

# Complicated postoperative course in isolated tricuspid valve surgery: looking for predictors

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## Abstract

**Background:** This study aims at better defining the profile of patients with a complicated versus non-complicated postoperative course following isolated tricuspid valve (TV) surgery to identify predictors of a favourable/unfavourable hospital outcome. **Methods:** All patients treated with isolated tricuspid surgery from March 1997-January 2020 at our institution were retrospectively reviewed. Considering the complexity of most of these patients, a regular postoperative course was arbitrarily defined as a length-of-stay in intensive care unit <4 days and/or postoperative length-of-stay <10days. Patients were therefore divided accordingly in two groups. **Results:** 172 patients were considered, among whom 97 (56.3%) had a regular (REG) and 75 (43.6%) a non-regular (NEG) postoperative course. The latter had worse baseline clinical and echocardiographic characteristics, with higher rate of renal insufficiency, previous heart failure hospitalizations, cardiac operations, and right ventricular dysfunction. NEG patients more frequently needed tricuspid replacement and experienced a greater number of complications ( $p<0.001$ ) and higher in-hospital mortality (13% vs 0%,  $p<0.001$ ). The majority of these complications were related to more advanced stage of the tricuspid disease. Among most important predictors of a negative outcome univariate analysis identified chronic kidney disease, ascites, previous right heart failure hospitalizations, right ventricular dysfunction, previous cardiac surgeries, TV replacement and higher MELD scores. At multivariate analysis, liver enzymes and diuretics' dose were predictors of complicated postoperative course. **Conclusions:** In isolated TV surgery a complicated postoperative course is observed in patients with more advanced right heart failure and organ damage. Earlier surgical referral is associated to excellent outcomes and should be recommended.

## Introduction

Interest in tricuspid valve (TV) pathology has recently grown, due to reported poor clinical outcome of patients affected by tricuspid regurgitation (TR) and the impact on long-term survival of such pathology<sup>1-3</sup>. In particular, isolated TR has been traditionally managed with medical therapy for a long time before

referring patients to surgery. Indeed earlier referral has been discouraged by the poor results of tricuspid repair or replacement whose hospital mortality has remained stable around 10%<sup>4–7</sup> over the years. The current European<sup>8</sup> and American<sup>9</sup> Guidelines for the management of valvular disease provide somehow different recommendations for isolated tricuspid surgery. The American guidelines tend to be more conservative and suggest waiting for signs or symptoms of “right heart failure” before recommending tricuspid repair (TVr) or replacement (TVR) (class IIa or IIb depending on the etiology). In asymptomatic patients with primary severe isolated TR and progressive RV dilation/dysfunction only a class IIb recommendation is given. Unfortunately, in severe isolated TR, “persisting symptoms” usually develop only in advanced stages of the disease being mainly the clinical manifestation of right ventricular failure, with organ damage and hepatorenal syndrome<sup>10</sup>. These patients face high morbidity and mortality after surgery, further fuelling the belief of TV surgery being a high-risk procedure. On the other hand, European Guidelines strongly support an earlier surgical referral, even in asymptomatic patients, with initial RV dilation/dysfunction to achieve low hospital mortality and better postoperative outcome<sup>8</sup>. Indeed, the surgical act of tricuspid repair or replacement is not technically demanding in itself and the outcome is therefore almost exclusively depending on the baseline patient’s profile. The absence of a validated risk score for such surgical procedures, poses further uncertainty regarding the best management of these patients and the correct timing of intervention<sup>11–14</sup>. A better understanding of the baseline characteristics of patients who experience a regular versus a non-regular postoperative course can help the decision-making regarding the surgical timing of those challenging cases.

The aim of this study was to better define the profile of patients who had a smooth versus a complicated postoperative course following isolated tricuspid valve surgery, in order to try to identify predictors of a favourable or unfavourable in-hospital outcome.

## Materials and Methods

A retrospective, single-centre study including patients affected by tricuspid regurgitation and treated with isolated tricuspid valve surgery from March 1997 to January 2020 at San Raffaele University Hospital, Milan, Italy, was conducted. All consecutive patients were individually reviewed and preoperative, intraoperative and postoperative data was collected in a dedicated database. The Ethical Committee of our Institution approved the Study and waived individual informed consent for this retrospective analysis. Patients were divided into regular (REG) and non-regular (NEG) postoperative course. Patients were arbitrarily defined as regular when length-of-stay (LOS) in intensive care unit (ICU) was less than 4 days and/or postoperative overall LOS was less than 10 days, without major complications. All patients had undergone transthoracic (TTE) and transesophageal echocardiography (TEE) before surgery and transthoracic echocardiogram before discharge. Transesophageal echocardiography was routinely used to better define the mechanism of TR. TR grade was graded on a four-grade scale as 1+ (mild), 2+ (moderate), 3+ (moderate-to-severe), and 4+ (severe). In the most recent years a multiparametric approach according to the current European Association of Echocardiography recommendations was adopted to confirm TR grading<sup>15–17</sup>.

Surgery was performed using standard techniques including bicaval cannulation or peripheral venous cannulation based on surgeon’s preference. TV surgery was performed either on beating-heart (BH) or arrested-heart (AH), using standard median sternotomy approach or right anterior thoracotomy<sup>18,19</sup>. Whenever feasible, tricuspid valve repair was performed. However, valve replacement was preferred in presence of major geometric deformations of the tricuspid valve with significant leaflet tethering.

The primary endpoint of the study was the definition of the profile of patients who had a complicated versus non-complicated postoperative course. Secondary endpoints were assessment of in-hospital mortality, number of postoperative complications and identification of predictors of a favourable or unfavourable hospital outcome.

### *Statistical analysis*

Statistical analysis was conducted using SPSS (IBM, Amonk, New York, USA) and Stata Software (Statacorp, LLC, TX, USA; version 15). Categorical variables were expressed as absolute number and percentages. Normal distribution of continuous variables was assessed with the Shapiro-Wilk test. Continuous variables

normally distributed were reported as mean  $\pm$  standard deviation (SD). Continuous variables not normally distributed were reported as median and interquartile range [IQR]. Poisson regression model was used to assess differences between groups in terms of number of complications (a negative binomial regression model was not employed due to no overdispersion). Univariate and multivariate logistic analysis was performed to identify predictors of a negative/non-regular postoperative course.

## Results

A total of 195 patients who underwent isolated tricuspid valve surgery at our institution were reviewed and, based on the postoperative course, divided in regular and non-regular categories. 23/195 patients (12%) were excluded from the study due to lack of sufficient data and therefore inability of correctly assigning them to either category (**Figure 1**). A total of 172 patients were finally considered for the purpose of this study, among whom 97 (56.3%) had a regular postoperative course and 75 patients (43.7%) a complicated one. In the overall population, 43 patients underwent TVr (25%) and 129 (75%) underwent TVR. Among the 43 patients submitted to repair, a ring annuloplasty was performed in 37 of them (86%), with or without concomitant leaflet repair (including edge-to-edge or clover technique), whereas the remaining 6 patients received suture annuloplasty and/or leaflet repair. 7/43 (16.3%) patients with TVr experienced a complicated postoperative course. In case of TVR a bioprosthesis was used in 123 patients (95.4%) and a mechanical prosthesis was used in the remaining 6 patients (4.6%). Among patients submitted to replacement, 68 (55.3%) had a non-regular postoperative course.

Analysing the preoperative characteristics, patients in the NEG group had worse baseline clinical and echocardiographic parameters, as shown in **Table 1**. Indeed, patients with an unfavourable postoperative course were more frequently presenting with higher New York Heart Association (NYHA) functional class, previous episodes of right heart failure, ascites and higher diuretics dose. In addition, NEG patients presented with organ damage, such as chronic kidney disease (CKD), low albumin levels, and higher liver enzymes. Interestingly enough, the MELD score (Model for End-stage Liver Disease) was calculated for all patients and was found to be significantly higher in patients with a negative postoperative course. Furthermore, both right ventricular size and function, together with left ventricular dilation and pulmonary hypertension were more marked in patients with a complicated postoperative course (**Table 1**).

Comparing the operative findings of the two groups, both cardiopulmonary bypass times (CPB) (55min [49-77] in NEG group vs. 56.5min [46-71],  $p=0.771$ ) and cross-clamp times (XCT) (39min [29-46] vs. 36min [28-46] in REG,  $p=0.205$ ) were similar. The number of beating heart operations were also similar between the two groups. As expected, in-hospital mortality was significantly higher in the complicated group, resulting in 13% vs 0% in REG patients ( $p<0.001$ ). Moreover, as shown in **Figure 2**, patients within the NEG group developed a higher number of postoperative complications, such as acute kidney injury (AKI), surgical revision for bleeding, low cardiac output syndrome (LCOS), need for high dose inotropic support and infection/sepsis (**Table 2**). There was a higher chance of requiring new pacemaker implantation in patients with an unfavourable course (OR=28.1, 95% CI [3.65-217.04],  $p=0.001$ ). This can be explained by the fact that patients with a complicated postoperative course needed TVR more frequently than patients with a smooth course, which were mainly subjected to TVr (**Figure 3**). Furthermore, a higher MELD score was associated with a higher risk of developing a greater number of postoperative complications, longer ICU and postoperative length-of-stay and was associated with a higher in-hospital mortality (**Table 3**).

The most important predictors of an unfavourable postoperative course (NEG group) at univariate analysis were chronic kidney disease, ascites, previous hospitalizations for right heart failure, RV dysfunction, previous heart surgeries, need of TVR and an elevated MELD score. The other (less powerful) predictors of this event identified at univariate analysis are detailed in **Table 4**. At multivariate analysis, liver enzyme values and preoperative dose of diuretics were identified as the only independent predictors of a negative outcome (**Table 4**).

## Comments

This retrospective, single-centre study evaluated the profile of patients undergoing isolated TV surgery based

on our surgical experience. The overall postoperative course of patients undergoing isolated TV surgery was complicated in approximately 43.6% of patients, as arbitrarily defined by an ICU LOS [?] 4days and/or total hospital LOS [?] 10days. We are aware that those cut-offs are not evidence based but, as a matter of fact, clinical experience has demonstrated that these are challenging patients in the vast majority of cases and that their postoperative course usually needs an ICU stay longer than 24 hours, even when no major complications occur. In our series, patients with a longer postoperative stay developed complications usually related to their more advanced disease at baseline, such as AKI, LCOS with the need of inotropic support and infections. This also translated in a higher in-hospital mortality, accounting for 13% within this subgroup. Only 3 patients, among those with a NEG postoperative course, experienced a permanent neurological damage, which is unlikely to be explained by the preoperative conditions. Although these events prolonged the ICU and hospital stays of those 3 patients, we believe that such a small percentage does not represent a relevant source of bias for our study. As in other series<sup>20</sup>, our study confirmed that NEG patients did have more advanced TV disease, with right ventricular failure (RVF), high dose diuretic therapy, ascites, organ damage, RV dysfunction and pulmonary hypertension. Despite being affected by more advanced disease, when analysing the intraoperative characteristics of the REG and NEG groups, both CPB and cross-clamp times were similar, further supporting the fact that the outcome of these patients is not related to TV surgery by itself, but mainly to the baseline profile of the patients<sup>14</sup>. Even the adoption of a beating heart approach was similarly distributed between the two groups and therefore not related to the postoperative outcome.

In-line with previously published studies reporting the development of late TR after left-sided heart surgery in 23-37% of patients<sup>21,22</sup>, NEG patients had undergone more frequently previous cardiac surgery and referred late for re-operation. Consequently, due to the advanced stages of their disease, TVR rather than TVr was unavoidable in the majority of them due to advanced RV remodelling and tethering of the tricuspid leaflets, which might also explain the higher percentage of new pacemaker implants in this group.

When analysing clinical predictors of poor outcome in patients in the NEG group, chronic kidney disease doubles the risk of an unfavourable course, together with ascites, previous right heart failure (RHF) hospitalizations, more-than-moderate RV dysfunction, REDO interventions, TV replacement and MELD score. These findings further underline the need of early referral and early intervention for patients affected by isolated TV disease<sup>3</sup>. Matter of factly, the MELD score<sup>23</sup> calculated for each patient, showed how long-standing disease and multi-organ involvement, resulting in liver dysfunction, was associated with overall worse outcomes. These findings also underline how patients affected by chronic RVF might require a more aggressive preoperative management, with either inotropic support or mechanical support devices, in order to improve postoperative outcomes and survival<sup>24,25</sup>.

Patients currently referred for tricuspid valve surgery are high-risk individuals, frequently elderly, with a high percentage of re-operations, high pulmonary artery pressure, end-stage functional class and concomitant pathologies. Such patients and such scenarios support the belief of the high-mortality rate associated to tricuspid surgery, as also seen in our experience. In this context new percutaneous technologies have been proposed but their effectiveness and durability is still suboptimal<sup>26,27</sup>. To-date, the most effective and durable treatment, when feasible with a reasonable risk, remains surgery<sup>28</sup>. However, out data emphasize that timely referral and early surgery are crucial to treat isolated TR with a very low operative risk. As a matter of fact, patients who were treated earlier, before organ damage, less pronounced RV dilation/dysfunction and lower dose diuretics, could receive a repair rather than a replacement procedure, with 1% postoperative permanent pacemaker, acceptable rate of low-cardiac output syndrome and no hospital mortality. Timing is of paramount importance in isolated tricuspid valve surgery<sup>11</sup> and should lead to a thoughtful consideration of how misleading can be the assumption that tricuspid valve surgery is by definition a high risk procedure. Isolated tricuspid valve surgery, particularly repair, is indeed a very simple operation which can be accomplished with a very low risk if carried out for severe TR before development of symptoms (which are usually expression of RV failure) and when only initial dilatation of the right ventricular chamber is detected. Unfortunately, despite current ESC/EACTS guidelines, this is almost never the case. Physicians and patients are reluctant to propose and accept surgery in the absence of symptoms

and prefer waiting for their development and refractoriness to high-dose of diuretics. At that stage patients present the features of the NEG group of our study with the inevitable unfavourable outcome. Our analysis identified several predictors of poor postoperative outcome in a rather heterogeneous population of patients with isolated TR. Among them diuretic dose and live enzymes emerged as independent risk factors for this event. In our opinion this is a first step towards the development of dedicated risk scores useful to predict the surgical candidacy and the postoperative course of such challenging patients. Nevertheless, our study further confirms that early referral is key to really impact on outcome and prognosis of this population.

### *Study limitations*

The main limitations of our study are related to the retrospective and single-centre nature of the study, which cannot therefore be compared to randomized trials. Furthermore, the numerosity of the population was partly limited due to lack of sufficient preoperative and postoperative data. A larger sample size might have been useful in identifying more preoperative predictors of unfavourable outcomes, making analyses and comparisons more effective. Larger multicentre studies on this topic are therefore warranted.

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### **Author contributions:**

- Alessandra Sala: concept/design, data analysis and interpretation
- Roberto Lorusso: critical revision of article
- Marta Bargagna: data collection
- Stefania Ruggeri: statistical analysis
- Nicola Buzzatti: data collection
- Mara Scandroglio: supervision
- Fabrizio Monaco: supervision
- Eustachio Agricola: supervision
- Andrea Giacomini: supervision
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- Elisabetta Lapenna: supervision
- Paolo Denti: supervision
- Andrea Blasio: supervision
- Ottavio Alfieri: supervision
- Alessandro Castiglioni: supervision
- Michele De Bonis: concept/design, critical revision of article

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## Tables

**Table 1. Baseline clinical, echocardiographic and intraoperative characteristics**

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Postoperative Complications	NEG N=75	REG N=97	p-value
Revision for bleeding	17 (22.7%)	2 (2.1%)	<0.001
AKI	29 (38.7%)	10 (10.3%)	<0.001
LCOS	20 (26.7%)	2 (2.1%)	<0.001
• Norepinephrine	21 (28%)	2 (2.1%)	<0.001
• Epinephrine	39 (52%)	30 (30.9%)	<0.001
• Dopamine	57 (76%)	34 (35.1%)	<0.001
Infection	34 (45.3%)	8 (8.2%)	<0.001
Permanent Neurologic damage	3 (4%)	0 (0%)	<0.001
New PM	17 (22.7%)	1 (1%)	<0.001
Death	10 (13.3%)	0 (0%)	<0.001

**Table 2. Postoperative complications**

**Table 3. MELD Score analyses associated to postoperative complications, length-of-stay and in-hospital mortality.**

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Table 4. Univariate and Multivariate analyses for predictors of negative outcome

Figure Legends

**Figure 1.** Flow-chart showing patients selection.

**Figure 2.** Chart showing increasing number of complications in patients with non-regular (NEG) postoperative course.

**Figure 3.** Chart showing difference between valve repair (TVr) and replacement (TVR) in patients undergoing a regular (REG) vs. non-regular (NEG) postoperative course.





