missing postdischarge forms. A secondary end point was a composite of major morbidity, such as the need for postoperative extracorporeal membrane

oxygenation or postoperative intra-aortic balloon pump implantation, deep sternal wound infection, stroke, perioperative myocardial infarction, pneumonia, prolonged mechanical ventilation (>24 hours), hemodialysis, or reoperation for bleeding. Myocardial infarction was considered to have occurred in cases of new persistent ST-segment changes in combination with a rise in cardiac troponin values (high-sensitivity troponin I > 10,000 ng/mL, troponin I > 10 mg/L) and/or transthoracic echocardiographic imaging evidence of new regional wall motion abnormalities. All suspected myocardial infarctions were validated by coronary angiography. A stroke of hemorrhagic or thrombotic origin was considered present when a clinically manifest motoric, sensory, or cognitive neurological deficit was recorded due to a cerebrovascular event and confirmed by computed tomography imaging. Major infections were diagnosed according to standard procedures, such as the presence of positive results of microbial culture, pyrexia, tachycardia, tachypnea, and elevated white blood cell counts or C-reactive protein concentrations. The need for reoperation was assessed by the same sources used to identify the main end point (exception: registration office).

### Statistics

Categorical variables are summarized as percentages and number of observations. Preoperative and perioperative continuous variables are presented as means and standard deviation (SD), unless otherwise stated. Normal distribution was checked using the Kolmogorov–Smirnov test. We used the unpaired *t*-test, the Mann–Whitney test, and Fisher's exact test to assess group differences in continuous and categorical variables, where appropriate. To generate low-risk to high-risk groupings for operative mortality and major morbidity, we classified our study cohort according to previously published risk scores by LaPar et al.<sup>7</sup> To this end, preoperative parameters such as age, sex, stroke, hemodialysis, chronic lung disease, LVEF, NYHA class, and operation priority, as well as the postoperative parameter reoperation, were used. The mortality score can reach a maximum of 22 and the morbidity score a maximum of 23 points. For data presentation, patients were classified by subgroups scoring 0–1, 2–3, 4–5, 6–7, 8–9, and ≥10 points and our results were compared with the predicted results introduced by LaPar et al.<sup>7</sup> In addition, we calculated the ratio of the observed (O) to the expected (E) outcomes. Overall survival was calculated using the Kaplan–Meier method. The log rank test was used to assess statistical differences between clinical risk score (CRS) categories. We performed all analyses using IBM SPSS Statistics version 27 (IBM Corporation, Armonk, New York, United States).

## Results

### Baseline and Perioperative Characteristics

Baseline characteristics of the study cohort are presented in ► **Table 1**. The majority of patients were female. Likewise, most of the patients were aged 70 years or older. A

**Table 1** Baseline characteristics of the study cohort

Parameter	Number	Percent
Age (y)		
< 50	50	13
50–59	45	12
60–69	69	19
≥70	205	56
Sex (female)	220	60
Body mass index (kg/m <sup>2</sup> )		
< 20	25	7
20–30	270	73
> 30	74	20
Diabetes mellitus	72	20
Hemodialysis	16	4
Estimated glomerular filtration rate (mL/min/1.73 m <sup>2</sup> )		
< 30	44	12
30–60	152	41
> 60	172	47
Left ventricular ejection fraction < 55%	146	40
Stroke	16	4
Myocardial Infarction	22	6
Chronic lung disease		
Moderate	40	11
Severe	23	6
Endocarditis	35	10
Coronary artery disease	79	21
Tricuspid valve insufficiency		
None	17	5
Low grade	7	2
Low-to-medium grade	10	3
Medium grade	17	5
Medium-to-high grade	55	14
High grade	263	71
New York Heart Association functional class		
I–II	136	37
III	193	52
IV	40	11
EuroSCORE II		
< 5	238	64
5–10	65	18
> 10	66	18
Pacemaker implant	98	27
Defibrillator implant	28	8
Previous cardiac surgery	147	40
Operation priority “emergent”	13	4

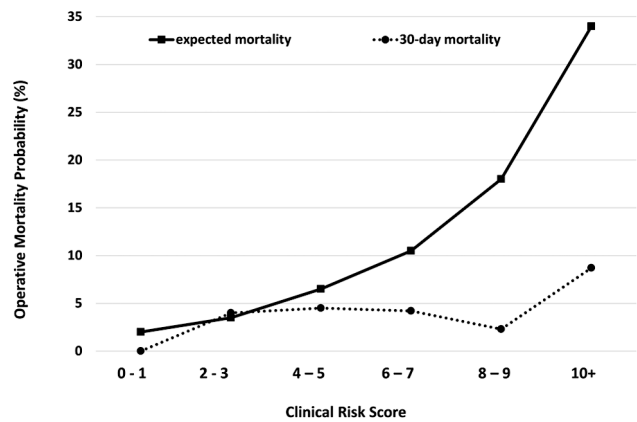
substantial number of patients had concomitant diagnoses, such as diabetes mellitus (20%), stroke (4%), coronary artery disease (21%), myocardial infarction (6%), chronic lung disease (17%), hemodialysis (4%), and endocarditis (10%). More than 50% were classified as having NYHA class III or IV. Several patients had a pacemaker (27%) or defibrillator (8%) implant. A large number of patients also had previous cardiac surgery (40%), but only 4% needed an emergent operation. Most patients had EuroSCORE values < 5. Of the study cohort, 25% underwent minimally invasive cardiac surgery and 31% tricuspid valve replacement.

**Mortality**

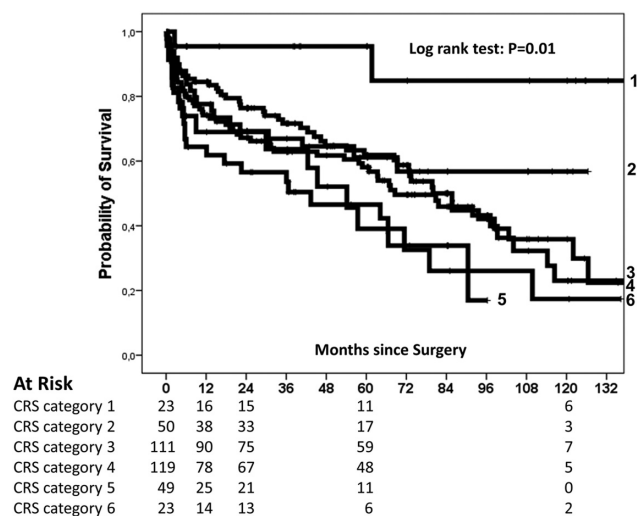
In-hospital and 30-day mortality in the entire study cohort were 6 and 4.1%, respectively. Thirty-day mortality was 3.9% in the tricuspid valve repair group versus 4.4% in the replacement group. Thirty-day mortality in sternotomy cases (277 patients) was 4.0% versus 4.3% when minimally invasive surgery was performed (92 patients). **Fig. 1** illustrates the observed 30-day mortality of our study group in comparison to the predicted operative mortality by scoring groups. **Table 2** presents the respective O/E ratios. In almost all scoring groups, the O/E ratio was substantially lower if observed in-hospital mortality was compared with expected operative mortality. The O/E ratio was even lower if observed 30-day mortality was compared with expected operative mortality. Long-term survival differed significantly between CRS categories (**Fig. 2**). Briefly, 5-year and 10-year survival was 100 and 84.5% in CRS category 1, 61.1 and 56.8% in CRS category 2, 61.9 and 35.9% in CRS category 3, 58.1 and 23.0% in CRS category 4, 46.5 and <17% in CRS category 5, and 39.1 and 17.3% in CRS category 6.

**Major Morbidity**

In the entire study cohort, major morbidity was 40.7%. **Fig. 3** illustrates the observed major morbidity of our study cohort in comparison to the predicted major morbidity by scoring groups. Results did not differ substantially, nor did the observed to expected major morbidity ratios (**Table 2**). In our study cohort, components of the composite end point of outcome parameters were as follows: extracorporeal membrane oxygenation (3%), intra-aortic balloon pump implant (3.5%), deep sternal wound infection (1.1%), stroke (4.3%), perioperative myocardial infarction (0.3%), pneumonia



**Fig. 1** Thirty-day mortality according to clinical risk score value in the original cohort and the Bad Oeynhausen study cohort.



**Fig. 2** Overall survival in tricuspid valve surgery by CRS mortality score category. Survival differed significantly between CRS mortality score categories (log rank test:  $p = 0.01$ ).

(11.9%), prolonged mechanical ventilation (26.3%), hemodialysis (28.5%), and reoperation for bleeding (7%).

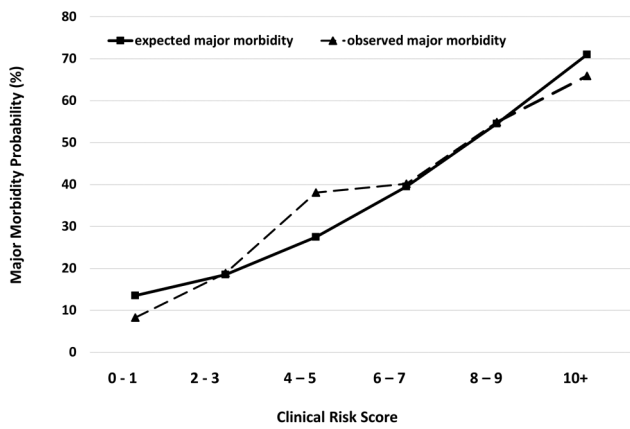
**Pre- and Postoperative Tricuspid Valve Function**

Preoperative TR was severe in 71.3% ( $n = 263$ ), moderate to severe in 14.9% ( $n = 55$ ), moderate in 4.6% ( $n = 17$ ), moderate

**Table 2** Observed-to-expected operative mortality and major morbidity by scoring group

CRS	Observed in-hospital mortality	Observed 30-day mortality	Expected operative mortality	O/E ratio in-hospital mortality	O/E ratio 30-day mortality	Observed major morbidity	Expected major morbidity	O/E major morbidity
0-1	0	0	2.0	0	0	8.3	13.5	0.62
2-3	5.0	4.0	3.5	1.43	1.14	18.9	18.5	1.02
4-5	3.6	4.5	6.5	0.55	0.69	38.1	27.5	1.39
6-7	5.9	4.2	10.5	0.56	0.40	40.2	39.5	1.02
8-9	11.6	2.3	18.0	0.64	0.13	54.9	54.5	1.01
10+	17.4	8.7	34.0	0.51	0.26	65.9	71.0	0.93

Abbreviations: CRS, clinical risk score; O/E, observed to expected.



**Fig. 3** Major morbidity according to clinical risk score value in the original cohort and the Bad Oeynhausen study cohort.

to mild in 2.7% ( $n = 10$ ), and mild or less in 6.5% ( $n = 24$ ). The corresponding postoperative values were 0% ( $n = 0$ ), 1.4% ( $n = 5$ ), 5.4% ( $n = 20$ ), 11.7% ( $n = 43$ ), and 81.6% ( $n = 301$ ). In the replacement group, zero patients had moderate-to-severe TR, while in the repair group 2% remained with moderate-to-severe TR. In the repair group, 74.1% of the patients had mild or less TR, while in the replacement group 98.3% had mild or less TR postoperatively (►Fig. 4).

### Discussion

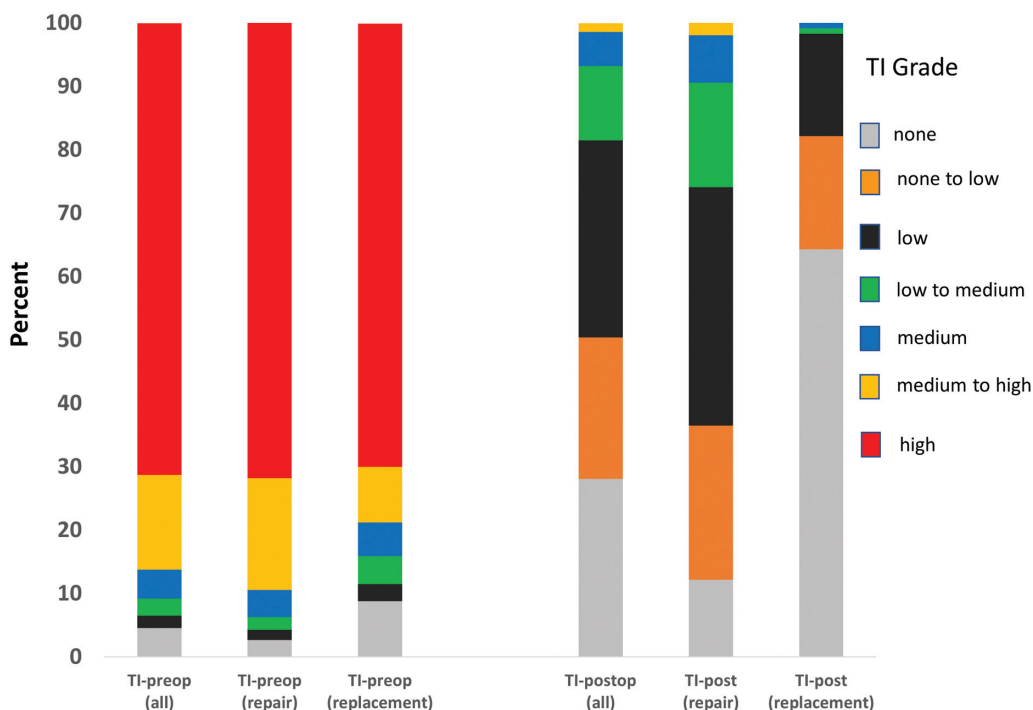
At our center, 30-day mortality in patients undergoing isolated tricuspid valve surgeries was 4.1%, and thus substantially lower than in the majority of other recent studies.<sup>2-7,9</sup> When comparing our data to national results (German Heart Surgery Report) for isolated tricuspid valve

surgery,<sup>8</sup> our results also indicate much lower overall in-hospital mortality rates (6 vs 9.7%). These findings suggest that tricuspid valve surgery patients might benefit from surgical care provided at high-volume centers.

Based on their preoperative risks, our patients were assigned to minimal-, low-, intermediate-, and high-risk groups according to the CRS model introduced by LaPar et al in 2018.<sup>7</sup> The CRS was developed by evaluating the United States Thoracic Surgeons database of over 2,000 patients, recruiting data from over 50 participating hospitals.

Very recently, Russo et al<sup>10</sup> analyzed the predictive value of the CRS and EuroSCORE II after isolated tricuspid valve surgery. Based on the multicenter data collection and analysis, the CRS model was considered useful to estimate expected mortality. Thirty-day mortality in our patients was markedly lower than the CRS would have predicted in all four groups, ranging from 0 to 8.7% in our group versus 2 to 34% in LaPar et al's data publication. Our data suggest that tricuspid valve surgery mortality not only is lower than historically reported but also indicates that the CRS score has limited value since it still substantially overestimates 30-day mortality risk in all categories.

With the aim of focusing on more specifically relevant risk factors, including liver function and right ventricular function, for tricuspid valve disease, Dreyfus et al introduced a different risk score.<sup>11</sup> In-hospital mortality was 10%, whereby a total of 466 patients from 12 French centers who received isolated tricuspid valve surgery between 2007 and 2017 were included. Although the data presented by our group do not permit conclusions about the clinical value of the score Dreyfus presented, overall in-hospital mortality in our large single-center dataset was 6%. Therefore, the question arises whether the Dreyfus score might



**Fig. 4** Pre- and postoperative tricuspid insufficiency, including subgroups of tricuspid valve repair and replacement.



overestimate the mortality risk in high-volume center settings as well.

The relatively low mortality rates from our data might also reflect a trend toward lower perioperative risk in current tricuspid valve surgery, which has been observed in an earlier analysis of U.S. national data.<sup>12</sup> Even though rather limited numbers of patients were included, several single-center studies published after the introduction of the CRS model report mortality rates ranging from 2.7 to 7.1% for isolated tricuspid valve surgery.<sup>13–16</sup> A very recently introduced multicenter analysis<sup>17</sup> comparing isolated tricuspid valve repair versus replacement 30-day mortality rates (4 vs 8%) supports this trend. Our data, as well as the above-named more current publications, reflect an evolving improvement of results and encourage further advancements in tricuspid valve surgery.

Since in our study morbidity was similar to the CRS morbidity score, whereas early mortality was substantially lower compared with the CRS mortality score, one may speculate that early mortality is effectively prevented in experienced high-volume centers despite pronounced morbidity. Nevertheless, patient morbidity may impact long-term survival, as indicated by the significant differences between CRS categories in overall survival in our study cohort.

Alternative treatment concepts including catheter-based interventional therapies are becoming increasingly available.<sup>18</sup> Over the last few years, a myriad of different devices for transcatheter interventions have been introduced. At this point, only limited data on peri-interventional and quality of results are available.<sup>18–21</sup> The pre- and postoperative evaluations of TR grade in our patient population demonstrate a substantial improvement in tricuspid valve function after surgery. Over 90% of our patients remained with less than moderate TR, and over 81% with mild or less TR postoperatively, comparing well with recently published high-volume center data.<sup>14</sup>

We consider it highly important to interpret catheter intervention techniques with attention to detail and to keep in mind that current surgical results, particularly gained from high-volume surgical centers, have created a benchmark, particularly in terms of postoperative tricuspid valve function. Further specification of the potential of up-to-date isolated tricuspid valve surgery in the light of randomized studies comparing surgical and interventional strategies is highly warranted to offer our future patients with tricuspid valve insufficiency the best possible individualized treatment approach.

Our study has the limitation that the value of our results is compromised by retrospective data analysis. Moreover, the questions which factors have specifically impacted our lower-than-expected outcomes and whether other high-volume centers share our experience remain.

In conclusion, our data on isolated tricuspid valve surgery over the recent 12 years show substantially lower-than-expected in-hospital mortality overall, as well as in different risk groups. Thus, recently published risk scores might not fit well for surgical care at large centers and therefore might not

be suitable for preoperative risk assessment. Substantial reduction of surgical tricuspid valve regurgitation leaving the great majority of patients with mild or less TR postoperatively, as demonstrated in our results, establishes a benchmark for interventional approaches.

With emerging transcatheter techniques, comparison of data from interventional and surgical approaches with regard to risks, valvular function results, and long-term outcomes is highly needed to further specify the current potential of isolated tricuspid valve surgery.

#### Funding

No funding.

#### Conflict of Interest

None declared.

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