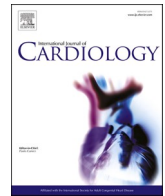




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Prognostic role of endocarditis in isolated tricuspid valve surgery. A propensity-weighted study

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ABSTRACT

Objectives: The role of the underlying etiology in isolated tricuspid valve surgery has not been investigated extensively in current literature. Aim of this study was to analyse outcomes of patients undergoing surgery due to endocarditis compared to other pathologies.

Methods: The SURTRI study is a multicenter study enrolling adult patients who underwent isolated tricuspid valve surgery ($n = 406$, 55 ± 16 y.o.; 56% female) at 13 international sites. Propensity weighted analysis was performed to compare groups (IE group $n = 107$ vs Not-IE group $n = 299$).

Results: No difference was found regarding the 30-day mortality (Group IE: 2.8% vs Group Not-IE = 6.8%; OR = 0.45) and major adverse events. Weighted cumulative incidence of cardiac death was significantly higher for patients with endocarditis ($p = 0.01$). The composite endpoint of cardiac death and reoperation at 6 years was reduced in the Group IE ($63.2 \pm 6.8\%$ vs $78.9 \pm 3.1\%$; $p = 0.022$). Repair strategy resulted in an increased late survival even in IE cases.

Conclusions: Data from SURTRI study report acceptable 30-day results but significantly reduced late survival in the setting of endocarditis of the tricuspid valve. Multi-disciplinary approach, repair strategy and earlier treatment may improve outcomes.

Abbreviations: TV, Tricuspid valve; TR, Tricuspid regurgitation; EuroSCORE, European System for Cardiac Operative Risk Evaluation; CPB, Cardio-pulmonary bypass; NYHA, New York Heart Association; EF, Ejection fraction; COPD, Chronic Obstructive Pulmonary Disease; RV, Right ventricle; RCT, Randomized controlled trial; IDVU, intravenous drug users; ITVS, Isolated tricuspid valve surgery.

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1. Introduction

Right-sided valvular infections are rising in prevalence [1,2] due to an increased amount of cardiac implantable devices and intravenous drug users (IVDU) [3–6]. In this setting, the tricuspid valve is involved in 90% of cases [7]. Interestingly, only 10–20% of patients are treated surgically [8].

Isolated tricuspid valve surgery (ITVS) is a rarely performed procedure associated with high in-hospital mortality, ranging from 5 to 16% [6,9–12] in different cohort. ITVS is usually performed either for functional (previous left-side intervention, atrial fibrillation-related, right ventricular dysfunction) or organic TR (degenerative, endocarditis, carcinoid related, trauma, pacemaker lead induced). In a recent multicenter study from France including 466 isolated tricuspid procedures, endocarditis represented the main surgical indication in one-third of cases [9].

Early and late outcome of isolated tricuspid procedures are associated to several factors, such as symptoms at time of surgery, signs of right heart failure, lower glomerular filtration rate, mean pulmonary artery pressure, age and moderate/severe RV dilatation [9,11]. In this setting the role of surgical technique is still a matter of debate and related to surgeon's experience and patient's presentation. No large data have been reported regarding the role of different etiology on the late survival. Moreover, no contemporary randomized trial or large registry data analyzing this specific aspect are available. In the previously mentioned multicenter study [9], in 142 patients undergoing ITVS for endocarditis, in-hospital mortality was significantly lower (5%) than for other etiologies (either functional or organic) and this result remained unchanged over time. In the Italian multicenter registry for endocarditis covering 25 years of ITVS, in-hospital mortality was higher (11%).

The International SUR-TRI study (Surgical-Tricuspid Study) is a multicenter retrospective study initiated by the Department of Cardiac Surgery at the Medical University of Vienna involving 13 international cardiac surgery units. The aim of the present sub-analysis of the international multicenter SUR-TRI study is to evaluate the impact of endocarditis on early and late outcomes of patients undergoing ITVS with contemporary and international data.

2. Methods

2.1. Design and data collection

The study has been approved by the Ethical Committee of the Medical University of Vienna (1289/2019) and was not funded. Each participating center underwent ethical approval according to local criteria.

Study details, inclusion and exclusion criteria, and methodology were previously described [12]. Briefly, all adult patients (age > 18 years) undergoing isolated tricuspid valve surgery from 2008 to 2019 in the participating centers were enrolled. Congenital etiology and concomitant other major cardiac procedures were the main exclusion criteria.

Baseline presurgical clinical and intraoperative features were retrospectively collected at each center by the international study consortium. Long-term follow-up was performed by institutional database analysis or direct assessment by local investigators in dedicated study visit, when feasible. Clinical follow-up data were complete regarding living status (dead or alive), cause of death (cardiac or not) and reoperation. The median follow-up duration was 22 months, with a range of 1–133 months.

The primary end-point of this study was to evaluate differences between groups (group IE = endocarditis related tricuspid disease; group N-IE = not-endocarditis related tricuspid disease) in terms of overall survival, freedom from cardiac death (chronic heart failure, myocardial infarction, major arrhythmias, major cardiovascular events) and a cumulative endpoint of freedom from cardiac death and reoperation on the

tricuspid valve (cardiac event-free survival). The secondary end-point was to assess any difference in terms of thirty-day mortality and rate of perioperative adverse events.

2.2. Statistical analysis

Descriptive statistical methods were applied to depict the study population at baseline. Continuous, normally distributed variables are presented as the mean \pm standard deviation; skewed data are presented as the median and interquartile range (25th and 75th percentiles). Categorical variables are presented as numbers (%). Differences between groups were compared with Student's *t*-test for normally distributed variables and the Mann-Whitney *U* test for not normally distributed variables. Categorical variables are summarized as the number and percentage of subjects in each category, and differences were compared with the Pearson chi-square test.

The propensity score was obtained using generalized boosted model [13]. The variables included in the propensity model were age, gender, diabetes, NYHA class, previous stroke, dialysis, COPD, previous cardiac surgery, LVEF, TR severity, urgency/emergency, repair/replacement, and sternotomy/thoracotomy, beating heart/arrested heart. Inverse probability of treatment weighting (IPTW) [14] was obtained for both the average treatment effect (ATE) and the average treatment effect on treated patients (ATT). Then, IPTW for ATT was chosen. The balance was tested with the standardized mean difference (SMD), which was considered optimal below 0.20. To adjust final results, IPTW was forced into multivariable analyses along with those variables where SMD was higher than 0.20. Early adverse events were analyzed as proportions of patient's number. The observed mortalities are described as rates (%). All deaths for unknown reasons were considered cardiac deaths. Kaplan-Meier analysis was performed to assess overall survival and freedom from a composite end-point (cardiac death and reoperation on the tricuspid valve). Differences between curves were compared using the log-rank test. To avoid competing risk, cumulative incidence was performed for cardiac death, non-cardiac death and reoperation on the tricuspid valve. Differences were investigated by means of Gray-test. Logistic regression, Generalized Linear Model and Cox regression were used as multivariable analyses for early binary outcome, for length of stay and for late outcomes, respectively. All reported *p*-values were considered statistically significant if below 0.05. R-Studio version 1.1.463 (2009–2018) was used for all statistical analyses.

3. Results

A cohort of 406 patients ($n = 406$; 56 ± 16 years; 56% female) were collected in the SUR-TRI database. Surgery was indicated for endocarditis in 107 patients (27%) (Group IE) and for other etiologies in 299 (73%) patients (Group Not-IE). Among them, functional regurgitation was present in 183 cases (45%), rheumatic disease in 41 (10%) and other etiologies (degenerative, pacemaker-related, carcinoid syndrome, unknown) in the remaining 75 cases (18%).

A repair strategy was carried out in 36% vs 51% of patients in the IE vs not-IE groups. Mean cardiopulmonary bypass time (IE 94 ± 43 vs Not IE 97 ± 52 min, $p = 0.12$) and cross clamp time were similar in the two groups (IE 59 ± 31 vs Not IE 58 ± 33 min; $p = 0.2$). Baseline patient's characteristics and differences between the two groups are listed in the Table 1. (See Figs. 1 and 2.)

After the IPTW adjustment, the two groups were similar for studied variables except NYHA class III/IV, chronic pulmonary disease (COPD) and Urgency/Emergency (Fig. 1 supplementary). Therefore, the final model was adjusted according these differences forcing the IPTW into logistic regression and generalized linear model.

3.1. Thirty-day adverse events

Twenty-two patients (5.4%) in the entire SUR-TRI cohort ($n = 406$)

Table 1

Pre- and operative data according to presence of endocarditis (group IE) or not (group NIE).

Variables	Group IE N = 107	Group Not-IE N = 299	Unadjusted SMD	Adjusted SMD
Age, (years)	44.3 ± 15.7	59.7 ± 14.4	-0.9819	-0.0527*
Males sex	64 (59.8%)	117 (39.1%)	0.4219	-0.0067*
NYHA class III/IV	45 (42.1%)	154 (51.5%)	-0.1914	-0.2290
Previous Stroke	7 (6.5%)	15 (5.0%)	0.0617	-0.1181*
COPD	24 (22.4%)	30 (10.0%)	0.2972	0.2135
Dialysis	5 (4.7%)	8 (2.7%)	0.0946	0.1591*
Diabetes	9 (8.4%)	50 (16.7%)	-0.2994	-0.0118*
Urgent or Emergency	52 (42.6%)	34 (11.4%)	0.7448	0.4384
LVEF (%)	55.8 ± 9.8	56.7 ± 8.5	-0.0926	-0.0711*
Moderate or Severe TR	92 (86.0%)	294 (98.3%)	-0.3556	0.0585*
Previous Cardiac Operation	15 (14%)	156 (52.2%)	-1.0990	0.0171*
Atrial Fibrillation	14 (13%)	120 (40%)	-1.088	0.0170*
Sternotomy	94 (87.9%)	247 (82.6%)	0.1604	-0.0066*
Beating Heart	19 (17.9%)	134 (44.8%)	-0.7081	0.1844*
TV Repair	39 (36.4%)	155 (51.8%)	-0.3198	-0.0257*

Legend. SMD = standardized mean difference; NYHA = New York Heart Association; COPD = chronic obstructive pulmonary disease; LVEF = left ventricular ejection fraction; TR = tricuspid regurgitation; TV = tricuspid valve.

* Good balance.

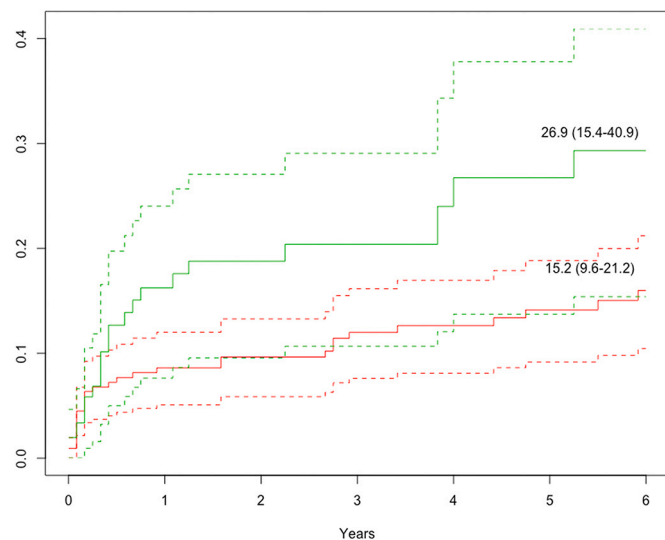


Fig. 1. Weighted cumulative incidence of cardiac death comparing endocarditis (IE Group, green lines) vs not-endocarditis (Not-IE group, red lines). Dotted lines indicate 95% confidence limits. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

experienced death during the first 30 days. Early mortality did not differ significantly when comparing endocarditis related vs not-endocarditis related patients (Group IE: 2.8% vs Group Not-IE = 6.8%; OR = 0.45). Postoperative new onset of atrial fibrillation was significantly more frequent in patients without endocarditis related tricuspid disease (Group IE: 6.6% vs Group Not-IE: 18.1%; OR = 0.26, 95CL 0.10–0.64, $p < 0.05$). No differences were recorded in the rate of other postoperative adverse events as mortality, new pacemaker implantation rate, stroke and wound infection. Table 2 summarizes early outcomes.

3.2. Late results

Among 384 survivors after the first post-operative month, 74 patients died; 51 out of them due to cardiac causes. Weighted cumulative

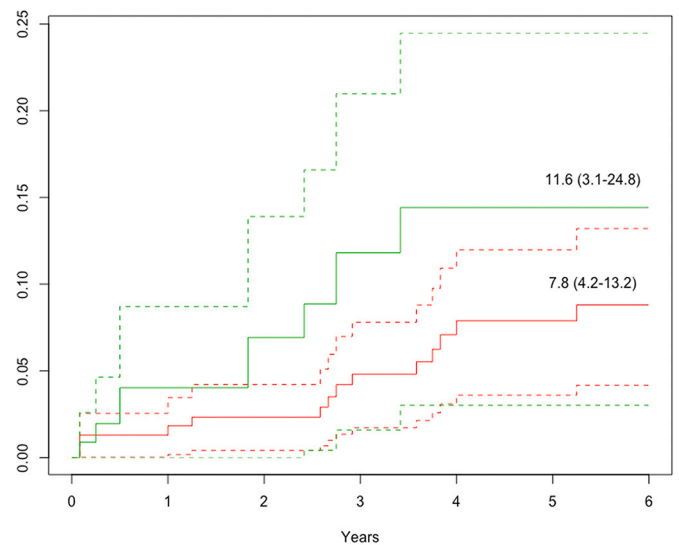


Fig. 2. Weighted cumulative incidence of non-cardiac death comparing endocarditis (IE Group, green lines) vs not-endocarditis (Not-IE group, red lines). Dotted lines indicate 95% confidence limits. (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

incidence of cardiac death was significantly higher for patients with endocarditis ($p = 0.01$) (Fig. 1). Conversely, non-cardiac death and reoperation were similar for both groups (Fig. 2 - Fig. 2 suppl).

Reoperation on the tricuspid valve was recorded in 15 patients (3%) during the follow-up period. The composite cardiac event-free survival (cardiac death + reoperation) at 1, 3 and 6 years was in the Group IE $80.9 \pm 4.5\%$, $71.8 \pm 5.6\%$ and $63.2 \pm 6.8\%$ vs $89.8 \pm 1.8\%$, $85.8 \pm 2.3\%$ and $78.9 \pm 3.1\%$ in the group Not-IE ($p = 0.022$) (Fig. 3 suppl).

3.3. Surgical approach in patients affected by endocarditis

In the subgroup of 107 patients affected by endocarditis (IE Group, $n = 107$), 68 (63%) TV replacements were performed while 39 patients (36%) were treated with surgical repair. In the same sub-group, 94 (87%) cases underwent surgery through full sternotomy and 13 (13%) patients via thoracotomy. No differences were found regarding in-hospital mortality when comparing surgical techniques (repair vs

Table 2

Thirty-day outcomes.

Outcomes	Group IE N = 107	Group Not-IE N = 299	Unadjusted OR (95CL)	Adjusted OR (95CL)
Mortality	3 (2.8%)	19 (6.4%)	0.42 (0.12–1.46)	0.45 (0.13–1.59)
PM implant	15 (14.1%)	25 (8.4%)	1.78 (0.90–3.53)	1.65 (0.76–3.04)
Dialysis	8 (8%)	18 (6.0%)	1.26 (0.53–2.99)	0.95 (0.39–2.42)
Blood transfusion	58 (54.2%)	149 (49.8%)	1.19 (0.77–1.86)	1.30 (0.82–2.07)
Re-exploration	11 (10.3%)	28 (9.4%)	1.11 (0.53–2.31)	1.26 (0.58–2.61)
Atrial fibrillation	7 (6.6%)	54 (18.1%)	0.32 (0.14–0.73)*	0.26 (0.10–0.64)*
Stroke	0	4 (1.3%)	N/A	N/A
Wound infection	6 (5.6%)	15 (5.0%)	1.13 (0.42–2.98)	1.31 (0.48–3.60)
Length of stay (days)	11 (7–21)	12 (8–21)	-3.97 (-12.7–4.87)§	-0.67 (-10.9–9.59)§

Legend. OR = odds ratio; CL = confidence limits.

* $p < 0.05$.

§ Estimate and 95CL from univariate GLM.

replacement) or surgical access (sternotomy vs thoracotomy).

When considering long-term freedom from death any cause according to both etiology and surgical technique, TV replacement in IE patients achieved the worst: $41.1 \pm 9.6\%$ vs repair-IE $79.9 \pm 8.3\%$ ($p = 0.002$) vs replacement-Not IE $75.7 \pm 4.7\%$ ($p < 0.001$) vs repair-Not IE $75.8 \pm 4.4\%$ ($p < 0.001$).

No difference in the long-term outcomes were observed comparing different access strategies.

4. Discussion

Isolated tricuspid valve surgery is generally considered at high risk for perioperative adverse events and reduced long-term survival when compared to other valvular procedures [15]. The procedure is rarely performed and international contemporary data are still limited. When dealing with patients affected by infective endocarditis, the tricuspid valve is surgically treated when left-side valves are involved while surgical indication in isolated tricuspid valve endocarditis remains an area of intensive discussion [16]. According to the last American Heart Association guidelines [17], surgery should be considered in symptomatic cases associated with heart failure in presence of optimal antibiotic and medical therapy. The three commonly discussed surgical approaches for tricuspid valve endocarditis are valvectomy, valve repair and valve replacement. In the majority of patients, bioprosthetic tricuspid valve replacement is the treatment of choice due to extensive valvular lesion or vegetation associated with the endocarditis process. [18].

The present study reports the results of a contemporary international dataset including 13 cardiac centers. Data from an entire cohort of 406 patients were analyzed and adjusted to obtain two comparable groups with the aim to compare outcome of endocarditis related (Group IE) and not endocarditis (Group Not-IE) related surgery. Patients who underwent isolated tricuspid valve surgery for endocarditis were younger (44 vs 59 years) and less symptomatic (NYHA III-IV 42% vs 51%). Moreover, they underwent less frequently tricuspid valve repair or beating heart operation when compared with patients in the Not-IE group (other etiology). The results of the present series showed comparable 30-day mortality rate (2.8% vs 6.8% in the IE and not-IE groups respectively). However, the numerical difference is high and a larger sample size would maybe reveal differences between both groups. Similarly, in another report [9], non-IE patients showed 2.5-fold higher mortality (4.9% vs 12.6% in all the remaining cohort.)

Furthermore, outcome regarding length of stay, blood transfusion, new pacemaker implantation and major bleeding was similar between groups. Interestingly, patients undergoing surgery without tricuspid valve endocarditis (Not-IE group) experienced post-operative atrial fibrillation more frequently ($p < 0.05$). This may indicate a prolonged disease of the right atrium and/or the right ventricle prior to surgery compared to the more acute disease onset in patient operated due to endocarditis.

The main focus of the current sub-analysis of the SUR-TRI database is to describe the long-term outcomes of patients underwent isolated tricuspid surgery focusing on the prognostic role of the endocarditis etiology. Our results showed that the surgical early mortality in isolated endocarditis of the tricuspid valve is acceptable (2.8% in the present series) and therefore a surgical management should be always considered after a complete assessment of the perioperative risk and a multidisciplinary patient evaluation.

Despite encouraging early results, the present study reports a reduced late survival of patients operated on for endocarditis associated with a significantly reduced composite end-point of late cardiac death and reoperation in the IE population over time. The described results are in consistence with a previous multicenter Italian experience [6] of 157 cases operated on from 1983 to 2018 (mean age 47 ± 16 years, 25% females) which reported very poor survival rates of 66%, 60%, and 44% at -10 , -20 , and -25 years respectively. Speculatively, worse outcome may also be driven by underlying risk factors, namely IV drug abuses or

the continuing presence of pacemaker leads, triggering further adverse events.

Recently, Dreyfus et al. [9] reported the results of a cohort of 466 ITVS in France. In this series, at a median follow-up of 2.6 years, patients affected by functional tricuspid regurgitation exhibited a significantly reduced survival and freedom from cardiovascular events when compared with organic TR. In this study, clinical presentation with right ventricle dilation, sign of right heart decompensation, low level of prothrombin time and low glomerular filtration rate were strong predictors of reduced survival. Therefore, patient status at the time of surgery contributes significantly to late outcome. Furthermore, delayed indication to surgery was associated with poor survival of patients undergoing ITVS [9]. The design of the French registry which compared in general functional vs primary TR was different from the present analysis who focused on endocarditis itself, comparing it with all the remaining etiologies. Therefore, we believe that the two studies could not be easily compared but their results should be integrated when dealing with complex cases. Moreover, in the study by Dreyfus et al. [9], when adjusted on patients' characteristics, TR mechanism or etiology were not predictors of outcome anymore.

In our experience, 36% of patients received a TV repair and 64% of patients received a TV replacement, while no patient underwent valvectomy. In contrast to Gaga et al. [18], who reported 54% replacement, 39% TV repair and 7.2% valvectomy showing similar survival, we were able to demonstrate that exists a survival benefit when performing repair over replacement also in the IE group. This concept has been recently reported in a propensity matched analysis of our cohort [19] and find in this sub-analysis a strong application. In a recent meta-analysis [20] including 15,069 patients, isolated tricuspid valve repair was associated with significantly reduced in-hospital mortality, renal failure and pacemaker implantation compared with replacement. In the present series, a sub-group analysis shows as TV replacement for infective endocarditis is the worst scenario.

An early surgery may therefore reduce the grade of valve destruction and increase the probability to perform of a successful and durable repair, which may improve long term outcomes. Furthermore, a repaired valve may be more resistant do re-infection and early degeneration compared to a biological valve replacement. The optimal timing, patient selection criteria and surgical strategy are key to improve short- and long-term outcomes of isolated tricuspid valve surgery and are still matter of intense research.

4.1. Limitations

Data collection was performed retrospectively without on-site monitoring. The study is a pure observational all-comers study, differences between peri-operative management, center-specific expertise and surgical technique are not fully reported. Surgical technique was not standardized as a per-protocol procedure.

Data regarding a complete echocardiographic assessment, right ventricular function and clinical presentation at admission were missing in a significant rate of cases enrolled and therefore not considered in the matching. In the setting of endocarditis, important missing information include micro-organism associated with infection, anatomical characteristics of vegetation, intra-venous drug abuse rate, antibiotics strategy, embolization events eventually occurred. Moreover, we are not able to report etiology of non-IE cohort. These data are currently collected in the prospective arm of the SUR-TRI study. The echocardiographic follow-up data and clinical results, such as the rates of valve-related events were incomplete and therefore were not included in the analysis.

5. Conclusion

Isolated tricuspid valve surgery represents a major challenge in cardiac surgery and several factors should be taken into account in the patient management process. Surgery performed in the setting of

endocarditis may be proposed with acceptable early results and adverse events rate. However, long-term survival is reduced compared to other isolated tricuspid procedures. In patients with IE, TV repair seems to offer better long-term outcomes. Multi-disciplinary approach and an earlier treatment may further improve results.

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcard.2022.09.020>.

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Data availability statement

Data are fully available at the Medical University of Vienna. All patient's data are fully anonymous.

Declaration of Competing Interest

Dr. Andreas and Prof. Laufer disclose financial relationship with Edwards, Abbott, Medtronic and LSI. Dr. Taramasso is consultant for Abbott, Boston Scientific, 4tech and receives fees from Edwards. Prof. Maisano discloses relationship with Abbott, Medtronic, Edwards Lifesciences, Biotronik, Boston Scientific Corporation, NVT, Terumo, Xeltis, Cardiovalve, Occlufit, Simulands. Others authors have no conflict of interest to state.

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