FULL LENGTH ARTICLE

Comparison of transcatheter versus surgical closure of perimembranous ventricular septal defect in pediatric patients: A systematic review and meta-analysis

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Objective: Perimembranous ventricular septal defect (pmVSD) is a common congenital heart disease (CHD) usually treated with either catheter or surgical closure. Superiority of one procedure over the other in children is still a matter of debate. We performed this meta-analysis to compare the clinical outcomes and cost of transcatheter and surgical closure of pmVSD in children.

Materials and methods: We searched seven databases (MEDLINE, PubMed, EMBASE, Google Scholar, CENTRAL, CINHAL, and Cochrane library) and literature references for articles published in the past 10 years (between January 2008 and January 2018) comparing closure of pmVSD by both procedures in children. The outcomes of interest were success rate, residual shunt, need for blood transfusion, complications especially complete atrioventricular block, length of hospital stay, and cost.

Results: A total of 1750 articles were identified. However, only five studies fulfilled the inclusion criteria. As regards success rate, no significant difference was found between surgical and catheter closure. Residual shunt was significantly lower in catheter closure than surgical closure [risk ratio (RR) = 0.44; 95% confidence interval (CI), 0.23–0.83, $p = 0.01$). The need for blood transfusion and the length of hospital stay were significantly lower in the catheter closure compared to surgical closure (RR = 0.02; 95% CI, 0.01–0.08; $p < 0.00001$), (RR = −4.81; 95% CI, −7.76 to −1.86; $p = 0.001$), respectively. However, overall complications, complete atrioventricular block, and the cost were comparable in both procedures.

Conclusion: Transcatheter closure of pmVSD in children was as effective as surgical closure with a lower residual shunt and need for blood transfusion, and shorter hospital stay.

Keywords: Children, Perimembranous ventricular septal defect, Surgical closure, Transcatheter closure

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1. Introduction

Ventricular septal defect (VSD) is one of the most common congenital heart diseases (CHD) in children, accounting for 20% of all CHDs [1]. Meanwhile, perimembranous ventricular septal defect (pmVSD) is the most common hemodynamically significant subtype [2]. Large eccentric pmVSDs were recommended to be closed for fear of infective endocarditis, aortic regurgitation, and pulmonary hypertension [3].

Surgical closure of pmVSD through thoracotomy was the treatment of choice for a long time before the introduction of catheter-based closure [4]. However, surgical closure has many complications such as postoperative pain, infection, and thoracostomy scar [5].

Transcatheter closure of pmVSD was first described by Rigby and Redington [6] in 1994 using the Rashkind double umbrella device. However, Hijazi et al. [7] were the first to close pmVSD using the new Amplatzer VSD occluder device in 2002 that became widely used in many centers worldwide because of its minimally invasive nature [8,9]. The high cost of catheter closure, as well as device-related complications such as complete heart block (CHB), device embolization, aortic and tricuspid valves regurgitation, had limited its use [10,11]. However, the outcomes of using the transcatheter procedure to treat pmVSDs have been improved significantly in recent years because of improvement in device design and operator skills [12].

Anatomically, infero-posterior margin of pmVSD is closely related to bundle of His and its branches. Hence, its closure has been associated with the risk of CHB. Surgeons now know the location of the conduction tissue in patients with pmVSD, even when there is atrioventricular septal malalignment, and can avoid its injury. This is not the case when a device is inserted to close such defects because the device cannot be inserted in such a way as to avoid the injury of the conduction tissues. Thus, iatrogenic complete atrioventricular block (CAVB) was recognized as an unavoidable potential risk of catheter closure. That is why surgical closure of pmVSD is still the preferred method for pmVSD closure in many countries [12].

Studies comparing the superiority of either intervention over each other in children are few with controversial results. So, we performed this meta-analysis to compare the efficacy, complications, outcome, and cost of both transcatheter and surgical closure of pmVSD in pediatric patients.

Abbreviations

CAVB	complete atrioventricular block
CHB	complete heart block
CHD	congenital heart disease
CI	confidence interval
MD	mean difference
pmVSD	perimembranous ventricular septal defect
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RR	risk ratio
SMD	standardized mean difference
VSD	ventricular septal defect

2. Materials and methods

The study was performed according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [13]. The study was approved by the local ethical committee of our faculty of medicine.

2.1. Eligibility criteria

To establish eligibility, we focused on the following criteria:

1. Studies of any design including retrospective cohort studies, prospective cohort studies, randomized controlled trials, or nonrandomized controlled trials published in the past 10 years (2008 to 2018).
2. Studies comparing the outcome of catheter closure versus surgical closure of pmVSD in pediatrics.

2.2. Exclusion criteria

Studies were excluded if they had fewer than 10 subjects, patients with other types of VSD, patients with metabolic or systemic disease, did not contain direct comparison between the two studied interventions, or did not include clinical outcomes; we also excluded studies in which missing data were not available despite attempts to contact authors.

2.3. Outcomes

The primary outcome was the success rate of pmVSD closure of either intervention. Secondary outcomes included residual shunt, complications, need for blood transfusion, length of hospital stay, and cost.

Table 1. Characteristics of the studies included in the meta-analysis.

Study	Year	Type of study	No. of patients Catheter/surgical	Age of patients Catheter/surgical	VSD size (mm) Catheter/surgical	Device type in catheter group
Xunmin et al. [16]	2007	Prospective nonrandomized	73/48	7.5 (3.1–17.5)/4.3 (2.2–12.1) y	4.8(2.4–11.5)/8.2 (5.5–14.5) mm	Amplatzer
Oses et al. [17]	2010	Retrospective	37/34	108.8 ± 61.4/ 21.6 ± 43.2 mo	9.4 ± 3.9/ 8.5 ± 2.6 mm	Amplatzer
Yang et al. [18]	2014	Prospective randomized	101/99	5.5 ± 2.6/ 5.8 ± 2.4 y	5.2 ± 6.1/ 5.9 ± 5.3 mm	Symmetrical Shanghai pmVSD occluder
Chen et al. [19]	2014	Retrospective	81/115	16 ± 11.7/ 3.8 ± 2.4 y	4.1 ± 1.2/ 4.3 ± 1.3 mm	Symmetrical Shanghai pmVSD occluder
Shang et al. [20]	2016	Prospective randomized	21/22	16 ± 8/16 ± 9 y	7.4 ± 2.5/ 6.7 ± 1.9 mm	Symmetrical Shanghai pmVSD occluder

2.4. Search strategy

We performed a systematic search of all articles published in the past 10 years (from 2008 to 2018) in MEDLINE, Web of Science, PubMed, EMBASE, Google Scholar, CENTRAL, CINHAL, and the Cochrane library. The keywords used in the search included: ''ventricular septal defect'', ''transcatheter'', ''surgical closure'', and ''pediatrics''. We also searched the references from included studies to identify additional publications. No language restrictions were used. We attempted to contact authors to retrieve missing details when necessary to obtain complete data.

2.5. Study selection

Study titles, abstracts, and full articles were reviewed independently by two authors (El-Kadeem and El Amrousy) for inclusion according to the pre-established eligibility criteria. Disagreements were resolved through discussion and consensus of the study team. Studies were included if there was a direct comparison between surgical ligation and catheter-based therapies for pmVSD in the pediatric population.

2.6. Data extraction

Two reviewers (El-Kadeem and El Amrousy) independently extracted and checked data regarding details on the methods, study population, intervention, and outcomes using standard data-extraction forms based on Cochrane Collaboration methods [14]. Data collected included study name, year of publication, study period, study design, number of cases, intervention type, age of the patients, sample size, size of VSD, type of occluder, as well as data on primary and secondary outcomes.

2.7. Risk of bias

Three reviewers (Zoair, El Nemr, and El Amrousy) individually assessed the risk of bias for each potential suitable study using the ''Risk of bias'' tool developed by The Cochrane Collaboration [15]. This includes five domains of bias: selection bias (random sequence generation and allocation concealment), performance bias (blinding of study personnel to which intervention the patient had received), attrition bias (adequate description of participant flow and data, reasons and balancing of missing outcome data between groups), detection and reporting bias (blinding of personnel evaluating the outcome and reporting the prespecified outcomes), as well as other bias category (early interruption of the study, bias

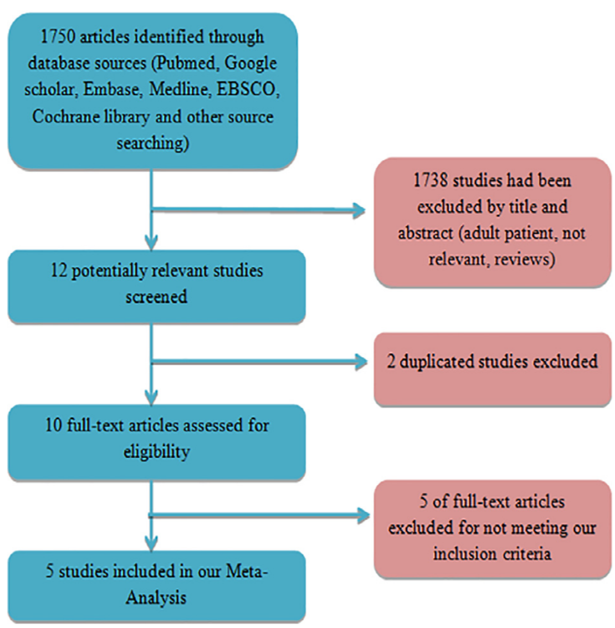

Figure 1. Flow diagram of screened, included and excluded articles.

related to the study design) to capture other potential threats to validity. For each of these items, we documented an overall judgment of the risk of bias (low, high, or unclear). At least two review authors assessed the risk of bias for each study. We used discussion and consensus to resolve any disagreements.

2.8. Statistical analysis

The Cochrane Collaboration RevMan version (5.3) software was used to perform the statistical analysis. For outcome measures, We calculated the risk ratio (RR) for binary outcomes as success rate, residual shunt, need for blood transfusion, and complication, and we calculated the mean difference (MD) or standardized mean difference (SMD) with 95% confidence interval (CI) for continuous outcomes as length of hospital stay and cost. Ratio values underwent log transformation prior to analysis to make analytical scales symmetrical. Statistical heterogeneity of treatment effects between studies was formally tested with the Cochrane test ($p < 0.1$). The I^2 statistics was examined, and $I^2 \geq 50\%$ indicated significant heterogeneity between the trials. We adopted a fixed-effects model when $I^2 < 50\%$ and random-effects model when $I^2 \geq 50\%$. Missing data were dealt with by contacting with the original investigators to request missing data or by analyzing only the available data if we could not obtain the missing data.

Publication bias was assessed by inspecting for asymmetry in the funnel plots and by using components recommended by the Cochrane Collaboration for publication bias.

3. Results

The electronic search has identified 1750 studies. A total of 1738 studies had been excluded based on review of title and abstract. After double publications were removed, 10 studies remained. Further five studies were excluded because they did not meet our inclusion criteria. Five studies [16–20] met our inclusion criteria and were included in the analysis (Fig. 1). Characteristics of the included studies are shown in Table 1. All studies included 631 pediatric patients, 313 in catheter closure group and 318 in surgical closure group.The outcome of all studies were summarized in (Table 2). Patients in the transcatheter closure group were older than those in the surgical closure group (mean age, 10.8 vs. 6.3 years).

Table 2. Outcomes of the studies included in the meta-analysis.

Study	Success rate Catheter/surgical	Residual shunt Catheter/surgical	Complications Catheter/surgical	Need for blood transfusion Catheter/surgical	Hospital stay Catheter/surgical	Cost Catheter/surgical
Xunmin et al. [16]	71/73 (97.3%)/ 48/48 (100%)	2/73 (2.7%)/ 2/48 (4.2%)	14/73 (19.2%)/ 25/48 (52.1%)	0/73 (0%)/ 18/48 (37.5%)	3 (2–6)/11 (8–20) d	48,521 (42,255–62,205)/44,058 (40,382–61,456) Y
Oses et al. [17]	36/37 (97.3%)/ 32/34 (94.1%)	4/37 (10.8%)/ 8/34 (23.5%)	10/37 (27%)/ 8/34 (23.5%)	0/37 (0%)/ 30/34 (88.2%)	1.4 ± 1.2/10.6 ± 7.2 d	
Yang et al. [18]	100/101 (99%)/ 97/99 (98%)	1/101 (1%)/ 2/99 (2%)	7/101 (6.9%)/ 32/99 (31.3%)	0/101 (0%)/ 23/99 (23.2%)	3.3 ± 1.6/7.2 ± 5.7 d	3550.4 ± 745.9/4846.3 ± 1628.1 US$
Chen et al. [19]	80/81 (98.8%)/ 113/115 (98.3%)	5/81 (6.2%)/ 18/115 (15.7%)	28/81 (34.7%)/ 41/115 (35.7%)	0/81 (0%)/ 24/115 (20.9%)	4.9 ± 2.8/8.9 ± 3.1 d	29,795.3 ± 2643.1/20,565.8 ± 3497.7 Y
Shang et al. [20]	21/21 (100%)/ 22/22 (100%)	0/21 (0%)/ 1/22 (4.5%)	1/21 (4.8%)/ 1/22 (4.5%)	0/21 (0%)/ 4/22 (18.2%)	7.7 ± 0.9/7.6 ± 0.8 d	23,000 ± 300/19,000 ± 100 Y
Total	308/313 (98.4%)/ 312/318 (98.1%)	12/313 (3.8%)/ 31/318 (9.7%)	60/313(19.2%)/ 107/318 (33.6%)	0/313(0%)/ 99/318 (31.1%)		

Y = yuan (Chinese currency).

3.1. Success rate

The success rate was reported in all five studies. The heterogeneous test ($I^2 = 0\%$, $p = 0.80$) showed no heterogeneity between the studies, so the fixed-effect model was used. The meta-analysis results of included studies demonstrated that there was no significant differences between the catheter group and surgical group regarding success rate of closure of pmVSD (RR = 1.00; 95% CI, 0.98–1.03; $p = 0.72$) (Fig. 2).

3.2. Residual shunt

The residual shunt was reported in all included studies. We set the end point at patient discharge from the hospital. The heterogeneous test ($I^2 = 0\%$, $p = 0.99$) showed no heterogeneity between the included studies, so the fixed-effect model was used. The meta-analysis combined result of the included studies demonstrated a significant reduction of residual shunt after catheter closure than after surgical closure (RR = 0.44; 95% CI, 0.23–0.83, $p = 0.01$) (Fig. 3).

3.3. Post-procedure complications

Data on post-procedure complications were available in all included studies. The heterogeneous test ($I^2 = 79\%$, $p = 0.0009$) showed heterogeneity between the included studies, so the random-effect model was used. The meta-analysis combined result of these included studies demonstrated that there was no significant difference between catheterization group and surgical group as regards overall complications (RR = 0.57; 95% CI, 0.28–1.15; $p = 0.12$) (Fig. 4).

Data for post-procedure CAVB were available in all included studies. The heterogeneous test ($I^2 = 0\%$, $p = 0.97$) showed no heterogeneity between the included studies, so the fixed-effect model was used. The meta-analysis combined result of these included studies demonstrated that there was no significant difference between the catheterization group and the surgical group as regards the incidence of CAVB (RR = 1.70; 95% CI, 0.49–5.90; $p = 0.40$) (Fig. 5).

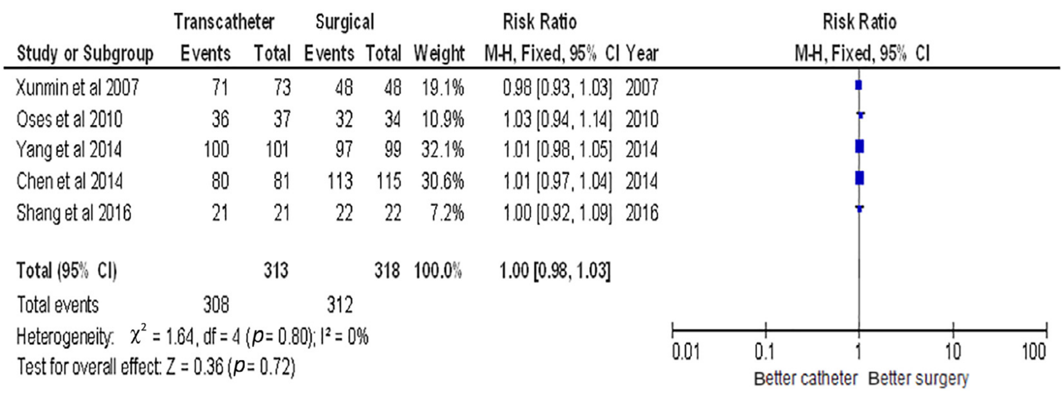

Figure 2. Forest plot of success rate of both procedures. CI = confidence interval.

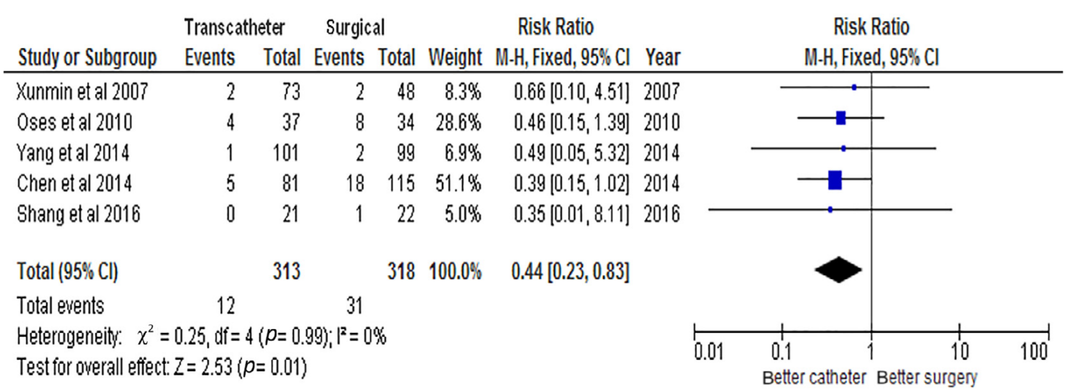

Figure 3. Forest plot of residual shunt after both procedures. CI = confidence interval.

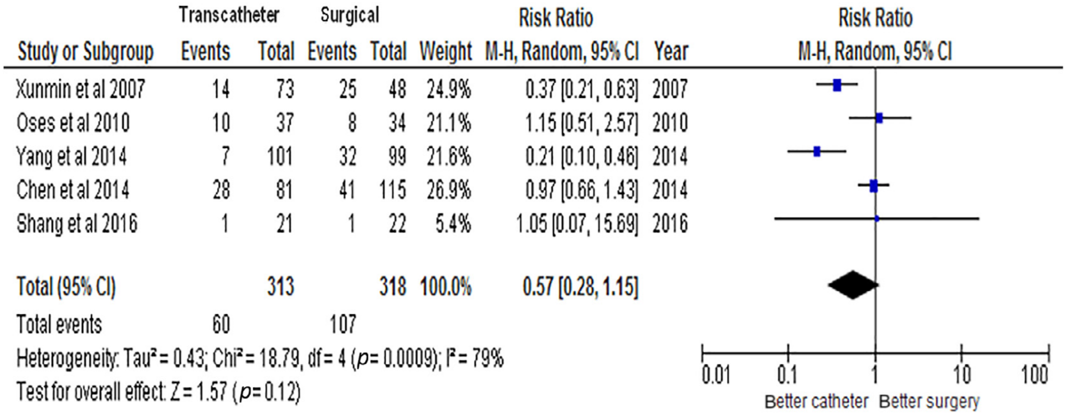

Figure 4. Forest plot of overall complications of both procedures. CI = confidence interval.

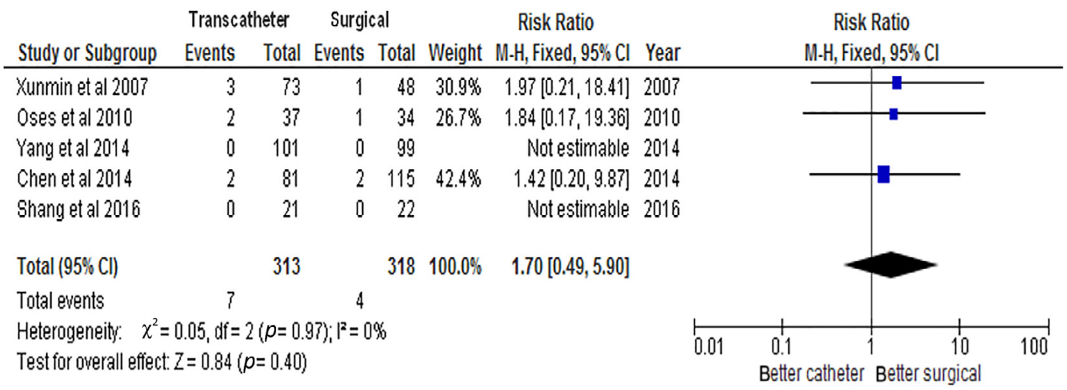

Figure 5. Forest plot of complete atrioventricular block (CAVB) after both procedures. CI = confidence interval.

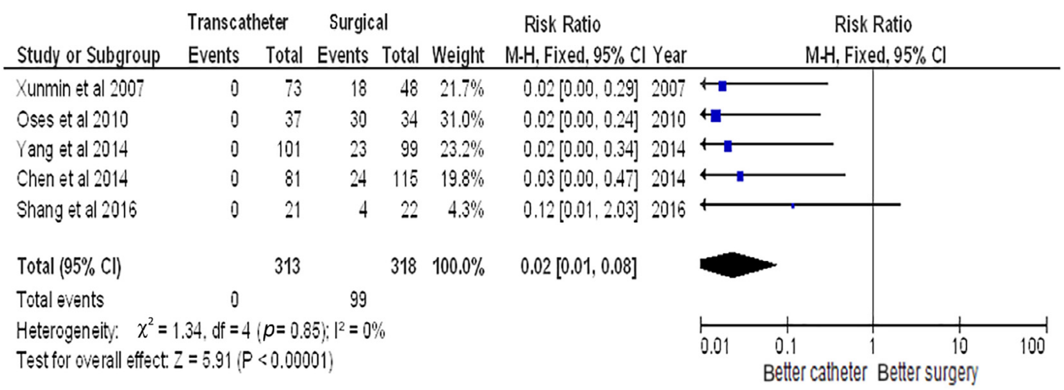

Figure 6. Forest plot of need for blood transfusion in both procedures. CI = confidence interval.

3.4. Need for blood transfusion

Data on blood transfusion during or after procedure were available in all five studies. The heterogeneous test ($I^2 = 0\%$, $p = 0.85$) showed no heterogeneity between the included studies, so the fixed-effect model was used. No patients in the transcatheter group required blood transfusion. The meta-analysis combined results of these included studies demonstrated that the need for blood transfusion was significantly lower in the catheterization group compared with the surgical group (RR = 0.02; 95% CI, 0.01–0.08; $p < 0.00001$) (Fig. 6).

3.5. Length of hospital stay

Data about the length of hospital stay were reported in all five studies and were analyzed using MD. The length of hospital stay was presented as mean and standard deviation in four studies [17–20] and as median and range in one study [16], which was then converted to mean and standard deviation to be included in the meta-analysis. The heterogeneous test ($I^2 = 97\%$, $p < 0.00001$) showed heterogeneity between the included studies, so the random-effect model was used. The meta-analysis combined results of these included studies demonstrated that the length of hospital stay was significantly shorter in the catheterization group compared with the surgical group as the MD was −4.81 (95% CI, −7.76 to −1.86; $p = 0.001$) (Fig. 7).

3.6. Cost

Data about the cost of either intervention were reported in four studies and were analyzed using SMD. The cost was presented as mean and standard deviation in three studies [18–20], and as median and range in one study [16], which was converted to mean and standard deviation to be included in the meta-analysis. The cost was converted from yuan (Chinese currency) to US dollars and then included in the meta-analysis. The heterogeneous test ($I^2 = 99\%$, $p < 0.00001$) showed heterogeneity between the included studies, so the random-effect model was used. The meta-analysis combined results of these included studies demonstrated that the cost was comparable between the catheterization group and the surgical group as the SMD was 0.89 (95% CI, −0.86 to 2.82, $p = 0.29$) (Fig. 8).

3.7. Publication bias

We performed funnel plot analysis for all primary and secondary outcomes, and no obvious publication biases were found (Fig. 9).

4. Discussion

Surgical closure of pmVSD is preferred in young children, particularly in cases characterized by low birth weight and large defects. However, surgical closure has many disadvantages such as pain, scar, psychological trauma, prolonged hospital stay, and more need for blood transfusion. Recently, the emergence of transcatheter closure of pmVSD has been attracting considerable attention. Intervention closure offered several such as advantages rapid recovery, less trauma, less need for blood transfusion, shorter duration of hospital stay, and fewer complications [21].

Indications of surgical closure of pmVSD are extremely different from those of transcatheter closure of pmVSD (as mentioned in the previous paragraph) that made it slightly difficult to find

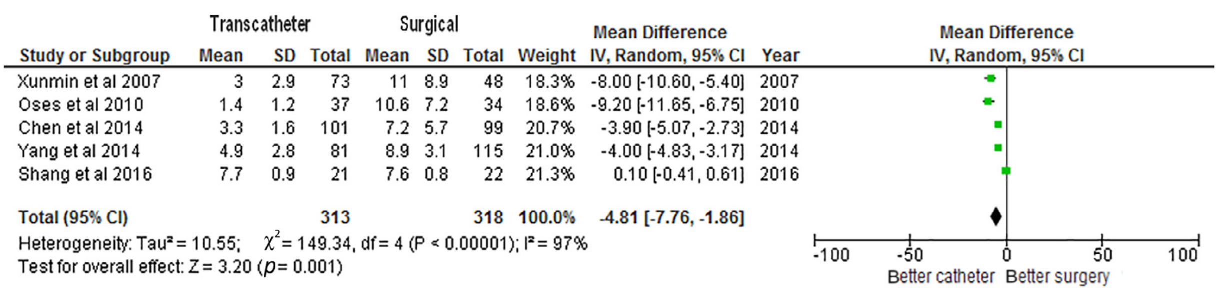

Figure 7. Forest plot of duration of hospital stay of both procedures. CI = confidence interval; SD = standard deviation.

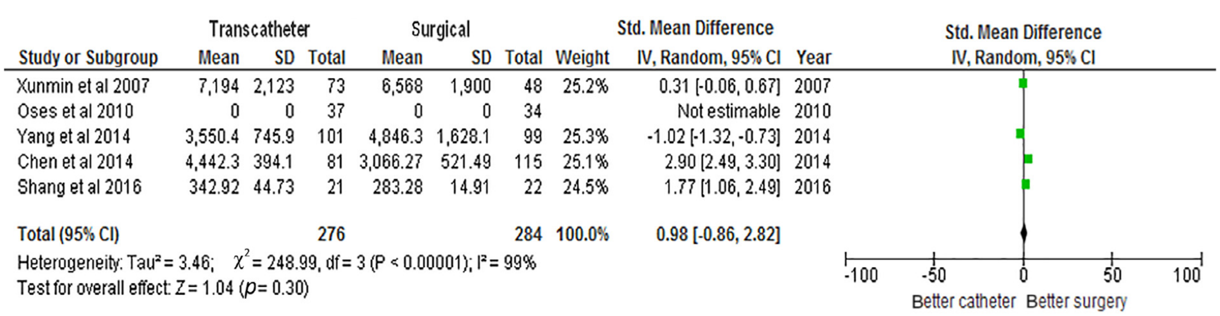

Figure 8. Forest plot of the cost of both procedures. CI = confidence interval; SD = standard deviation.

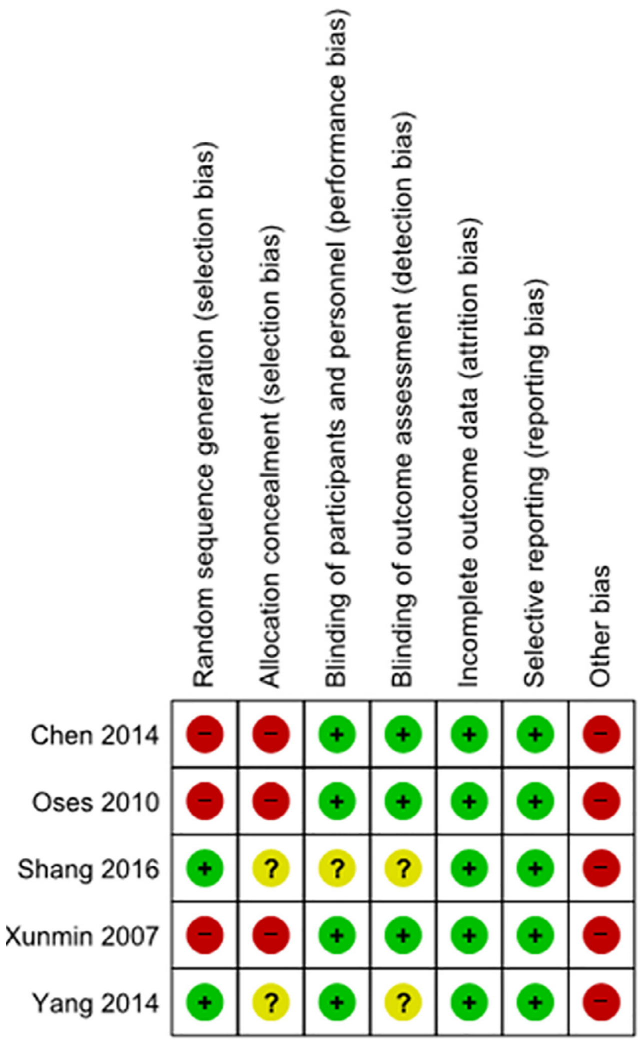

Figure 9. Risk of bias in included studies.

comparable groups regarding age and weight of patients undergoing pmVSD closure by either technique, but we did our best to choose studies that involved patients with more or less comparable ages. To our knowledge, this is the first meta-analysis to compare the clinical outcome and cost between transcatheter and surgical closure of pmVSD in children.

Our meta-analysis revealed that transcatheter closure of pmVSD in pediatric patients was as effective as surgical closure in terms of the success rate. However, the transcatheter closure of pmVSD was associated with a significant decrease in residual shunt, need for blood transfusion, and length of hospital stay compared with the surgical closure. Meanwhile, overall complications, the incidence of CAVB, and the cost were comparable in both interventions.

Data analysis from the five studies showed no significant difference was found between the catheterization group and surgical group as regards the success rate of pmVSD closure. Successful closure of pmVSD was achieved in both groups with good clinical outcomes. The success of transcatheter closure of pmVSD usually depends on VSD size, VSD morphology and operator skill. Large pmVSDs are more difficult to be closed completely by the catheter. Most studies [17–20] in this review showed comparable VSD size, but two studies [16,19] had significantly smaller VSD size in the catheter group compared with the surgical group. Moreover, the success rate of the transcatheter closure of pmVSD depends to a great extent on the age of the patient. In three of the included studies [16,17,19], pediatric patients in the transcatheter group were significantly older than those in the surgical group. These can account for the high success rate in transcatheter closure.

As regards residual shunt, data analysis from the five studies showed that there was a significant reduction of residual shunt after transcatheter closure compared with surgical closure. This clinical outcome seems to agree with other meta-analysis results which reported lower residual shunt after transcatheter closure of pmVSD [22]. This can be attributed to the development of a more advanced generation of occluder devices such as Shanghai pmVSD occluder and to more skill and experience of cardiologists with device occlusion.

As regards post-procedural complications, our meta-analysis results showed that there was no significant difference between transcatheter and surgical closure of pmVSD. Complete heart block is one of the most dangerous complications associated with either transcatheter device closure or surgical closure of pmVSD because of mechanical stimulation or compression of the conduction system. Several studies have reported the association of CAVB with transcatheter closure of pmVSD with an incidence rate varying from 2% to 7.5% [10,22]. This is attributable to the presence of the conduction system of the heart in close association with the rim of the pmVSD. Device oversizing, low weight, and younger age are the main risk factors for the occurrence of this complication [11,22,23]. Our results showed that the number of patients who developed CAVB after catheter closure was twice the number of patients who developed CAVB in the surgical closure, but this difference did not reach a statistical significance. The marked decrease in the incidence of CAVB after transcatheter closure of pmVSD can be attributable to the improvement of the skills of the operators, and to the development of new symmetric occluder devices that are characterized by their easier deployment and smaller size with decreased pressure exerted on the interventricular septum, thus reducing the damage of the conduction system compared to asymmetric occluders [24]. In spite of the decreased number of CAVBs after catheter closure of pmVSD in recent years, post-catheter iatrogenic CAVB is still considered an unavoidable potential risk.

Regarding the need for blood transfusion, our meta-analysis results showed that none of the children in the transcatheter group required a blood transfusion, whereas 99 out of 318 patients in the surgical group required a blood transfusion. Therefore, there was a significantly lower need for blood transfusion after catheter closure than after surgical closure of pmVSD. This can be attributable to the invasive nature of surgical closure and the presence of younger patients in the surgical group.

Our meta-analysis results showed that the length of hospital stay was significantly shorter for children who underwent catheter closure than those who underwent surgical closure. This is because surgical closure of pmVSD is a major surgery that requires a longer duration of postoperative monitoring and recovery. By contrast, the transcatheter closure procedure is less invasive and needs shorter post-procedure monitoring and recovery.

Our results revealed that the cost of transcatheter closure and surgical closure of pmVSD was comparable. This can be explained by the fact that the high cost of the occluder device in the catheter group is comparable to the high cost of longer hospital stay in the surgical group.

Lastly, our results revealed that the outcomes of transcatheter closure of pmVSD were continuing to improve, which can be attributed to the continuous improvement of the device design and increasing technical expertise of operators. However, indications and requirements of transcatheter closure of pmVSD limit its use to older children, and in cases characterized by smaller defects with an adequate subaortic rim.

Our meta-analysis study has several limitations. First, our meta-analysis was based on only five studies with a relatively small number of patients; however, low heterogeneity was observed between the included studies as the target population was more or less the same. Second, patients in transcatheter closure were older than those in the surgical group, so the efficacy and outcome of transcatheter closure could not be checked in very young children. Third, the five studies included in our meta-analysis used two different occluder devices, and there is no data on the relative efficacy and outcome of each device alone. Fourth, most of the included studies were performed in developing countries (China), where the surgeon's fees are not as expensive as those in developed countries (e.g., United States and Europe), which can affect the result of the cost in our meta-analysis.

5. Conclusion

Transcatheter closure of pmVSD in children was as effective as surgical closure with a lower residual shunt, lower need for blood transfusion, and shorter hospital stay.

Conflict of interest

The authors declare no conflict of interest.

Funding

None.

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