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Research Article

Transcatheter Versus Surgical Closure of Patent Ductus Arteriosus in Pediatric Patients: A Systematic Review With Meta-Analysis

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Abstract

Objective: Patent Ductus Arteriosus (PDA) is a common Congenital Heart Disease (CHD) usually treated with catheter closure or surgical ligation. Yet, there is no superiority of one procedure over the other. No prospective randomized trials have been done comparing device closure of PDA versus surgical closure of PDA. We performed this meta-analysis to compare the outcome of both treatment options to determine which option is superior to the other.

Methods: We performed a literature search of MEDLINE, PubMed, EMBASE, Google Scholar, CENTRAL, CINHAL, Cochrane library and literature references for articles published in the last 20 years between January 1997 and January 2017. We excluded studies of adult or premature patients, patients with other CHD, patients with metabolic or systemic disease and those without a direct comparison between surgical and catheter closure of PDAs. Outcomes of interest were success rate, residual shunt with reintervention, need for blood transfusion, complications and length of stay.

Results: Seven thousand five hundred seventy-eight articles were identified. Six studies fulfilled the inclusion criteria. Regarding success rate, no significant difference was found between surgical and catheter closure (RR: 1.01; 95% CI: 0.99- 1.03, P=0.35). Residual shunt was significantly lower in catheter closure than surgical closure (RR: 0.45, 95% CI: 0.21-0.94, P=0.03). Complications and need for blood transfusion were significantly lower in catheter closure (RR: 0.19, 95% CI: 0.11-0.32, P<0.00001) and (RR: 0.12, 95% CI: 0.05-0.32, P<0.0001) respectively. Length of hospital stay was significantly shorter after catheter closure (CI: -3.5- -3.1, P<0.0001).

Conclusion: Catheter closure was superior to surgical closure with lower residual shunt, complications, need for blood transfusion and shorter hospital stay but overall success rate was not higher than surgical closure.

Introduction

Patent Ductus Arteriosus (PDA) is a common Congenital Heart Disease (CHD) in children accounting for 7% to 10% of all CHD [1]. Once significant PDA is present, closure is always indicated to prevent associated complication such as pulmonary hypertension, arrhythmias, infective endocarditis, aneurysm formation and heart failure [2-3].

Surgical closure with ligation and division of PDA through thoracotomy was the treatment of choice beyond the age of neonate for a long time before invention of catheter closing technique [4]. Nowadays, surgical closure of PDA is restricted to small babies with large significant PDA, unfavorable duct anatomy and unaffordable cost of transcatheter closure [5]. Surgical closure could be done through standard lateral thoracotomy or through video assisted throracoscopic clipping which is less invasive than standard thoracostomy [6]. However, surgical ligation has many complications such as bleeding, pneumothorax, chylothorax, recurrent laryngeal nerve injury, infection, chest deformity and remarkable pain [7].

Being minimally invasive technique with shorter hospital stay, catheter closure of PDA becomes widely used in many centers in the last two decades [8-9]. The high cost of catheter closure as compared to surgical ligation of PDA has limited their use especially in low income countries. Moreover, the use of catheter closure is not recommended in newborn and young infants less than 5 kg in weight, with very large PDA, or with associated CHD requiring surgical intervention. Catheter closure of PDA had its own complications such as residual shunt, coil embolization, aortic obstruction, left pulmonary artery stenosis, hemolysis, recanalization, arrhythmia, cardiac perforation and vascular injury to femoral artery and vein [10-12]. Therefore, surgical closure of PDA is still being preferred [13].

The superiority of either intervention over each other is still controversial. Prospective randomized trials have not been done comparing device closure of PDA versus surgical closure of PDA. So, we performed a meta-analysis for the comparison between the efficacy and outcome of both catheterization and surgical closure in pediatric PDA patients.

Methods

The study was performed according to the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [14]. The study was approved by the local ethical committee of faculty of medicine, Tanta University, Egypt.

Eligibility criteria

1. Studies of any design including retrospective cohort studies, prospective cohort studies, randomized controlled trials or non randomized controlled trials published in the last 20 years from 1997 to 2017.
2. Studies comparing the outcome of catheter closure versus surgical closure of PDA in pediatrics.
3. Studies in pediatric age group.

Exclusion criteria

Studies were excluded if they had fewer than ten subjects or if they included preterm infants or adult patients, patients with other CHD, patients with metabolic or systemic disease, if it didn't contain direct comparison between the two studied interventions, or an absence of clinical outcomes, or if separate/missing data were not available despite attempts to contact authors.

Outcomes

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

Search strategy

We performed a systematic search of all articles published in the last 20 years from 1997 to 2017 in MEDLINE, PubMed, EMBASE, Google Scholar, CENTRAL, CINHAL and the Cochrane library. Our search strategy included the terms patent ductus arteriosus, transcatheter, surgical closure, pediatrics. We also searched the references from included studies to identify additional publications. No language restrictions were used. The authors attempted to contact authors to retrieve missing data when necessary to determine whether the article met the inclusion/exclusion criteria or to complete missing data.

Study selection

Study titles, abstracts and full articles were reviewed independently by two authors (El-Nady M and El Amrousy D) for inclusion according to the pre-established eligibility criteria. Disagreements were resolved by 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 PDAs in the pediatric population.

Data extraction

Two reviewers (El-Nady M and El Amrousy D) 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 [15]. 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 the PDAs, type of occlude, as well as data on primary and secondary outcomes.

Risk of bias

Three reviewers (Zoair A, Shehab N and El Amrousy D) individually assessed the risk of bias for each potential suitable study using the 'Risk of bias' tool developed by The Cochrane Collaboration [16]. 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 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.

Statistical analysis

For outcome measures, we calculated the Risk Ratio (RR) for studies reporting binary outcomes as success rate, residual shunt need for blood transfusion and complication and we calculated the Standardized Mean Difference (SMD) with 95% Confidence Interval (CI) for those reporting continuous outcomes as length of hospital stay. Ratio values underwent log transformation prior to analysis to make analytical scales symmetrical. Statistic heterogeneity of treatment effects between studies was formally tested with the Cochrane test ($P < 0.1$). The I^2 statistics was examined and we considered $I^2 \geq 50\%$ to indicate significant heterogeneity between the trials. We adopted a fixed-effects model when $I^2 < 50\%$; otherwise, the origination of the heterogeneity was analyzed to verify whether a random-effects model could be used. Missing data was dealt with by contacting with the original investigators to request missing data or by analyzing only the available data if they were thought to be missing at random.

Publication bias was assessed by inspecting for asymmetry in the funnel plots and by using components recommended by the Cochrane Collaboration for publication bias. All analyses were performed using The Cochrane Collaboration RevMan version (5.3) software.

Results

The electronic search has identified 7578 studies. 7543 studies had been excluded based on review of title and abstract. After double publications were removed, 16 studies remained. Further ten studies were excluded because they didn't meet our inclusion criteria. Six studies [17-22] met our inclusion criteria and were included in the analysis (Figure 1). Characteristics of the included studies were shown in table 1. All studies included 779 pediatric patients, 385 in catheter closure group and 394 in surgical closure group.

Success rate

Success rate was defined as complete closure of PDA with no residual shunt after either procedure; transcatheter or surgical closure of PDA documented by echocardiography at discharge. The success rate was reported in all 6 studies. The combined result

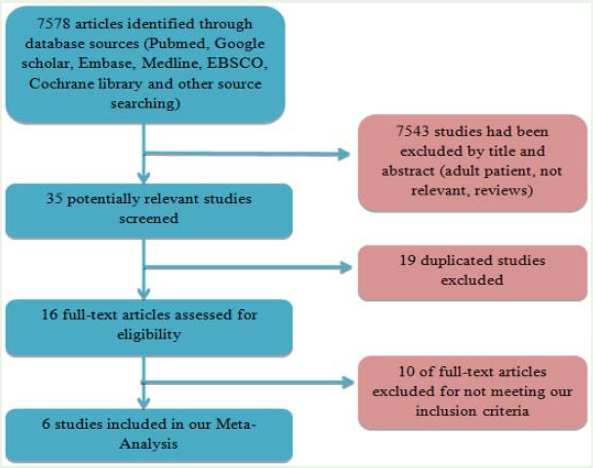

Figure 1: Flow diagram of screened, included and excluded articles.

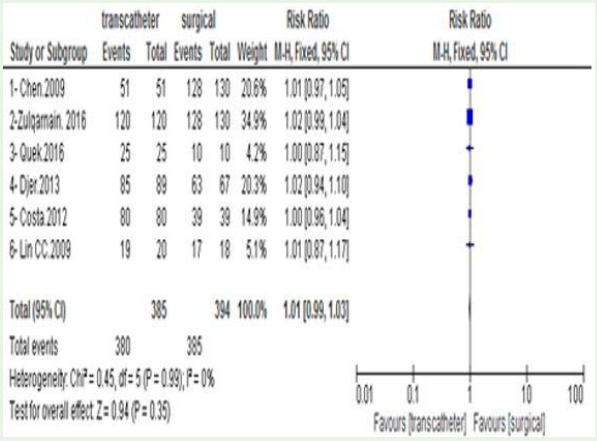

Figure 2: Forest plot showing the success rate between the catheterization and surgical repair groups.

of these included studies demonstrated that there was no significant differences between the catheter group and surgical group regarding primary success rate (RR: 1.01, 95% CI: 0.99-1.03, P=0.35) with low heterogeneity among the studies (I^2=0, P=0.99) (Figure 2).

Residual shunt

Residual shunt was defined as presence of residual flow through the closed PDA. Small residual flow less than 2 mm in diameter was considered small and needs no further intervention except follow up. Residual flow more than 2 mm in diameter was considered significant and usually needs further intervention in the form of surgical closure or catheter closure according to the size of the residual shunt and type of primary intervention. The residual shunt was reported in all 6 studies. We set the end point at patient discharge from the hospital. There were no residual shunt cases after the transcatheter procedures in 3 studies [17,21,22]. The combined result of included studies demonstrated a significant reduction of residual shunt after catheter closure than after surgical closure (RR: 0.45, 95% CI: 0.21-0.94, P=0.03) with low heterogeneity among the studies (I^2=0, P=0.8) (Figure 3).

Post procedure complications

Data on postprocedure complications were available in all 6 studies. We sat the endpoint when the patients were discharged from the hospital. Complications in both surgical and catheter groups in all included studies were presented in table 2. The combined results of these included studies demonstrated that complications were significantly lower in catheterization group than surgical group (RR: 0.19, 95% CI: 0.11-0.32, P<0.00001). Statistically significant study heterogeneity was identified among studies (I^2=68%, P=0.007) (Figure 4).

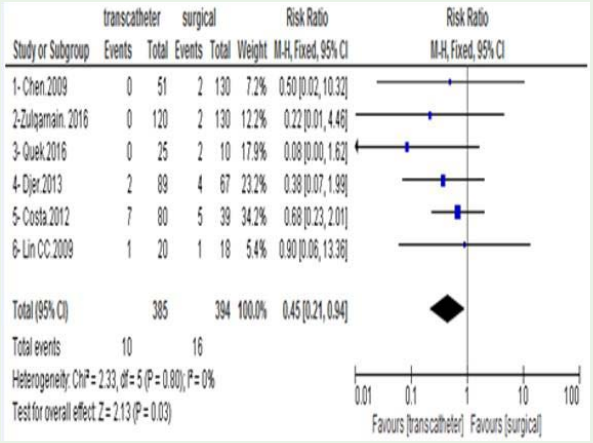

Figure 3: Forest plot showing the residual shunt between the catheterization and surgical repair groups.

Table 1: Characteristics of the studies included in the Meta-Analysis.

study	Year	Type of the study	No of patients Catheter/ surgical	Age of patients Catheter/ surgical	PDA size (mm) Catheter/ surgical	Device type in catheter
Chen et al [17]	2009	Cohort	51/130	18.2 ± 13/11.4 ± 11.9 years	6.8 ± 2.3/6.4 ± 1.9 mm	Amplatzer
Lin et al [18]	2009	Cohort	20/18	51.8±21.1/39.9±20.7 days	4.13± 0.61/4.42 ± 0.92 mm	Amplatzer
Costa et al [19]	2012	Cohort	80/39	0.5-13/0.5-12 years	3.2 ± 1.1/3.8 ± 1.2 mm	Amplatzer , Amplatzer II, Amplatzer vascular plug II, Nit-Occlud, Gianturco coils, Cera TM
Djer et al [20]	2013	Cohort	89/67	.5-13 /.5-12 years	1.3-13/3-11 mm	Amplatzer
Quek et al [21]	2016	Cohort	25/10	9±6.8/2±3.7 years	3.8 ± 1.3/3.9 ± 1.2 mm	Amplatzer
Zulqarnain et al [22]	2016	Cohort	120/130	8.15+7.8/9.79+7.5 years	4.28± 1.68/4.20± 1.56 mm	SHSMA occluder

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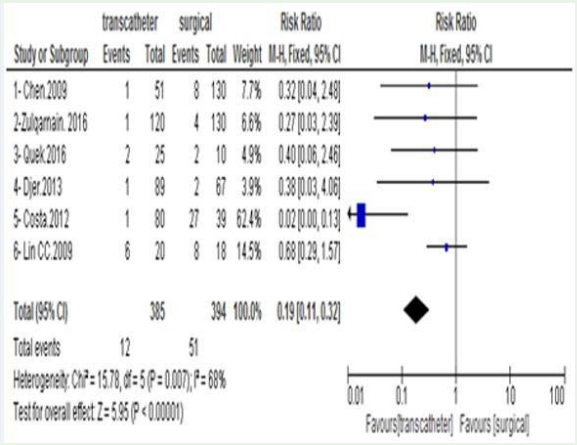

Figure 4: Forest plot showing complications between the catheterization and surgical repair groups.

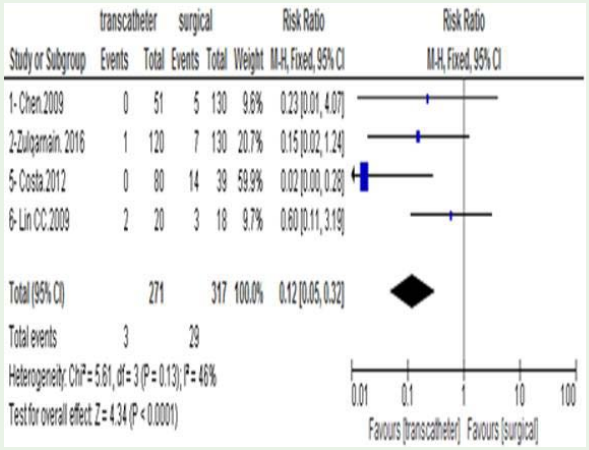

Figure 5: Forest plot showing blood transfusion between the catheterization and surgical repair groups.

Table 2: Complications in catheterization and surgical repair groups in all included studies.

The included study	Complication in surgical group	Complication in catheter group
Chen et al. [17]	-Pleural effusion : 2/130	0/51
	-chylothorax: 1/130	0/51
	-pneumothorax: 3/130	0/51
	- vomiting: 2/130	0/51
	-arrythmia: 0/130	0/51
Lin et al. [18]	-anemia: 3/18	2/20
	-impaired femoral pulse: 0/18	1/20
	-infection: 4/18	1/20
	-pleural effusion/chylothorax: 1/18	0/20
	-diaphragmatic paralysis:1/18	0/20
	-right pulmonary stenosis:1/18	0/20
	-left pulmonary stenosis: 1/18	2/20
	-aortic stenosis: 0/18	2/20
Costa et al. [19]	- chylothorax: 3/39	0/80
	- pneumothorax: 1/39	1/80
	- respiratory problems: 6/39	0/80
	-arterial hypertension: 27/39	0/80
	-infection: 2/39	0/80
Djer et al. [20]	-arrythmias: 2/67	1/89
	- device embolization: 0/67	2/89
Queck et al. [21]	-minor complications: 4/10	2/25
Zulqarnain et al. [22]	-major complications: 4/130	1/120

Need for blood transfusion

Three studies [17,19,22] with 551 patients provided data regarding blood transfusion during or after the procedure. The combined results of these included studies demonstrated that the need for blood transfusion was significantly lower in catheterization group (RR: 0.12, 95% CI: 0.05-0.32, P<0.0001) with low heterogeneity among these studies (I^2=46%, P=0.13) (Figure 5).

Length of hospital stay

The data about the length of hospital stay was reported in the 6 studies, and was analyzed by Mean Difference (MD). The length of hospital stay was presented as mean and standard deviation in 5 studies [17,18,20,21,22] and as median and range in one study [19] and was converted to mean and standard deviation to be included in the meta-analysis. The combined results of these included studies

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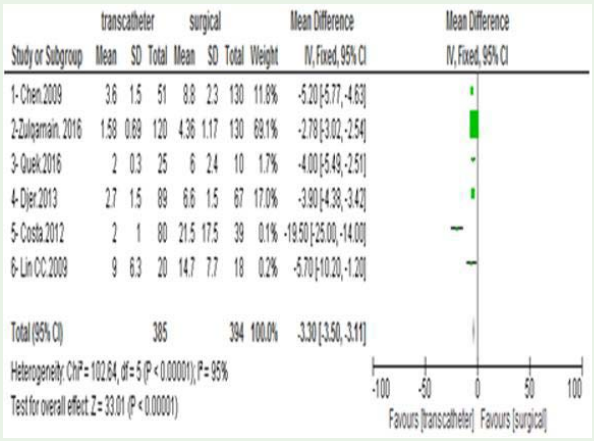

Figure 6: Forest plot showing length of hospital stay between the catheterization and surgical repair groups.

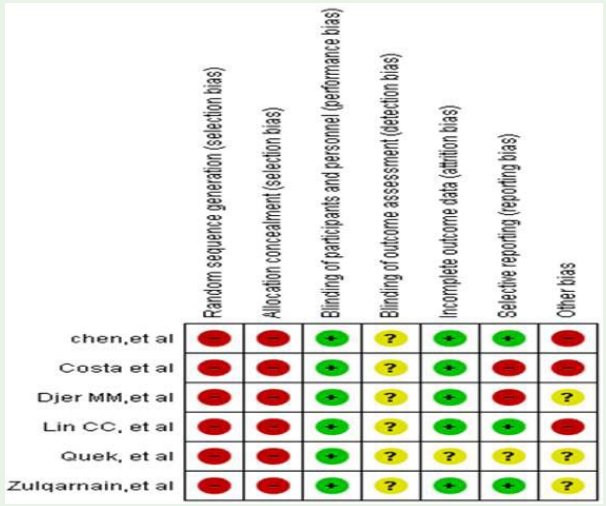

Figure 7: Risk of bias in included studies.

demonstrated that the length of hospital stay was significantly shorter in catheterization group as MD was -3.3 (95% CI: -3.5 to -3.1, P<0.00001). Meanwhile, there was significant statistical heterogeneity between studies regarding this outcome (I^2=95%, P<0.00001) (Figure 6).

Publication bias

We performed funnel plot for all primary and secondary outcome. Although, it was difficult to perform and interpretate the results of publication bias because of limited number of included studies, no obvious publication biases were founded (Figure 7).

Discussion

Our meta-analysis revealed that transcatheter closure of PDA was superior to surgical closure in pediatric patients. Although, they had the same success rate of PDA closure, transcatheter closure of PDA was associated with significant decrease in residual shunt, complications, blood transfusion and length of hospital stay than surgical closure.

Regarding success rate, data analysis from the six studies, showed no significant difference between the catheterization groups and surgical groups regarding success rate of PDA closure. Successful closure of PDA was achieved in both groups with good clinical outcomes. Post-procedure and follow-up echocardiogram at 6-months revealed complete ductal occlusion for all patients in both groups.

The success of PDA closure via transcatheter intervention usually depends on PDA size and morphology and operator skill. Large PDAs often require more coils and are more difficult to be closed completely. Most studies [17,18,21,22] in this review showed comparable duct size between transcatheter closure group and surgical closure group, even duct it was smaller in transcatheter group than surgical group in two studies [19,20]. Moreover, it has been clear that the success rate of transcatheter closure is not only dependent on duct size and the skill of the operator, but also on the age and clinical status of the patient. In five of included studies, the age of pediatric patients in transcatheter group was more than those in surgical closure group. These can explain the high success rate with lower complications in transcatheter closure.

Regarding residual shunt, data analysis from the six studies, showed that there were no residual shunt after transcatheter procedures in 3 studies [17,21,22]. The combined results of all included studies demonstrated a significant lower residual shunt after transcatheter closure than after surgical closure. This clinical outcome seems to contradict other meta-analysis result which reported lower residual shunt after surgical closure than after transcatheter closure of PDA [23]. This can be attributed to more recent studies included in our meta-analysis (from 2009-2016) with more advanced generation of occluder devices and surely more skill and experience of operators with device occlusion by time.

Regarding postprocedural complications and need for blood transfusion, data analysis from the six studies, showed that only 12 out of 385 patients in catheterization group had complications and only 3 patients needed blood transfusion while 51 out of 394 patients in surgical group had complications and 29 patients needed blood transfusion. Therefore, there was significant lower incidence of complications and need for blood transfusion after catheter closure than after surgical closure of PDA. This can be due to invasive nature of surgical ligation and younger patients in surgical closure group.

Regarding hospital stay, data analysis from the six studies showed that the length of hospital stay was significantly shorter for patients who underwent catheter closure than those who underwent surgical closure. This could be explained by the fact that surgical ligation is a major surgery that needed longer postoperative monitoring and longer duration for recovery. Moreover, more complications were associated with surgical ligation that can prolong length of hospital stay. In contrast, transcatheter closure procedure is far less invasive with less complication, so shorter post procedure monitoring is needed with shorter recovery period.

Lastly, our results suggested that the outcome of transcatheter closure of PDA have been changed with time to be better, which can be due to newer device, techniques and approach.

Where reporting was sufficient, the overall quality of studies in this review was reasonable as assessed by The Cochrane

Collaboration's 'Risk of bias' tool. Many studies were assessed as having a low risk of bias across a number of domains. This review included non-randomised studies, meaning that selection bias was a potential concern. However, many of the non-randomized studies in this review were sought to minimize the impact of potential selection bias. Importantly, many papers provided insufficient information to make an informed judgment about the risk of bias, highlighting the need for more careful reporting of research method. Outcomes, as intended in the study protocol, were important in assessing the risk of bias of a study.

Limitation of our meta-analysis study: first, our analysis was based on only 6 cohort studies but most of them had enough sample size with low heterogeneity between the included studies as the target population was more or less the same. Second, lack of randomized controlled trials in our analysis so obtaining results from observational non randomized retrospective studies can introduce bias in the results.

Conclusion

Catheter closure was superior to surgical closure with lower residual shunt rate, complications, need for blood transfusion and shorter hospital stay but overall success rate was not higher than surgical closure.

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