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Concomitant Tricuspid Valve Surgery in Patients Undergoing Left Ventricular Assist Device: A Systematic Review and Meta-Analysis

Authors: Yuxiang Luo[1#] MD, Jiajie Leng[1#] MD, Rui Shi[2] PhD, Yingjiu Jiang[1] PhD, Dan Chen[1] PhD, Qingchen Wu[1]* PhD, Hongtao Tie[1]* PhD

[1] Department of Cardiothoracic Surgery, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China

[2] Department of Critical Care Medicine, The First Affiliated Hospital of Sun Yat-sen University, Guangzhou, Guangdong, China

[#] These authors have contributed equally to this work

*Corresponding authors

Address for Correspondence:

Hongtao Tie, Department of Cardiothoracic Surgery, The First Affiliated Hospital of Chongqing Medical University, Chongqing, China

E-mail: ht_tie@hospital.cqmu.edu.cn

Tel: +86 023 8901 1132

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Highlights

1. Concomitant TVS failed to show benefits in patients undergoing LVAD.
2. Concomitant TVS during LVAD implantation was associated with increased risks of RHF, RVAD implantation, and early mortality.
3. Detailed TR management strategies in LVAD recipients should be carried out to reduce postimplant RHF.

Data Statement

The original contributions presented in the study are included in the article or in the Supplementary Materials, further inquiries can be directed to the corresponding author.

Hongtao Tie
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Abstract

Introduction: This study aims to investigate the effect of concomitant tricuspid valve surgery (TVS) during left ventricular assist device (LVAD) implantation due to the controversy over the clinical outcomes of concomitant TVS in patients undergoing LVAD.

Methods: A systematic literature search was performed in PubMed and EMbase from the inception to Aug 1st, 2023. Studies comparing outcomes in adult patients undergoing concomitant TVS during LVAD implantation (TVS group) and those who did not (no-TVS group) were included. The primary outcomes were right heart failure (RHF), right ventricular assist device (RVAD) implantation and early mortality. All meta-analyses were performed using random-effects models, and a two-tailed $p<0.05$ was considered significant.

Results: 21 studies were included, and 16 of them were involved in the meta-analysis, with 660 patients in the TVS group and 1291 in the no-TVS group. Patients in the TVS group suffered from increased risks of RHF (risk ratios [RR]=1.31, 95% confidence interval [CI]: 1.01-1.70, p=0.04; I^2=38%, p_H=0.13), RVAD implantation (RR=1.56, 95%CI: 1.16-2.11, p=0.003; I^2=0%, p_H=0.74), and early mortality

(RR=1.61, 95%CI: 1.07-2.42, p=0.02; I^2=0%, p_H=0.75). Besides, the increased risk of RHF holds true in patients with moderate to severe tricuspid regurgitation (RR=1.36, 95%CI: 1.04-1.78, p=0.02). TVS was associated with a prolonged cardiopulmonary bypass time. No significant differences in acute kidney injury, re-operation requirement, hospital length of stay, or intensive care unit stay were observed.

Conclusions: Concomitant TVS failed to show benefits in patients undergoing LVAD, and it was associated with increased risks of RHF, RVAD implantation, and early mortality.

Keywords: Left ventricular assist device, tricuspid valve surgery, right heart failure, systematic review, meta-analysis

Introduction

Left ventricular assist device (LVAD) is a recommended therapy for end-stage heart failure (HF).(1, 2) With the improvement and enrichment of the surgical strategy of LVAD implantation, the necessity of concomitant procedures alongside the operation is in debate. Previous studies have shown that tricuspid regurgitation (TR) occurred before or after the operation in a percentage of patients who received LVAD implantation.(3-5) As moderate to greater TR was confirmed to be associated with poorer perioperative performance and declined survival in patients undergoing LVAD, the necessity of concomitant tricuspid valve surgery (TVS) during LVAD implantation has been noticed and evaluated over time.(4, 6, 7) Initially, TVS was identified as instrumental in promoting reverse remodeling of the right ventricle (RV), reducing the incidence of right heart failure (RHF), and improving clinical outcomes.(3, 8, 9) With the deepening of research, some studies found that isolated LVAD could improve RV function, and reduce the severity of pulmonary hypertension (PHT) and TR.(10-12) Other studies demonstrated that concomitant TVS alongside LVAD implantation failed to improve survival or quality of life (QOL), but was associated with increased risks of adverse events.(13-15) Based on the controversy, this systematic review and meta-analysis aims to investigate whether concomitant TVS provides benefits or risks to patients undergoing LVAD implantation.

Methods

Search Strategy

This systematic review and meta-analysis was registered at PROSPERO (https://www.crd.york.ac.uk/PROSPERO/; registered ID: XXXXXXXXXX), and was reported following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA, Supplemental Digital Content 1, http://links.lww.com/JS9/B916, Supplemental Digital Content 2, http://links.lww.com/JS9/B917) Statement and AMSTAR, Supplemental Digital Content 3, http://links.lww.com/JS9/B918 (A MeaSurement Tool to Assess systematic Reviews) Guidelines.(16, 17) Two

independent investigators (Author 1 and Author 2) conducted all the procedures in this study, while a supervisor (Author 3) was responsible for inspecting and resolving disagreements. A systematic literature search without language restriction was performed in PubMed and EMbase from the inception to Aug 1st, 2023. The detailed search strategy is provided in Table S1, Supplemental Digital Content 4, http://links.lww.com/JS9/B919. The reference list of retrieved studies was repeatedly manually screened until no further potentially eligible studies were retrieved. The titles and abstracts of the non-duplicate articles were reviewed to identify the potentially eligible studies, and the full texts of these studies were read to confirm inclusion.

Selection Criteria

Both prospective and retrospective studies were incorporated if they contained the comparison of the outcomes in adult patients who received concomitant TVS (including tricuspid valve replacement and tricuspid valve repair) during LVAD implantation (TVS group) and those who did not (no-TVS group). Case reports, reviews, editorials, expert opinions, and studies with duplicated data were excluded.

Data Extraction

The following information was extracted from each included study: the first author, year of publication, study design, number of patients, gender, age, etiology, rhythm abnormality of atrial fibrillation (AF), pulmonary artery pressure (PAP), TR severity, procedure type of TVS, and LVAD device type. Etiology was categorized into ischemic and others, and TR severity was categorized into moderate to severe (significant TR) and others. TR grading criteria and indication of TVS were recorded and documented in Table S2, Supplemental Digital Content 5, http://links.lww.com/JS9/B920. Although studies which acquired data from online multicenter databases were qualified for inclusion, they were not involved in the meta-analysis due to probable bias driven by their huge samples. The long-term outcomes of studies included in meta-analysis were documented and listed separately.

Outcome Measures

Primary outcomes were the incidence of RHF, the incidence of right ventricular assist device (RVAD) implantation, and early mortality. Secondary outcomes included cardiopulmonary bypass (CPB) time, acute kidney injury (AKI), re-operation, hospital length of stay (HLOS), and intensive care unit (ICU) length of stay. We accept each study's definitions of RHF and AKI, which are presented in Table S2, Supplemental Digital Content 5, http://links.lww.com/JS9/B920.(18, 19) Early mortality was defined by 30-day mortality or in-hospital mortality. When a study possessed data on both 30-day and in-hospital mortality, the latter measure was preferred to be pooled for early mortality.

Quality Assessment

The quality assessment of each study was conducted using the Newcastle-Ottawa scale(20) for nonrandomized studies and the Cochrane risk of bias(21) for randomized studies. Newcastle-Ottawa scale consists of three group items (selection of participants, comparability of study groups, and the outcomes) with a maximum of 9 points. The more points mean better quality. We treated studies as low (0-3 points), moderate (4-6 points), and high quality (7-9 points), respectively. The Cochrane risk of bias consists of six parts, including randomization process, timing of identification or recruitment of participants, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each study was evaluated as low risk of bias, some concerns, or high risk of bias.

Statistical Analysis

Mean differences (MD) were calculated for continuous variables, and risk ratios (RR) were calculated for dichotomous variables. For continuous variable data presented as median with interquartile range (IQR), methods of estimating the mean and standard deviation (SD) from the available data in the articles were used.(22, 23) The I^2 statistics were calculated to assess the heterogeneity of the studies, and I^2>50% was

regarded as substantial heterogeneity.(24) All meta-analyses were performed by using random-effects models. Studies that included only patients with moderate to severe TR were incorporated into sensitivity analyses. Sensitivity analyses were only performed for primary outcomes. Review Manager v5.4 (The Cochrane Collaboration, 2020) was used for statistical analysis. All values were calculated with a 95% confidence interval (CI), and a two-tailed $p<0.05$ was considered significant.

Results

Literature Search

A total of 982 records were identified by the systematic literature search, of which 65 duplicated records were removed. After the exclusion via screening records and the addition via viewing references, 37 studies were assessed for eligibility by reading the full text. Among them, 16 studies were excluded. Ultimately, 21 studies were included in the systematic review, including five studies from online multicenter databases(5, 13, 14, 25, 26), fifteen retrospective cohort studies(3, 7, 9, 15, 27-37), and one prospective randomized study(38). A PRISMA flow diagram of study selection is presented in **Figure 1**.

Baseline Characteristics

The baseline characteristics of studies included in the meta-analysis are described in **Table 1**. Sixteen studies with a total of 1951 participants were included in the meta-analysis, with 660 in the TVS group and 1291 in the no-TVS group. These studies were published between 2011 and 2023, with the sample size varied from 24 to 526. There were 432 males and 152 females in the TVS group, while 819 males and 383 females were in the no-TVS group. The pooled average age of both groups was 57.3 years old. In studies which recorded the etiology of HF and AF status, 191 patients in the TVS group suffered from ischemic cardiomyopathy, while 92 patients in the TVS group had AF at the time of the implantation. The pooled average PAP of both groups was 32.6 mmHg. In studies which recorded the TR severity, 459 patients had moderate to severe TR in the TVS group, whereas the remaining 84 patients did not

experience TR that reached the severity of moderate. While in the no-TVS group, there were 36 fewer patients with moderate to severe TR compared to those with other TR severities. In studies which recorded the surgical procedure of TVS, 28 patients underwent tricuspid valve replacement, and 589 patients underwent tricuspid valve repair. All retrospective cohort studies were scored at least 7 according to the Newcastle-Ottawa quality scale, and the one prospective randomized study was evaluated as low risk of bias, indicating the high quality of each study (Table S3, Supplemental Digital Content 6, http://links.lww.com/JS9/B921). The baseline characteristics and main findings of studies from online multicenter databases are presented in **Table 2**.

Primary Outcomes

As shown in **Figure 2A**, a pooled estimate from eight studies consisting of 507 patients and 204 events showed that concomitant TVS was associated with a significantly increased RHF risk after LVAD implantation (RR=1.31, 95%CI: 1.01-1.70, p=0.04), with a low heterogeneity (I^2=38%, p_H=0.13). Meta-analysis of eleven studies with 1561 patients and 173 events revealed that the risk of RVAD implantation was higher in patients undergoing concomitant TVS during LVAD implantation (RR=1.56, 95%CI: 1.16-2.11, p=0.003; I^2=0%, p_H=0.74; **Figure 2B**). With nine studies including 790 participants and 93 events, the pooled estimate showed that concomitant TVS was related to increased early mortality (RR=1.61, 95%CI: 1.07-2.42, p=0.02; I^2=0%, p_H=0.75; **Figure 2C**).

Secondary Outcomes

The CPB time was found to be significantly increased by approximately 40 minutes in the TVS group, compared to that in the no-TVS group (MD=40.67 minutes, 95%CI: 27.69-53.65, p<0.001; I^2=67%, p_H=0.009; **Figure 3A**). No differences in the incidence of AKI (RR=1.13, 95% CI: 0.82-1.56, p=0.45; I^2=22%, p_H=0.25; **Figure 3B**), incidence of re-operation (RR=1.27, 95% CI: 0.91-1.77, p=0.16; I^2=0%, p_H=0.69; **Figure 3C**), HLOS (MD=3.67 days, 95% CI: −1.37-8.70, p=0.15; I^2=0%,

p_H=0.86; **Figure 3D**), or ICU stay (MD=5.61 days, 95% CI: −2.99-14.21, p=0.20; I^2=60%, p_H=0.08; **Figure 3E**), were observed between the two groups.

Long-Term Outcomes

The long-term outcomes of studies included in meta-analysis are listed in **Table 4**. Fifteen studies provided long-term outcomes of patients who underwent concomitant TVS during LVAD implantation and those who did not. All fifteen studies have reported the impact of concomitant TVS on survival, and thirteen of them found that concomitant TVS was not associated with improvement on survival. Eight of these studies have reported the effect of concomitant TVS on postoperative TR severity, and five of them found that concomitant TVS was associated with improvement on postoperative TR severity.

Sensitivity Analyses

Using data derived from seven studies consisting of only patients with moderate to severe TR, sensitivity analyses were performed for primary outcomes. The results of sensitivity analyses are summarized in **Table 3**. An increased risk of RHF after LVAD implantation in patients with moderate to severe TR who underwent concomitant TVS remained still (RR=1.36, 95% CI: 1.04-1.78, p=0.02; I^2=36%, p_H=0.17). No significant differences in the incidence of RVAD implantation (RR=1.49, 95% CI: 0.85-2.59, p=0.16; I^2=0%, p_H=0.42) and early mortality (RR=1.28, 95% CI: 0.69-2.38, p=0.43; I^2=0%, p_H=0.91) were found in patients with moderate to severe TR between the two groups.

Discussion

This meta-analysis suggested that patients undergoing concomitant TVS during LVAD implantation have higher risks of RHF incident and RVAD implantation after the implantation. CPB time was also longer when concomitant TVS was performed. In addition, an increased risk of early mortality was also observed in patients who underwent TVS during the implantation. No statistically significant difference was

observed in AKI, re-operation, HLOS, and ICU stay. In sensitivity analyses, concomitant TVS also increases the risk of postimplant RHF in patients with moderate to severe TR.

Our results differ from two previous meta-analyses, which failed to find significant differences in mortality and RHF between patients who underwent concomitant TVS during LVAD implantation and those who did not.(39, 40) The discrepancies may be due to changes in the expansion of the included studies and different definitions of clinical outcomes. Our meta-analysis has updated the records from 2017 to 2023 when researchers found more evidence that tended to nonsupport concomitant TVS during the implantation. One of our included studies, a randomized clinical trial conducted by Pla et al(38), is by far the only prospective study that has concluded that concomitant TVS during LVAD implantation failed to reduce early RHF adverse event rates or mortality. By proper matching and strict randomization, it illustrated that concomitant TVS would not be indispensable to patients with moderate to severe TR when undergoing LVAD implantation. Our work has synthesized the relevant studies and had similar results that nonsupport concomitant TVS during LVAD implantation.

The included studies from online multicenter databases have diverse results. Briasoulis et al(25) found that concomitant TVS brought a higher burden of co-morbidities during LVAD implantation. Mullan et al(13) found that concomitant TVS was not associated with improved survival or QOL, but with an increased risk of adverse events among patients with significant TR. Robertson et al(14) found that concomitant TVS could not reduce RVAD use, on the contrary, it increased renal failure incidence, dialysis, re-operation, total transfusion requirement, HLOS, etc. Studies from the INTERMACS database respectively conducted by Song et al(5) and Veen et al(26) also failed to find compelling evidence to support concomitant TVS during LVAD implantation. Under the large sample, the TVS group had no advantage in survival but had a higher incidence of adverse events, which is in accordance with

our findings.

It has been revealed that functional TR frequently occurs in patients with HF.(41) Piacentino et al found that significant TR occurred in almost half of the patients before LVAD implantation as well.(42) Since preimplant TR has been confirmed to be associated with worse clinical outcomes,(4, 5, 7, 9) surgeons were hoping to eliminate such an undesirable factor by performing concomitant TVS. One may argue that TVS is theoretically instrumental in decreasing RV volume, promoting RV reverse remodeling, and thus, improving overall RV performance.(43, 44) Another argument is that TR severity was strongly associated with postimplant RHF, so a forward intervention during the implantation would make a difference.(6, 45, 46)

Although tricuspid valve insufficiency was eliminated or reduced by TVS, however, the benefits were not as good as expected. Our results demonstrated that higher risks of postimplant RHF and RVAD implantation were observed in patients who underwent concomitant TVS during LVAD implantation, and they also experienced an increased risk of early mortality. The incidence of postimplant RHF is expected to be higher in those patients with greater TR severity. However, concomitant TVS failed to protect them from suffering RHF or to improve their survival. It is also debatable whether to perform TVS by spending more CPB time, which is related to adverse events, when advantages are ambiguous.(35) Additionally, evidence showed that TR still recurred in some patients even if concomitant TVS was performed.(47) It suggests from another perspective that TR may not be the primary problem we should focus on.

The etiology of TR in LVAD implantation is mostly functional, resulting in annulus enlargement and leaflet tethering secondary to RV overload, PHT, and RV dysfunction.(48-50) LVAD helps decompress the left ventricle (LV), and LV decompression helps reduce PAP. Thus, the RV afterload can be decompressed during the process, resulting in improved RV function and reduced TR severity.(11) Studies

have observed that TR would be reduced after isolated LVAD implantation,(10-12) leading TR intervention during the implantation into debate.

The long-term effect of concomitant TVS during LVAD implantation is not completely revealed. The majority of previous research found that concomitant TVS was not associated with improvement on survival. Interestingly, some studies even found that concomitant TVS failed to provide improvement on postoperative TR severity. Future studies should validate the long-term effect of TVS. Perhaps as long-term follow-up results of the prospective study by Pla et al(38) are further disclosed, the potential benefits of TVS will eventually be revealed.

In the sensitivity analyses of our study, even when TR severity was confined to be significant, which means the baseline RV function between the two groups is more comparable, the results in the TVS group did not show better benefits than those in the no-TVS group. This proves that for patients who were deemed to require TVS during the implantation but did not undergo it, their outcomes were still comparable to those who received concomitant TVS, indicating that intervening with TVS in significant TR during the implantation may not always be necessary.

Scholars called for additional criteria to evaluate whether to intervene in preimplant TR in LVAD recipients.(13) Tricuspid annular dilation, for example, adversely affects survival after LVAD implantation according to Kukucka et al(51), and Goldraich et al(52) identified it as a predictor of postimplant RHF, suggesting a potential subgroup that may benefit from TVS. Anwer et al(53) found TR progression was accelerated in LVAD patients with preoperative AF, indicating that concomitant TVS may be worthwhile in patients with AF. Coincidentally, Volevski et al(37) found that patients with severe PHT tend to benefit more from concomitant TVS. Other factors, such as right ventricle end diastolic dimension, right ventricle ejection fraction, pulmonary capillary wedge pressure, central venous pressure, or tricuspid annular plane systolic excursion, should also be discussed.(54) Unfortunately, no study can systematically

answer the question at the moment. Non-functional TR ought to be treated concomitantly, such as tricuspid structural abnormality with mechanical damage due to the implantable cardioverter defibrillator lead or pacemaker. Because LVAD is theoretically intended to improve LV function, TR that cannot be alleviated after improvement of LV function and is predicted to deteriorate postimplant RV function should be considered for surgical intervention.

Limitations

Since this is a meta-analysis consisting primarily of retrospective studies, inherent limitations exist in our study.(55) Heterogeneity exists because the definitions of outcomes differ from each study, as well as the device type and procedure type of TVS, etc. Some skewed data that cannot be described as the mean and SD were excluded from the meta-analysis, leading to potential statistical bias. We did not compare long-term outcome measures via meta-analysis, leaving insufficient discussion about the long-term effect of concomitant TVS. The specific variation of TR severity in each group after the implantation could not be evaluated since we did not collect data on postimplant TR severity. We also failed to indicate which type of TR intervention during LVAD implantation is more appropriate due to the scarce comparison of the procedure type of TVS. Based on the results of our study, we cannot identify a certain population that would benefit from concomitant TVS, either. At the same time, our results should be interpreted with caution. Although the TVS group indeed had worse outcomes, this may be due to the fact that patients in the TVS group had worse baseline characteristics and were already at higher risk of RHF.

Conclusions

Patients undergoing concomitant TVS during LVAD implantation have higher risks of RHF, RVAD implantation, and early mortality after the implantation. When restricting the study population to those with moderate to severe TR, a higher risk of postimplant RHF was still observed. Identifying which population can truly benefit from concomitant TVS and developing detailed TR management strategies in LVAD

recipients to reduce postimplant RHF is necessary.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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Figure 1 Flow diagram of study selection.

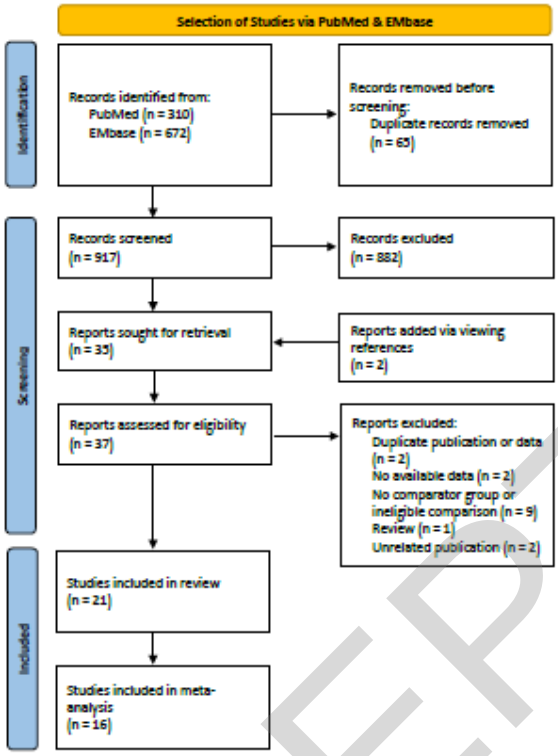

Figure 2 Forest plots of primary outcomes. A) RHF; B) RVAD; C) early mortality. Abbreviations: RHF, right heart failure; RVAD, right ventricular assist device; TVS, tricuspid valve surgery; M-H, Mantel-Haenszel.

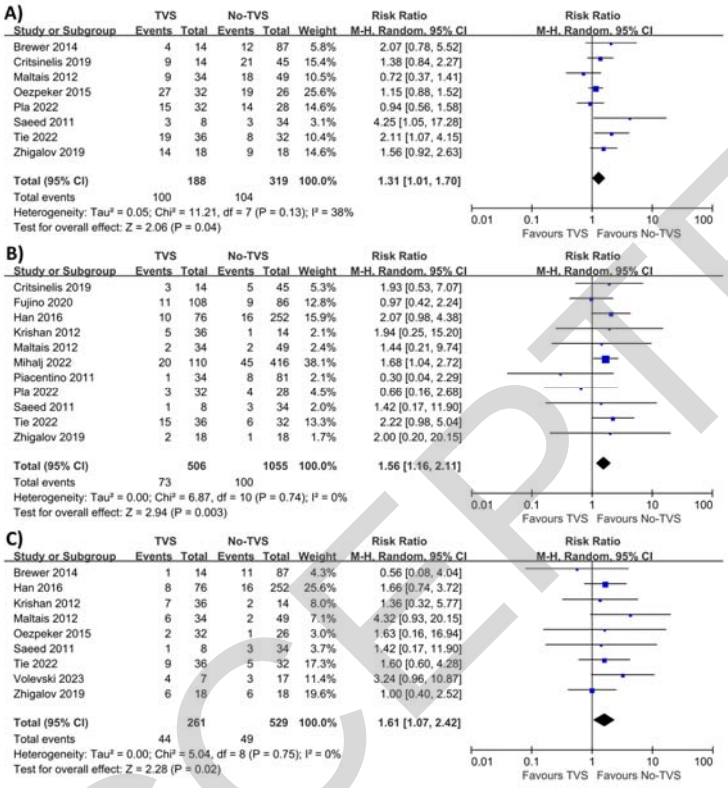

Figure 3 Forest plots of secondary outcomes. A) CPB time; B) AKI; C) re-operation; D) HLOS; E) ICU stay.

Abbreviations: CPB, cardiopulmonary bypass; AKI, Acute kidney injury; HLOS, hospital length of stay; ICU, intensive care unit; TVS, tricuspid valve surgery; SD, standard deviation; M-H, Mantel-Haenszel.

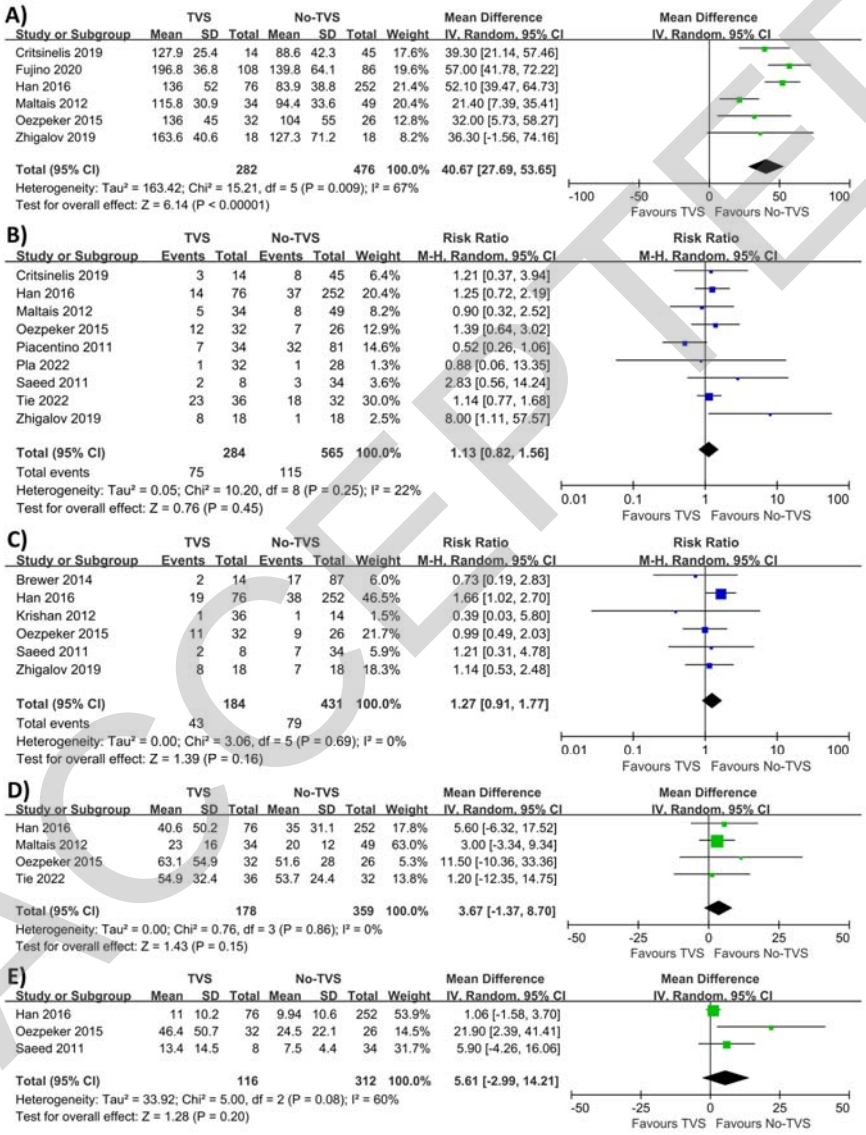

Table 1: Baseline Characteristics of Studies Included in Meta-Analysis

Study ID	Study Design	TVS *vs.* no-TVS								
		No. of Patients	Gender (Male/Female)	Age in years	Etiology (Ischemic/Others)	AF Status (with AF/without AF)	PAP in mm Hg	TR Severity (Moderate to Severe/Others)	TVS (Replacement/ Repair)	Device Type
Brewer 2014	Retrospective study	14 *vs.* 87	10/4 *vs.* 65/22	54±15.3 *vs.* 53.2±11.2	2/12 *vs.* 32/55	NA	NA	4/0 *vs.* 40/47	0/14	HeartMate II or HeartWare HVAD
Crisinelis 2019	Retrospective study	14 *vs.* 45	11/3 *vs.* 33/12	51.7±16.7 *vs.* 53.3±12.6	4/10 *vs.* 17/28	NA	35.2±9.7 *vs.* 34.4±8.9	1 4/0 *vs.* 45/0	2/12	HeartMate II or HeartWare HVAD
Fujino 2020	Retrospective study	108 *vs.* 86	73/35 *vs.* 60/26	57 (47, 67) *vs.* 61 (52, 68)[a]	34/74 *vs.* 31/55	52/56 *vs.* 31/55	NA	56/52 *vs.* 16/70	7 1/10	CF-LVAD
Fujita 2014	Retrospective study	69 *vs.* 72	NA	NA	NA	NA	33±10 *vs.* 31±10	2.6±1.0 *vs.* 1.3±0.8[b]	0/69	Pulsatile LVAD or CF-LVAD
Han 2016	Retrospective study	76 *vs.* 252	58/18 *vs.* 211/41	57±13 *vs.* 57±14	28/48 *vs.* 109/143	18/58 *vs.* 62/190	34.4±8.14 *vs.* 35.0±9.94	7 5/1 *vs.* 45/194[c]	8/68	HeartMate II, HeartWare HVAD, VentrAssist Dura Heart or DeBakey VAD
Imamura 2019	Retrospective study	31 *vs.* 34	20/11 *vs.* 20/14	58.0±9.3 *vs.* 62.4±11.0	22/9 *vs.* 21/13	11/20 *vs.* 13/21	NA	3 1/0 *vs.* 0/34	0/31	HeartMate II or HeartWare HVAD

Study ID	Study Design	TVS *vs.* no-TVS								TVS (Replacement/ Repair)	Device Type
		No. of Patients	Gender (Male/Female)	Age in years	Etiology (Ischemic/Others)	AF Status (with AF/without AF)	PAP in mmHg	TR Severity (Moderate to Severe/Others)			
Krishan 2012	Retrospective study	37 *vs.* 14	31/6 *vs.* 14/0	52±13.7 *vs.* 50±13.4	10/27 *vs.* 5/9	NA	25.0±8.0 *vs.* 25.6±7.2	2/15 *vs.* 1/13		1/36	HeartMate II, HeartMate XVE, or Ventr Assist
Malatais 2012	Retrospective study	34 *vs.* 49	24/10 *vs.* 44/5	64.0±12.0 *vs.* 61.6±12.7	17/17 *vs.* 26/23	NA	36.2±8.6 *vs.* 36.0±9.9	NA		6/28	HeartMate II
Mihalj 2022	Retrospective study	110 *vs.* 416	83/27 *vs.* 200/216	55.0±12.6 *vs.* 54.5±12.6	35/75 *vs.* 196/220	NA	NA	87/16 *vs.* 56/100 [c]	0	0/11	HeartMate II, HeartMate 3, or HeartWare HVAD
Oezpeker 2015	Retrospective study	32 *vs.* 26	28/4 *vs.* 24/2	53.5±15.0 *vs.* 56.9±13.98	8/24 *vs.* 15/11	NA	30±10 *vs.* 35±10	2/0 *vs.* 26/0		0/32	HeartMate II, HeartWare HVAD, or others
Piacentino 2011	Retrospective study	34 *vs.* 81	22/12 *vs.* 64/17	52.5±12.8 *vs.* 55.6±13.9	NA	NA	NA	4/0 *vs.* 81/0		5/29	NA
Pla 2022	Prospective study	32 *vs.* 28	25/7 *vs.* 23/5	59.3±12.0 *vs.* 58.4±12.2	12/20 *vs.* 10/18	NA	NA	2/0 *vs.* 28/0		5/27	HeartMate 3 or others

Study ID	Study Design	TVS *vs.* no-TVS							TVS (Replacement/ Repair)	Device Type
		No. of Patients	Gender (Male/Female)	Age in years	Etiology (Ischemic/Others)	AF Status (with AF/without AF)	PAP in mmHg	TR Severity (Moderate to Severe/Others)		
Saeed 2011	Retrospective study	8 *vs.* 34	8/0 *vs.* 25/9	55±12 *vs.* 53±13	NA	NA	38±12 *vs.* 38±11	8/0 *vs.* 34/0	0/8	HeartMate II, HeartMate XVE, Novacor LVAD, HeartWare HVAD, or VentrAssist
Tie 2022	Retrospective study	36 *vs.* 32	30/6 *vs.* 23/9	55.5 (42.5, 61.5) *vs.* 54.5 (45.5, 63.5) [a]	9/27 *vs.* 15/17	NA	NA	36/0 *vs.* 32/0	NA	HeartMate II, HeartMate 3, or HeartWare HVAD
Volevski 2023	Retrospective study	7 *vs.* 17	NA	NA	NA	NA	NA	NA	NA	NA
Zhigalov 2019	Retrospective study	18 *vs.* 18	9/9 *vs.* 13/5	64.7±8.9 *vs.* 64.3±10.1	10/8 *vs.* 11/7	11/7 *vs.* 10/8	NA	18/0 *vs.* 18/0	0/18	HeartMate II, HeartMate 3, or HeartWare HVAD
Overall	/	**60 *vs.* 1291**	**432/152 *vs.* 819/383**	**57.3±3.3 *vs.* 57.3±3.3**	**191/351 *vs.* 488/599**	**92/141 *vs.* 116/274**	**32.6±6.9 *vs.* 32.6±6.9**	**459/84 *vs.* 422/458**	**89**	**28/5**	/

Abbreviations: ID, identity; TVS, tricuspid valve surgery; TR, tricuspid regurgitation; CF-LVAD, continuous-flow left ventricular assist device; (L)VAD, (left) ventricular assist device; NA, not available.
[a] Median (interquartile range); [b] TR severity was graded by a scale of 0 (none)-4 (severe); [c] deficient data

Table 2: Baseline Characteristics and Main Findings of Studies from Online Multicenter Databases

Study ID	Study Design	No. of Patients	TR Severity (Moderate to Severe/Others)	Main Findings
		TVS *vs.* no-TVS	TVS *vs.* no-TVS	
Briasoulis 2020	retrospective study from NIS database	1329/25171	NA	Concomitant TVS during LVAD implantation was associated with a) higher incidence of GI bleeding (14.1%, $p<0.05$) and AKI (9.2%, $p<0.05$), b) higher cost of hospitalization (279504 ±154938 dollars, $p<0.05$), c) and higher nonroutine discharge rates (65.0%, $p<0.05$).

Mullan 2020	retrospective study from INTERMACS database	2547/ 12900	1844/ 703 *vs.* 5387/751 3	Concomitant TVS during LVAD implantation was associated with a) increased risk of bleeding (HR=1.32, 95%CI: 1.23-1.42, $p<0.001$), b) increased risk of arrhythmia (HR=1.23, 95%CI: 1.13-1.34, $p<0.001$), c) increased risk of stroke (HR=1.71, 95%CI: 1.15-2.54, $p<0.01$), d) increased risk of mortality in patients with moderate to severe TR (HR=1.13, 95%CI: 1.00-1.27, $p=0.04$), a) and no improvement on overall

Study ID	Study Design	No. of Patients		TR Severity (Moderate to Severe/Others)		Main Findings
		TVS *vs.* no-TVS		TVS *vs.* no-TVS		
						survival (aHR=1.0, 95%CI: 0.95-1.17, *p*=0.34) or 2-year QOL (median: 67.7, IQR: 50.5−82.3 *vs.* median: 68.2, IQR: 51.6−82.3, *p*=0.85).

Roberts on 2014	retrospective study from INTERMACS database	588/1608	588/0 *vs.* 1608/0	Concomitant TVS during LVAD implantation was associated with a) increased risk of post-operative renal failure (RR=1.53, 95%CI: 1.13-2.08, p<0.01), b) increased risk of dialysis (RR=1.49, 95%CI: 1.03-2.15, p=0.03), c) increased risk of re-operation (RR=1.24, 95%CI: 1.07-1.45, p<0.01), d) greater total transfusion requirement (RR=1.03, 95%CI: 1.01-1.05, p<0.01), e) and longer HLOS (RR=1.29, 95%CI:

Study ID	Study Design	No. of Patients	TR Severity (Moderate to Severe/Others)	Main Findings
		TVS *vs.* no-TVS	TVS *vs.* no-TVS	
Song 2016	retrospective study from INTERMACS database	215/757	215/0 *vs.* 757/0	1.16-1.43, $p<0.001$). Concomitant TVS during LVAD implantation was associated with no improvement on survival ($p=0.83$).

Study ID	Study Design	No. of Patients	TR Severity (Moderate to Severe/Others)	Main Findings
		TVS *vs.* no-TVS	TVS *vs.* no-TVS	
Veen 2019	retrospective study from EUROMACS database	299/3024	239/52 *vs.* 807/1697 [a]	Concomitant TVS during LVAD implantation was associated with a) higher risk of unplanned all-cause readmission (p=0.006), b) higher risk of postoperative RHF (p=0.011), c) no improvement on postoperative TR severity, and d) and no improvement on survival (p=0.41).

Abbreviations: ID, identity; TVS, tricuspid valve surgery; TR, tricuspid regurgitation; NIS, national inpatient sample; LVAD, left ventricular assist device; GI, gastrointestinal; AKI, acute kidney injury; INTERMACS, the Interagency Registry for Mechanically Assisted Circulatory Support; HR, hazard ratio; CI, confidence interval; aHR, adjusted hazard ratio; QOL, quality of life; IQR, interquartile range; RR, risk ratio; HLOS, hospital length of stay; EUROMACS the European Registry for Patients with Mechanical Circulatory Support; RHF, right heart failure; NA, not available.

[a] deficient data

Table 3: Sensitivity Analyses of Primary Outcomes in Patients with Moderate to Severe TR

Outcomes	No. of Studies	No. of Patients TVS *vs.* no-TVS	Estimates [a]	*p*-value	I^2(%)	p_H
RHF	6	140 *vs.* 183	1.36 (1.04, 1.78)	0.02	36	0.17
RVAD	6	142 *vs.* 238	1.49 (0.85, 2.59)	0.16	0	0.42
Early mortality	4	94 *vs.* 110	1.28 (0.69, 2.38)	0.43	0	0.91

Abbreviations: TR, tricuspid regurgitation; TVS, tricuspid valve surgery; *p*-value, probability value; p_H, probability value of heterogeneity; RHF, right heart failure; RVAD, right ventricular assist device.

[a] Described as risk ratio (lower limit 95%CI, upper limit 95%CI)

Table 4: Long-Term Outcomes of Studies Included in Meta-Analysis

Study ID	Long-Term Outcomes
Brewer2014	Concomitant TVS during LVAD implantation was associated with significant improvement on survival after adjustment for possible confounders (HR=0.1, p<0.05).
Crisinelis2019	Concomitant TVS during LVAD implantation was associated with a) no improvement on survival (p=0.51), b) and no improvement on 2-year postoperative TR severity (p>0.05).
Fujino2020	Concomitant TVS during LVAD implantation was associated with a) no improvement on 2-year survival (p=0.566) or 2-year HF readmission-free survival (p=0.537), b) and no improvement on 2-year significant TR-free rate (p=0.545).
Fujita2014	Concomitant TVS during LVAD implantation was associated with a) significant improvement on 2-year postoperative TR severity (p<0.001), b) and no improvement on survival (p=0.281).
Han2016	Concomitant TVS during LVAD implantation was associated with a) significant improvement on postoperative TR severity (OR=0.38, 95%CI: 0.19-0.76, p=0.006), b) no improvement on 2-year survival (p=0.24), c) and no improvement on 2-year mean cumulative readmission for RHF (p=0.95).
Imamura2019	Concomitant TVS during LVAD implantation was associated with a) no improvement on 1-year HF readmission-free survival (56% *vs*. 45%, p=0.30), b) and no improvement on 1-year postoperative TR severity (p>0.05).
Krishan2012	Concomitant TVS during LVAD implantation was associated with no improvement on cumulative death (21.6% *vs.* 21.4%, p=0.99).
Maltais2012	Concomitant TVS during LVAD implantation was associated with no improvement on survival (p=0.26).
Mihalj2022	Concomitant TVS during LVAD implantation was associated with a) significant improvement on all-cause readmission (p=0.021), b) significant improvement on postoperative TR severity (OR=0.03, 95%CI: 0.00-0.22, p<0.001), c) no improvement on RHF-related readmission (p=0.183), d) and no improvement on survival (p=0.984).
Oezpeker2015	Concomitant TVS during LVAD implantation was associated with no improvement on 1-year survival (53.1% *vs*. 73.1%, p=0.176).
Piacentino2011	Concomitant TVS during LVAD implantation was associated with a) improvement on postoperative TR severity, b) and a trend toward improvement on survival.

Study ID	Long-Term Outcomes
Pla2022	Concomitant TVS during LVAD implantation was associated with a) improvement on postoperative TR severity, b) no improvement on 6-month RHF (46.9% *vs*. 50.0%, *p*=0.81), c) and no improvement on 6-month survival (12.5% *vs*. 25.0%, *p*=0.65).
Saeed2011	/
Tie2022	Concomitant TVS during LVAD implantation was associated with no improvement on survival (*p*=0.964).
Volevski2023	Concomitant TVS during LVAD implantation was associated with no improvement on survival (*p*=0.628).
Zhigalov2019	Concomitant TVS during LVAD implantation was associated with no improvement on survival (*p*>0.05).

Abbreviations: ID, identity; TVS, tricuspid valve surgery; LVAD, left ventricular assist device; HR, hazard ratio; TR, tricuspid regurgitation; HF, heart failure; RHF, right heart failure; OR, odds ratio; aHR, adjusted hazard ratio; QOL, quality of life; IQR, interquartile range.