Tricuspid valve detachment for ventricular septal defect closure: A meta-analysis of existing evidence

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Abstract

Background: Ventricular septal defect (VSD) is one of the most common congenital cardiac defects, However, in some cases VSD sites are difficult to expose due to obstruction from chordal attachments and leaflets of the tricuspid valve (TV)[6](#ref-0006). To systematically review the efficacy and safety of tricuspid valve detachment,(TVD) versus conventional surgical repair (non-TVD) in the treatment of ventricular septal defect (VSD) .This article is aimed to compare the many outcomes from existing studies and provide evidence regarding the necessity of performing TVD. **Methods:**We searched the following databases: PubMed via NCBI, the Cochrane Central Register of Controlled Trials (no date restriction),Medline via Ovid (from 1966 to May 2020); Embase via Ovid (no date restriction) and China National Knowledge Infrastructure for studies comparing the efficacy of tricuspid valve detachment (TVD) and other surgical techniques in VSD repair. Cardiopulmonary bypass time, Cross-clamp time; postoperative complications including residual defect ,Postoperative atrioventricular block ,Implantation of pacemakers, tricuspid regurgitation ;Length of stay, Length of ICU stay were analyzed. **Results:** Only 9 studies were included after selection (Table 1), including 7 retrospective cohort studies, 1 respective cohort study and 1 prospective observational stud,a patient pool of 1404 patients with 374 underwent TVD and 1030 underwent non-TVD procedures,met the inclusion criteria.Meta analysis has drawn to the following conclusions. Firstly, TVD prolongs CPB time (MD=7.75, 95% CI=2.60-12.89, p=0.003) and cross-clamp time(MD=7.77, 95% CI=4.76-10.78, p<0.001) compared with non-TVD techniques in VSD repair surgeries. Secondly, no significant difference exists in LOS, length of ICU stay, postoperative atrioventricular block, implantation of pacemakers, incidence of [?]mild TR postoperatively and at discharge, as well as incidence of [?]small residual VSD after surgery and during follow-up(all P ¿ 0. 05). Thirdly, application of TVD increases the risk of TR during follow-up(OR=2.42, 95% CI=1.55-3.76, p<0.001). **Conclusion:** VSD closure using TVD technique results in longer CPB and cross-clamp time, and increases risk of TR during follow-up. TVD provides equally viable and safe alternative in treating VSD.

Title page

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Abstract

Background: Ventricular septal defect (VSD) is one of the most common congenital cardiac defects, However, in some cases VSD sites are difficult to expose due to obstruction from chordal attachments and leaflets of the tricuspid valve (TV)[6]. To systematically review the efficacy and safety of tricuspid valve detachment,(TVD) versus conventional surgical repair (non-TVD) in the treatment of ventricular septal defect (VSD) .This article is aimed to compare the many outcomes from existing studies and provide evidence regarding the necessity of performing TVD.

Methods: We searched the following databases: PubMed via NCBI, the Cochrane Central Register of Controlled Trials (no date restriction),Medline via Ovid (from 1966 to May 2020); Embase via Ovid (no date restriction) and China National Knowledge Infrastructure for studies comparing the efficacy of tricuspid valve detachment (TVD) and other surgical techniques in VSD repair. Cardiopulmonary bypass time, Cross-clamp time; postoperative complications including residual defect ,Postoperative atrioventricular block ,Implantation of pacemakers, tricuspid regurgitation ;Length of stay, Length of ICU stay were analyzed.

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Conclusion: VSD closure using TVD technique results in longer CPB and cross-clamp time, and increases risk of TR during follow-up. TVD provides equally viable and safe alternative in treating VSD.

【Key words】 Ventricular septal defect; Tricuspid valve detachment; Meta analysis

Introduction

Ventricular septal defect (VSD) is one of the most common congenital cardiac defects, occurring in 3570 infants per million live births on average[1]. Surgical closure of VSD was first attempted by Lillehei and colleagues in 1955[2], and after six decades of surgical practice and technical iteration, nowadays cardiac surgeons can minimize the mortality rate after VSD repair thanks to comprehensive application of cardiopulmonary bypass (CPB) practices, myocardial preservation techniques, improved anesthesia and careful postoperative care[3-5].

The transatrial approach for VSD repair is most widely accepted surgical technique and can enable adequate exposure of the margins of the defect, thus facilitate complete repairs. However, in some cases VSD sites are difficult to expose due to obstruction from chordal attachments and leaflets of the tricuspid valve (TV)[6]. Incomplete repair of VSD increases the incidence of morbidities like complete heart block, tricuspid valve regurgitation (TR) and residual VSD, leading to compromised surgical efficacy or even death[5-7].

To achieve optimal visualization of hard-to-expose VSD, detachment of the TV, radical incision of the TV from leaflet edge to the annulus or detachment of chordal have been suggested, and existing data shows promising results[8-10]. However, controversies surrounding whether or not tricuspid valve detachment (TVD) procedure should be performed on patients still exists, some specialists argue that TVD may prolong CPB time and cross-clamp time[5,7]; whereas some others believe when following certain inclusion criteria for TVD, the procedure can significantly improve surgical efficacy[11]. This article is aimed to compare the many outcomes from existing studies and provide evidence regarding the necessity of performing TVD.

Methods

2.1 Search strategy

A systematic review of published articles was conducted according to the protocol specified by the Cochrane collaboration[12] and reported in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for conducting meta-analyses on intervention studies[13]. We searched the following databases: PubMed via NCBI, the Cochrane Central Register of Controlled Trials (no date restriction), Medline via Ovid (from 1966 to May 2020); Embase via Ovid (no date restriction) and China National Knowledge Infrastructure for studies comparing the efficacy of tricuspid valve detachment (TVD) and other surgical techniques in VSD repair. No restriction was put onto publication type or reporting language. Searching terms included: "ventricular septal defect," "tricuspid valve," and "detachment." Furthermore, conference proceedings of important international conferences like Society of Thoracic Surgeons (STS), American Heart Association (AHA) and European Society of Cardiology (ESC) were also consulted.

2.2 Study Characteristics

Studies were included in this meta-analysis only after all the following inclusion criteria were met:

1. Randomized controlled trials or cohort studies comparing TVD and other techniques with no fewer than 10 patients in each group;
2. Demographic data and comorbidities of the patients (postoperative, at discharge or during follow-up) were provided;
3. Diagnosis of VSD had been made by transesophageal echocardiogram (TEE) or transthoracic echocardiogram (TTE) prior to surgery;
4. At least 1 of the basic outcome criteria (CPB time, cross-clamp time, postoperative morbidities) was provided;

It is worth noting that an extensive effort was made to minimize the impact of convert duplicate or metachronous republication from the same surgical groups on the patient sample size. For these cases, only the latest studies were included. Also, if a surgical group was found to have participated in multiple studies, only the study with the largest patient population will be included.

2.3 Data extraction

Inclusion and exclusion criteria were defined to determine the selection of clinical studies. References of all included articles were manually examined and added to our electronic citation manager to ensure that all pertinent published works had been identified. With no prior knowledge of the authors or results of the selected publications, 2 reviewers (Cao Z and Ling Y) rated the clinical and methodological quality of each study using a standardized scoring system independently after acquiring full texts of the studies. Studies that did not rate above a quality score threshold were excluded from data extraction.

2.4 Outcome measures

Primary outcomes of the meta-analysis included procedural outcomes like CPB time and cross-clamp time. The secondary outcomes included procedural outcomes like implantation of pacemakers and postoperative atrioventricular block, as well as clinical outcomes like length of stay (LOS), length of ICU stay, incidence of [?]mild TR after surgery, at discharge and during follow-up, incidence of [?]small residual VSD after surgery and during follow-up. Risk of bias assessment was performed according to the Newcastle–Ottawa Quality

Assessment Scale[14] criteria. [?]mild TR was defined as TR with a grade of [?]2 using TTE or TEE. [?]small residual VSD was defined as residual VSD with a diameter of [?]2 mm after surgical repair.

2.5 Meta Analysis

Statistical analysis was performed using RevMan software (Review Manager version 5.3, Nordic Cochrane Centre, Copenhagen, Denmark). A p-value of <0.05 was considered significant. Mean difference with a 95% confidence interval was utilized to describe continuous outcomes, and odds ratio with a 95% confidence interval was used to describe dichotomous outcomes. A random effects model was used in case of significant heterogeneity, and a fixed effect model was applied when heterogeneity was low. Heterogeneity was assessed using the Cochrane Q square test ($P < 0.05$ was considered an indicator of significant heterogeneity) and the I^2 estimates ($< 50\%$ low heterogeneity, $> 50\%$ high heterogeneity).

3.Results

3.1 Eligible studies and characteristics of studies

A total of 120 articles were identified, and 80 remained after title abstract screen and duplicate deletion. Altogether 71 articles were excluded for the following reasons: 33 articles were case reports, reviews or case series; 20 studies included no VSD patients; 12 studies performed no TVD procedure; 3 studies provided inadequate raw data for analysis; and 2 studies included insufficient patient population (Figure 1).

Only 9 studies were included after selection (Table 1), including 7 retrospective cohort studies, 1 respective cohort study and 1 prospective observational study. Quality assessment of included studies was summarized in Table 2. In the study led by Sasson[11], patients were divided into three groups, group 1 included patients with no indication for TVD, group 2 for patients with indications for TVD and underwent TVD and group 3 for patients with indications for TVD but underwent non-TVD procedures. Our analysis took only group 2 and group 3 into consideration.

3.2 Patient characteristics

All selected studies formed a patient pool of 1404 patients with 374 underwent TVD and 1030 underwent non-TVD procedures.

Based on existing data, mean age was 12.96 months and 8.15 months (p=0.1752), mean weight was 6.62 kg and 6.74 kg (p=0.8362) respectively for TVD and non-TVD group. Weighted mean follow-up time was 39.89±24.24 months in TVD group and 43.36±27.15 months in non-TVD group.

3.3 Procedural outcomes

3.3.1Cardiopulmonary bypass time

Mean CPB time was 82.55 minutes with 95% CI of 79.89-85.21 minutes in the TVD group and 73.78 minutes with 95% CI of 72.26-75.31 minutes in the non-TVD group (p<0.001). 374 patients receiving TVD and 1030 patients receiving non-TVD procedures were assessed for this outcome and recruited from all 9 included studies.

In the meta-analysis, significant difference in CPB time was identified (MD=7.75, 95% CI=2.60-12.89, p=0.003) (**Fig.2a**).

3.3.2Cross-clamp time

Mean cross-clamp time was 52.02 minutes with 95% CI of 50.02-54.02 minutes in the TVD group and 43.70 minutes with 95% CI of 42.66-44.74 minutes in the non-TVD group (p<0.001). 333 patients receiving TVD and 977 patients receiving non-TVD procedures were assessed for this outcome and recruited from 8 included studies.

In the meta-analysis, significant difference in cross-clamp time was identified (MD=7.77, 95% CI=4.76-10.78, p<0.001) (**Fig.2b**).

3.3.3Postoperative atrioventricular block

The meta-analysis for postoperative atrioventricular block included 193 patients undergoing TVD and 479 patients undergoing non-TVD procedures from 4 studies, no significant difference in postoperative atrioventricular block was identified(OR=0.73, 95% CI=0.18-3.01, p=0.66) (**Fig.2c**).

3.3.4

Implantation of pacemakers

The meta-analysis for implantation of pacemakers included 125 patients undergoing TVD and 456 patients undergoing non-TVD procedures from 3 studies, no significant difference in implantation of pacemakers was identified(OR=0.95, 95% CI=0.19-4.71, p=0.95) (**Fig.2d**).

3.4 Clinical outcomes

3.4.1 Length of stay

Mean LOS was 5.74 days with 95% CI of 5.06-6.43 days in the TVD group and 5.6 days with 95% CI of 4.08-7.12 days in the non-TVD group (p=0.9182). 132 patients receiving TVD and 411 patients receiving non-TVD procedures were assessed for this outcome and recruited from 2 included studies.

In the meta-analysis, no significant difference in LOS was identified (MD=0.01, 95% CI=-0.23-0.24, p=0.96) (**Fig.3a**).

3.4.2 Length of ICU stay

Mean length of ICU stay was 5.74 days with 95% CI of 5.06-6.43 days in the TVD group and 5.6 days with 95% CI of 4.08-7.12 days in the non-TVD group (p=0.9182). 132 patients receiving TVD and 411 patients receiving non-TVD procedures were assessed for this outcome and recruited from 2 included studies.

In the meta-analysis, no significant difference in length of ICU stay was identified (MD=-0.14, 95% CI=-1.31-1.03, p=0.82) (**Fig.3b**).

3.4.3 Postoperative [?]mild TR

The meta-analysis for postoperative [?]mild TR included 205 patients undergoing TVD and 515 patients undergoing non-TVD procedures from 4 studies, no significant difference in postoperative [?]mild TR was identified(OR=1.05, 95% CI=0.53-2.09, p=0.88) (**Fig.3c**).

3.4.5 [?]mild TR at discharge

The meta-analysis for [?]mild TR at discharge included 67 patients undergoing TVD and 142 patients undergoing non-TVD procedures from 2 studies, no significant difference in [?]mild TR at discharge was identified(OR=0.70, 95% CI=0.30-1.60, p=0.40) (**Fig.3d**).

3.4.6 [?]mild TR during follow-up

The meta-analysis for [?]mild TR during follow-up included 250 patients undergoing TVD and 813 patients undergoing non-TVD procedures from 7 studies, significant difference in [?]mild TR during follow-up was identified(OR=2.42, 95% CI=1.55-3.76, p<0.001) (**Fig.3e**).

3.4.7 Postoperative [?]small residual VSD

The meta-analysis for postoperative [?]small residual VSD included 113 patients undergoing TVD and 284 patients undergoing non-TVD procedures from 3 studies, no significant difference in postoperative [?]small residual VSD was identified(OR=0.74, 95% CI=0.42-1.29, p=0.29) (**Fig.3f**).

3.4.8 [?]small residual VSD during follow-up

The meta-analysis for [?]small residual VSD during follow-up included 98 patients undergoing TVD and 400 patients undergoing non-TVD procedures from 3 studies, no significant difference in [?]small residual VSD during follow-up was identified(OR=0.86, 95% CI=0.26-0.87, p=0.81) (**Fig.3g**).

4.Discussion

Detachment of the septal leaflet of tricuspid valve was first attempted by Hudspeth and colleagues in 1962 to achieve optimal visualization of VSD in surgical repair[15]. And in the last few decades several studies applied TVD techniques to repair hard-to-expose VSD sites, but the majority of which were single institution cohort studies with limited sample sizes and high risk of bias.

This meta-analysis was designed to evaluate and compare important procedural and clinical outcomes after VSD repair using TVD and non-TVD techniques. To date this is the most comprehensive comparative analysis focusing on the efficacy and safety of TVD in surgical repair of VSD. This analysis has drawn to the following conclusions. Firstly, TVD prolongs CPB time and cross-clamp time compared with non-TVD techniques in VSD repair surgeries. Secondly, no significant difference exists in LOS, length of ICU stay, postoperative atrioventricular block, implantation of pacemakers, incidence of [?]mild TR postoperatively and at discharge, as well as incidence of [?]small residual VSD after surgery and during follow-up. Thirdly, application of TVD increases the risk of TR during follow-up.

There have been worries that prolonged CPB and cross-clamp time during surgeries using TVD techniques may harbor additional ischemic damages, and that a more complicated technique may do harm to the conduction system and change the geometry of the heart. However, our meta-analysis has shown that although TVD procedure requires longer CPB and cross-clamp time to be completed, it did not result in any significant differences in clinically relevant outcomes except incidence of TR during follow-up compared with non-TVD procedures. The following factors may contribute to this finding. As has been exemplified in the study led by Sasson[11], most included studies allocate patients into TVD group under strict criteria to maximize patients' benefit from TVD: (1) multiple tricuspid valve chordal arrangement obscuring the margins of the defect; (2) tricuspid valve aneurysm that precludes easy access to the defect; and (3) high position of the defect with outlet extension requiring excessive traction on the tricuspid valve leaflet for exposure. During surgery, an incision parallel to the atrioventricular groove on the right atrium was suggested to reduce the risk of damaging the conduction system. In addition, marking sutures was used at the beginning and end of the detachment to enhance positioning accuracy. After closure, cold saline was injected into the ventricle to assess TV leaflet competence and coaptation, and reoperation was applied immediately should any issues occur.

As for why the incidence of TR is relatively high in the TVD group during follow-up, to date no studies have raised concerns on this topic. We speculate that the reason may be Prolene sutures used to reattach detached leaflets or chordae gradually become incompatible to the healing and renewing tissue. In addition, minor errors during reattachment after TVD maybe amplified by the change of heart size and adapting hemodynamics. This result serves as a reminder that achieving separation of the body and lung circulations should not be the only goal of VSD closure, mitigating trauma to the myocardium and preservation of heart geometry should also be surgeons' main consideration[4].

5. Conclusion

In summary, VSD closure using TVD technique results in longer CPB and cross-clamp time, and increases risk of TR during follow-up. Studies with longer follow-up periods, more detailed clinical data and lesser risk of bias are needed to further testify the effectiveness of TVD technique.

Conflicts of interest :The authors declare that there are no conflict of interests

Author contribution statement : Yongjun Qian: Conceptualization, Methodology, Supervision; Dou Yuan: Writing- Original draft preparation; Liping Chen: Writing-Review & Editing. Xiaoling Zhang: Editing. All authors read and approved the final version of the manuscript.

Abbreviation and Acronyms

CPB = cardiopulmonary bypass

LOS = length of stay

MD = mean difference

RO = risk ratio

TEE = transesophageal echocardiogram

TVD = tricuspid valve detachment

TR = tricuspid valve regurgitation

TTE = transthoracic echocardiogram

VSD = ventricular septal defect

ID	Author/Year	Country	No. of patients TVD	No. of patients Non-TVD	Study design
1	Bilen/2020[16]	Turkey	50	120	Retrospective cohort
2	Fraser/2018[10]	USA	83	164	Retrospective cohort
3	Pourmoghadam/2018[5]	USA	26	89	Retrospective cohort
4	Bang/2016[7]	Korea	49	247	Retrospective cohort
5	Bol-Raap/2003[17]	Netherlands	46	142	Retrospective cohort
6	Aeba/2003[18]	Japan	23	64	Retrospective cohort
7	Gaynor/2000[19]	USA	36	136	Retrospective cohort
8	Weymann/2013[6]	Germany	20	15	Respective cohort
9	Sasson/2006[11]	Isarel	41	53	Prospective observational

Table 1 – Characteristics of included studies.

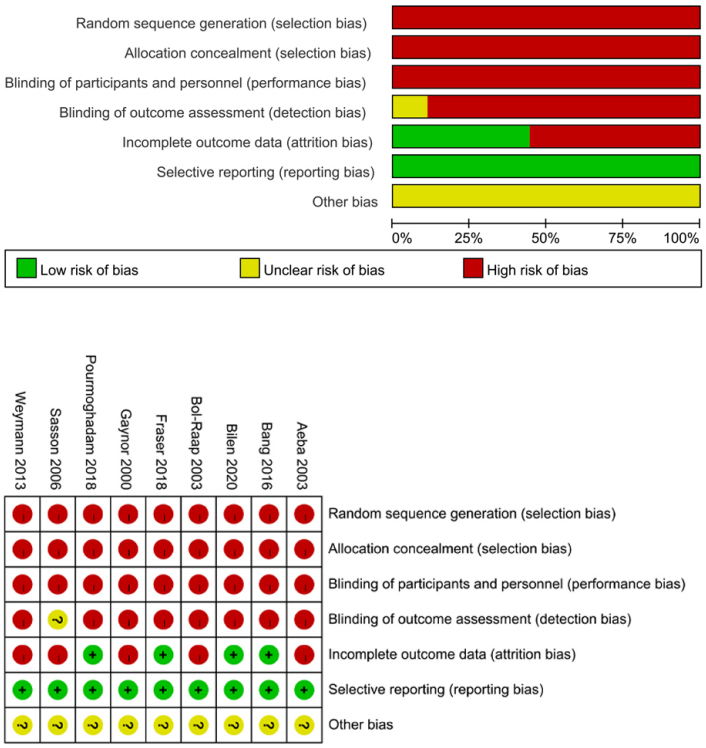

Table 2 – Risk of bias summary and table.

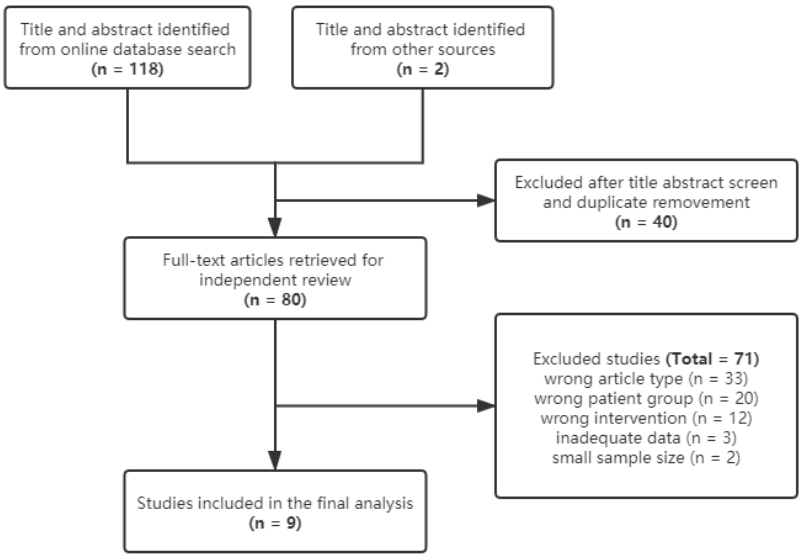

Fig.1. Flow diagram demonstrating the selection of studies for the meta-analysis.

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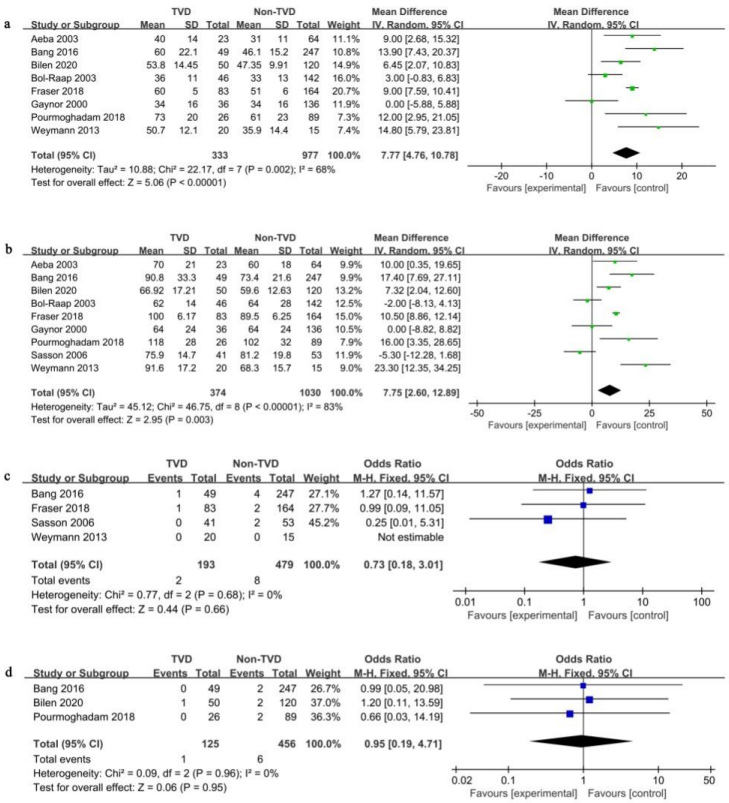

Figure 2 – Forest plot of procedural outcomes.

(a) Cardiopulmonary bypass time (min);

(b) Cross-clamp time (min);

(c) Postoperative atrioventricular block;

(d) Implantation of pacemakers.

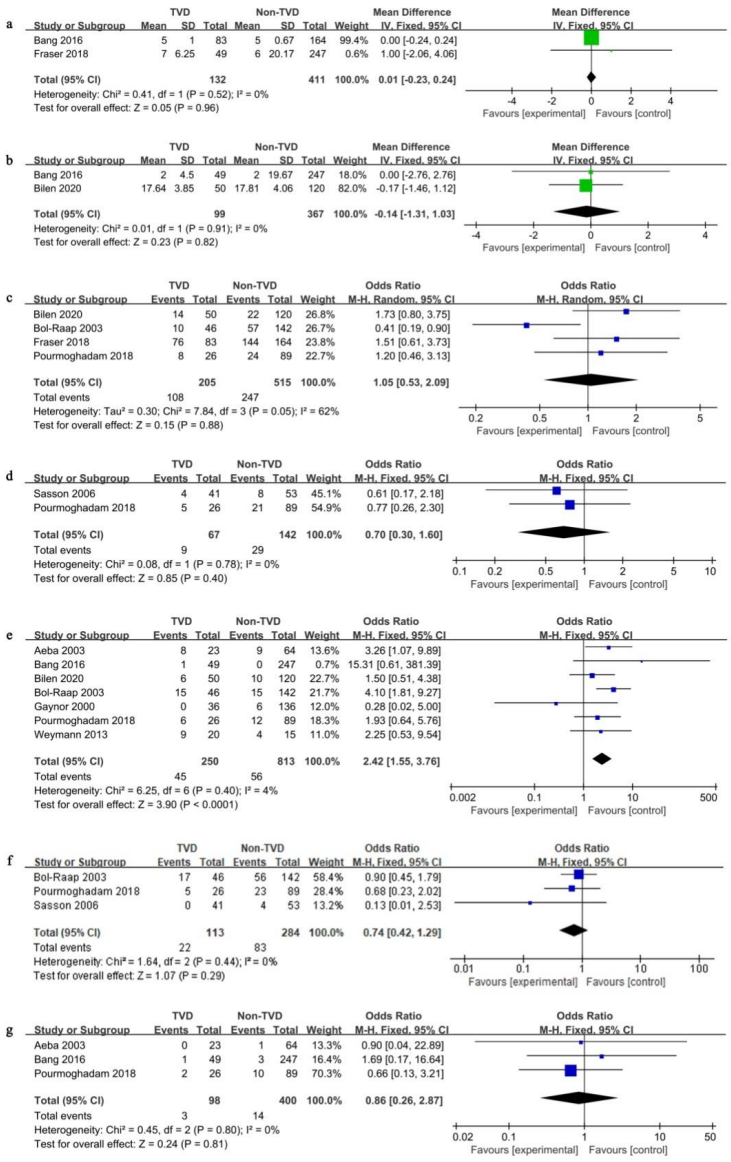

Figure 3 – Forest plots of clinical outcomes.

(a) Length of stay (day); (b) Length of ICU stay (day);

(c) incidence of [?]mild postoperative tricuspid regurgitation;

(d) [?]mild tricuspid regurgitation at discharge;

(e) [?]mild tricuspid regurgitation during follow-up;

(f) [?]small postoperative residual ventricular septal defect;

(g) [?]small residual ventricular septal defect during follow-up.

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