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Review

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Percutaneous closure of patent ductus arteriosus versus surgical treatment in low-birth-weight preterms: a systematic review and meta-analysis

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Abstract

Introduction: The optimal management of a patent ductus arteriosus in a population of preterm infants is controversial. Traditionally, when the patent ductus arteriosus does not close either with conservative treatment or in response to pharmacological therapy, the only option is surgical closure. However, transcatheter occlusion might provide a therapeutic alternative. *Methods:* We searched PubMed, Embase, and Cochrane databases for non-randomised and randomised controlled trials that compared transcatheter percutaneous closure of patent ductus arteriosus with surgical ligation in low-birth-weight preterm infants (<2,500 g). A random-effects model was used for outcomes with high heterogeneity. *Results:* We included twelve studies comprising 4,668 low-birth-weight preterm infants, of whom 966 (20.7%) were in the transcatheter percutaneous closure group, and 3,702 (79.3%) patients were included in the surgical group. All-cause mortality (OR 0.28; 95% confidence interval 0.18–0.423; $p < 0.00001$; $I^2 = 0\%$) and haemodynamic instability (OR 0.10; 95% confidence interval 0.05–0.21; $p < 0.001$; $I^2 = 14\%$) were significantly lower in the transcatheter percutaneous closure group. There was no significant difference between transcatheter and surgical patent ductus arteriosus closure for the outcomes of bronchopulmonary dysplasia (0.93; 95% confidence interval 0.46–1.87; $p = 0.83$; $I^2 = 0\%$) and major complications (OR 0.76; 95% confidence interval 0.34–1.69; $p = 0.51$; $I^2 = 43\%$). *Conclusion:* These findings suggest that transcatheter patent ductus arteriosus closure in preterm infants under 2,500 g is a safe and effective alternative to surgical treatment. There was a substantial reduction in all-cause mortality and haemodynamic instability with transcatheter intervention compared to surgical closure.

Introduction

The ductus arteriosus connects the aorta and the pulmonary artery and is considered essential for intrauterine life. After birth, the ductus arteriosus typically closes spontaneously in around 48–72 hours due to muscle contraction and the decrease in placental prostaglandins. If this process does not occur, a patent ductus arteriosus is present.[1] Preterm infants and low birth weight are risk factors for this condition. Patent ductus arteriosus is present in approximately 50% of preterm infants.[2]

Persistence of the ductus arteriosus can lead to critical physiological changes, most notably increased pulmonary flow, which is clinically manifested by respiratory distress and an increased need for oxygen and ventilation. In the long term, this may result in chronic lung injury and bronchopulmonary dysplasia. The pathophysiology of a patent ductus arteriosus also includes a volumetric overload of the left-sided chambers, which can cause systolic dysfunction and heart failure. In cases of a wider patent ductus arteriosus, systemic blood shunting may lead to low systemic blood flow and a drop in diastolic pressure, which may be associated with comorbidities such as necrotising enterocolitis, retinopathy of prematurity, and periventricular haemorrhage.[3,4]

Despite evolving over the years, the optimal patent ductus arteriosus treatment strategy remains controversial. Surgical closure of the patent ductus arteriosus used to be the only option when medical therapy failed; however, it could lead to severe complications, such as retinopathy of prematurity, bronchopulmonary dysplasia, and neurodevelopmental impairment.[5,6]

Therefore, transcatheter percutaneous closure has been developed as an alternative to surgical patent ductus arteriosus closure.

More recently, with the development of the Amplatzer Duct Occluder II Additional Sizes and Piccolo devices in 2015, it has become possible to perform transcatheter percutaneous closure in children weighing less than 2,000 g.[7] Nevertheless, there are also concerns regarding the procedure's safety, especially in low-birth-weight infants, who may develop left pulmonary artery stenosis and coarctation of the aorta.[8] Therefore, we aimed to perform a meta-analysis on the efficacy and safety of transcatheter percutaneous closure versus surgical ligation of patent ductus arteriosus in low-birth- weight preterm infants (<2,500 g).

Methods

Enrollment and exclusion criteria

The enrollment criteria included the following: (1) randomised or nonrandomised studies; (2) including low-birth-weight preterm infants (<2.5 kg); (3) diagnosed with patent ductus arteriosus; and (4) comparing transcatheter percutaneous closure with surgical ligation of patent ductus arteriosus. We excluded reviews, meta-analyses, editorials, animal studies, and case reports. Studies on other CHDs or systemic or metabolic diseases were also excluded. Abstracts were included. There were no language restrictions. The study protocol was registered in the International Prospective Register of Systematic Reviews (PROSPERO) on 01/17/2023 (PROSPERO ID CRD42023389847).

Endpoints

The outcomes of interest were mortality, haemodynamic instability (haemodynamic instability was defined as a post-ligation cardiac syndrome and the need for inotropic medication), bronchopulmonary dysplasia, major unexpected complications (pneumothorax, chylothorax, infection, and pulmonary artery injury), and associated morbidities (necrotising enterocolitis, retinopathy of prematurity, intraventricular haemorrhage, and periventricular leukomalacia). Haemodynamic instability was defined as a post-ligation cardiac syndrome and the need for inotropic medication.

Literature search

We systematically searched PubMed, the Cochrane Library, and Embase from inception to November 16, 2023. Literature searches were carried out using Medical Subject Headings terms and free-text terms. The search strategy included the keywords "neonates", "preterm", "low weight", "low birth weight", "patent ductus arteriosus", "transcatheter", and "Amplatzer". Reference lists of included articles and previous meta-analyses were searched for other related studies.

Two independent reviewers (BO and JL) examined the electronic searches and obtained full reports of all citations that were likely to meet the predefined selection criteria. Disagreements were resolved by consensus and discussion with a third reviewer (SE). If data provided by the studies were insufficient or did not meet inclusion criteria, the article was excluded.

Data extraction and quality assessment

Two authors (BO and JL) independently extracted the data following predefined search criteria and quality assessment. Information collected from studies included: author study, year of publication, number of patients, sex distribution, gestational age at birth, birth weight, age at intervention, weight at intervention, and ductus arteriosus size.

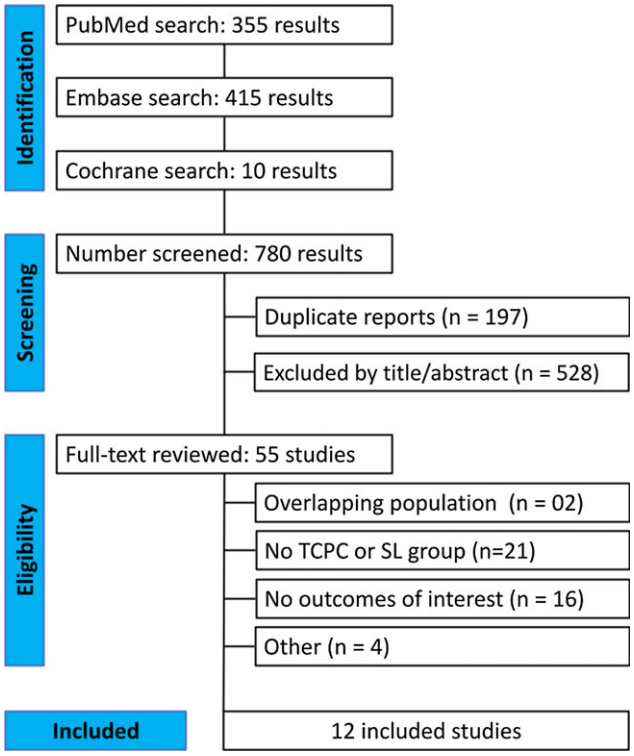

Figure 1. PRISMA flow diagram of study screening and selection.

The risk of bias was assessed with the Cochrane Risk of Bias in Non-Randomized Studies of Interventions tool, following recommendations from the Cochrane Handbook for Systematic Reviews of Interventions. Two independent investigators (CM and MP) performed the risk of bias. Disagreements were resolved with the senior author (SE).[8]

Statistical analysis

The Cochrane Collaboration Review Manager version 5.4 software was used for statistical analyses. We calculated odds ratios for dichotomous data and weighted mean differences with 95% confidence intervals for continuous data. The Cochran Q test formally tested inter-study heterogeneity of treatment effects ($p < 0.10$). The I^2 statistic was examined, and we considered $I^2 \geq 25\%$ to indicate significant heterogeneity between the trials. We adopted a fixed-effects model when $I^2 < 25\%$; otherwise, the origination of the heterogeneity was analysed to verify whether a random-effects model could be used.

Results

Search results

The initial search yielded 780 publications, of which 725 were excluded by review of title and abstract or due to duplicate records. The remaining 55 studies were reviewed in full. Of these, 43 studies were excluded due to overlapping populations, no transcatheter percutaneous closure or surgical ligation group, no outcome of interest, or other exclusion criteria. Ultimately, 12 retrospective cohorts were included (Fig. 1).

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Table 1. Characteristics of the trials included

Study (Year)	Number of patients	Patients TC/SL	Female, n (%) TC/SL	Gestational age at birth in weeks (TC/SL)	Birth weight in grams (TC/SL)	DA size (TC/SL)	Weight at intervention TC/SL in grams	Age at intervention TC/SL in days
Doshi (2022)	3,765	490/ 3,275	NA	<32	NA	NA	NA	NA
Lefort (2022)	154	76/78	NA	26/28 weeks	NA	NA	<2,000 g	NA
Lenoir (2021)	44	22/22	11 (50%)/ 11 (50%)	25.9/25.5 weeks median	754/798 g mean	3.2 mm/ 2.8 mm	1,186/1,157 g mean	NA
McLean (2020)	40	20/20	NA	25/25 weeks median	704/760 g median	NA	1,065/1,105 g median	27/32,5 days median
Ogando (2017)	78	25/53	12 (48%)/ 21 (40%)	26.5/25.8 weeks mean	919/792 g mean	NA	1,330/990 g mean	35/23 days mean
Pamukcu (2017)	57	26/31	10 (38.5%)/ 11 (35.5%)	30/28.6 weeks mean	NA	2 mm/ 2.9 mm	1,455/1,254 g median	27.6/31.3 days mean
Philip (2019)	150	100/50	NA	<27 weeks	<1,000 g	>2.5 mm	1,050/940 g median	33/26 days median
Rauser (2019)	34	13/21	NA	25.3/24.9 weeks mean	NA	2.6 mm/ 2.8 mm	NA	38/21 days mean
Tabb (2023)	112	76/36	35 (46.1%)/ 19 (52.8%)	25.6/24.6 weeks mean	753/684 g mean	NA	1,211/900 g mean	NA
Sathanandam (2018)	120	80/40	40 (50%)/ 21 (52%)	25/25 weeks median	702/690 g median	>2 mm	1,060/920 g median	34/26 days median
Serrano (2019)	83	24/59	NA	25.90/25.21 weeks median	<1,500 g	NA	1,930/1,740 g median	58.5/58.2 days median
Wei (2021)	31	14/17	09 (64%)/ 08 (47%)	28.5/24.7 weeks median	772.5/731 g median	NA	1,278/795 g median	20.5/26 days median

DA = ductus arteriosus; TCPC = transcatheter percutaneous closure; SL = surgical ligation; NA = not applicable.

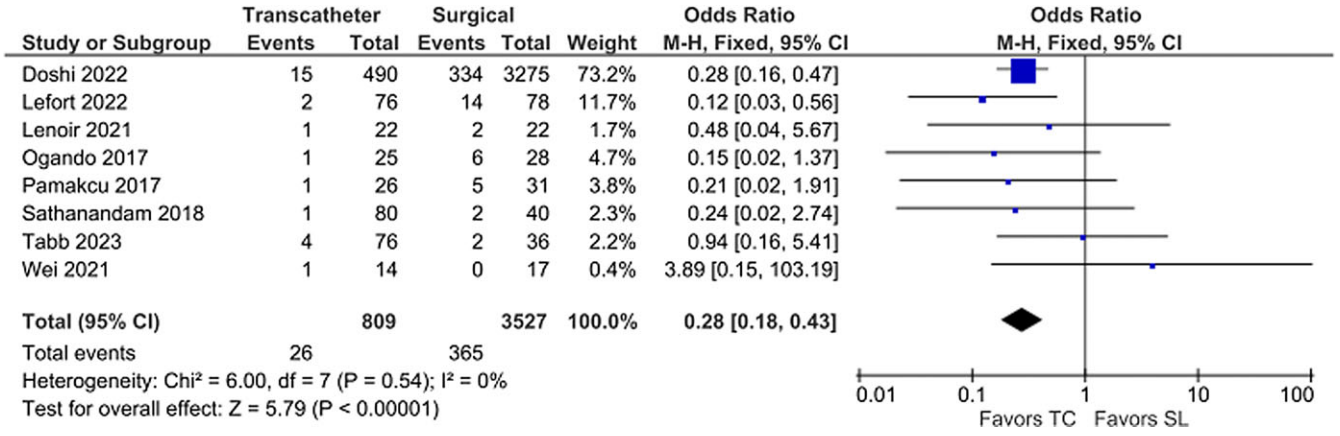

Figure 2. All-cause mortality was significantly reduced in the transcatheter closure group.

Study characteristics

The included studies were published between 2017 and 2023. In total, there were 4,668 preterm infants with low birth weight and patent ductus arterious, of whom 966 (20.7%) were in the transcatheter group and 3,702 (79.3%) patients were included in the surgical group. Table 1 presents the baseline characteristics of the studies analysed in this meta-analysis, including the average gestational age and range of ductus arteriosus size.

Pooled analysis of all studies

All-cause mortality was significantly reduced with transcatheter percutaneous closure compared to surgical ligation (OR 0.28; 95% confidence interval 0.18–0.43; $p < 0.00001$; $I^2 = 0\%$, Fig. 2). Similarly, haemodynamic instability was less frequent in the transcatheter group (OR 0.10; 95% confidence interval 0.05–0.21; $p < 0.001$; $I^2 = 14\%$; Fig. 3).

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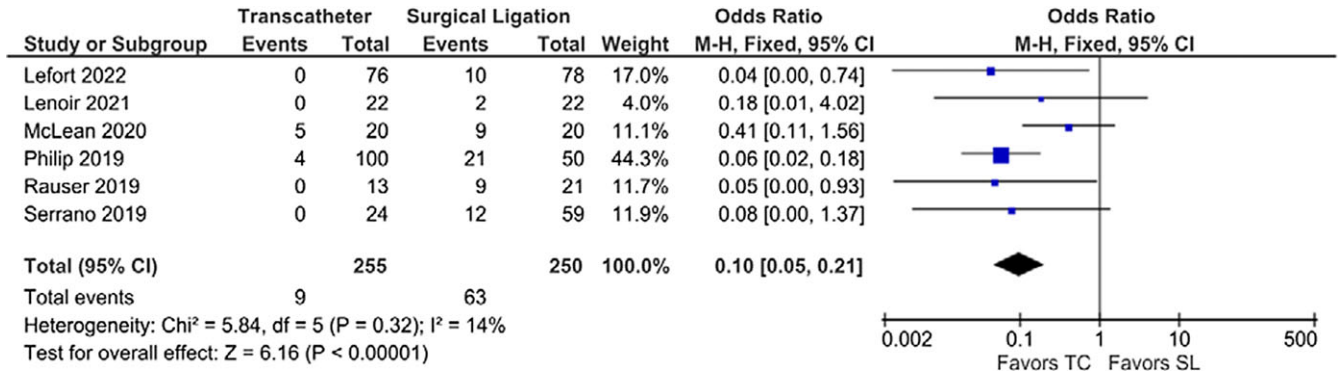

Figure 3. Haemodynamic instability was significantly reduced in the transcatheter closure group.

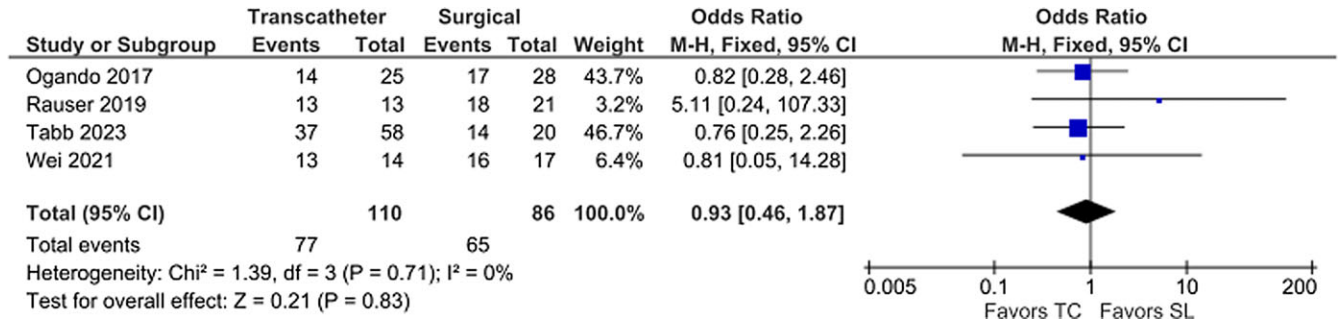

Figure 4. Bronchopulmonary dysplasia was not significantly different between transcatheter closure and surgical ligation.

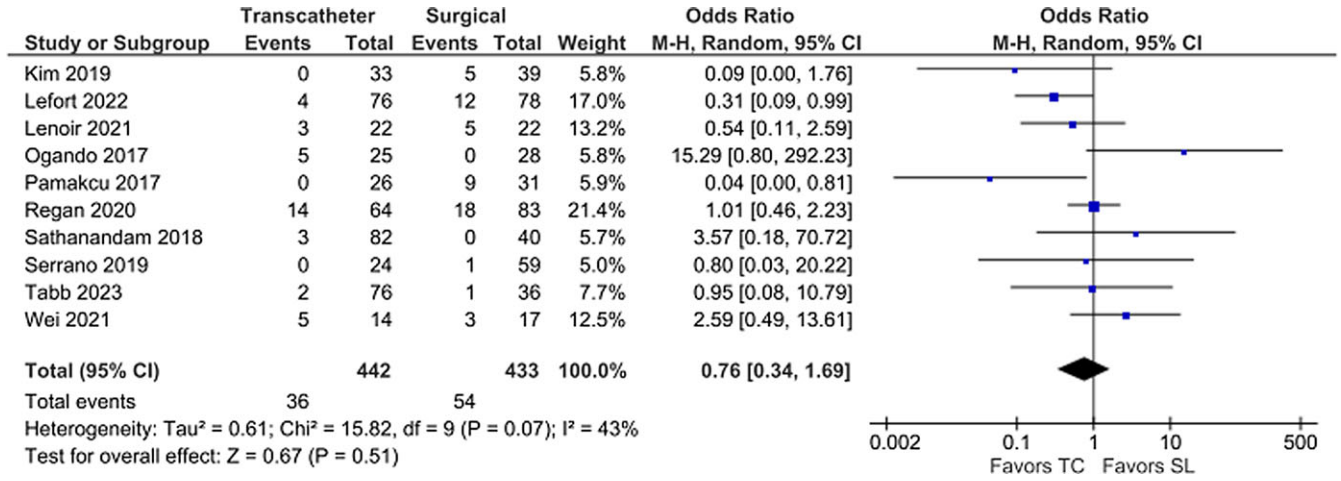

Figure 5. Major unexpected complications were not significantly different between transcatheter closure and surgical ligation.

There was no significant difference between the transcatheter and surgical groups for the outcome of bronchopulmonary dysplasia (OR 0.93; 95% confidence interval 0.46–1.87; $p = 0.83$; $I^2 = 0\%$; Fig. 4) or major complications (OR 0.76, 95% confidence interval 0.34–1.69; $p = 0.51$; $I^2 = 43\%$; Fig. 5). Major procedural complications were defined as pneumothorax, chylothorax, infection, or injury to the pulmonary artery.

Similarly, the incidence of patent ductus arterious-related morbidities was not significantly different between groups. These included intraventricular haemorrhage (OR 0.87, 95% confidence interval 0.43–1.76; $p = 0.69$; $I^2 = 39\%$, Fig. 6), necrotising enterocolitis (OR 0.85, 95% confidence interval 0.43–1.67; $p = 0.63$; $I^2 = 0\%$, Fig. 7), periventricular leukomalacia (OR 0.49, 95% confidence interval 0.31–0.77; $p = 0.002$; $I^2 = 0\%$, Fig. 8), and retinopathy of prematurity (OR 0.70, 95% confidence interval 0.53–0.93; $p = 0.01$; $I^2 = 0\%$, Fig. 9).

Risk of bias assessment

The risk of bias was assessed with the ROBINS-I tool.[9] Seven studies were classified as serious risk of bias, whereas four were deemed at moderate risk of bias. A comprehensive assessment is outlined in Table 2. The increased risk of bias was mostly related to the risk of confounding. Due to the non-randomised nature of the

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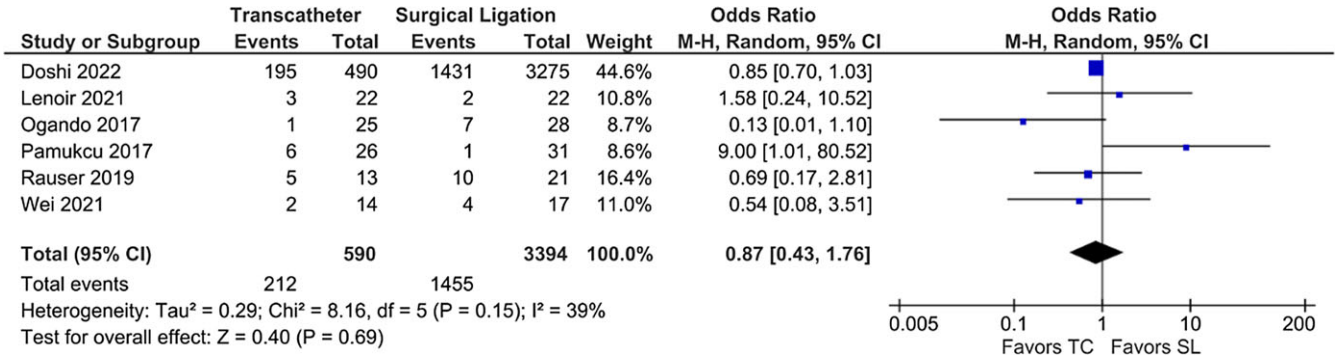

Figure 6. Intraventricular haemorrhage was not significantly different between transcatheter closure and surgical ligation.

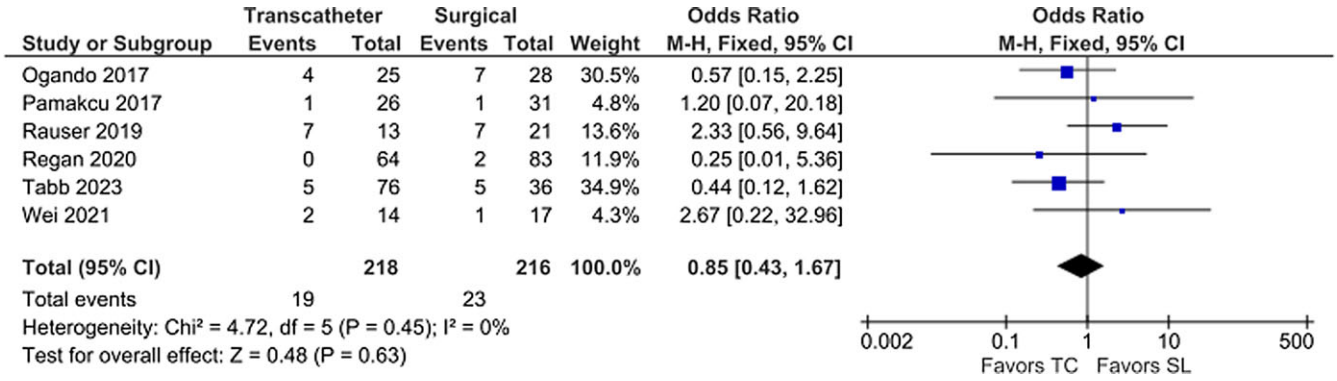

Figure 7. Necrotising enterocolitis was not significantly different between transcatheter closure and surgical ligation.

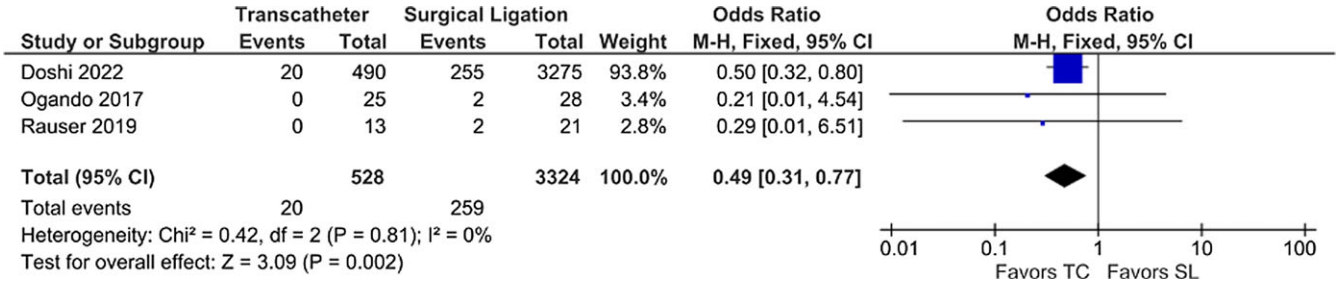

Figure 8. Periventricular leukomalacia was significantly reduced in the transcatheter closure group.

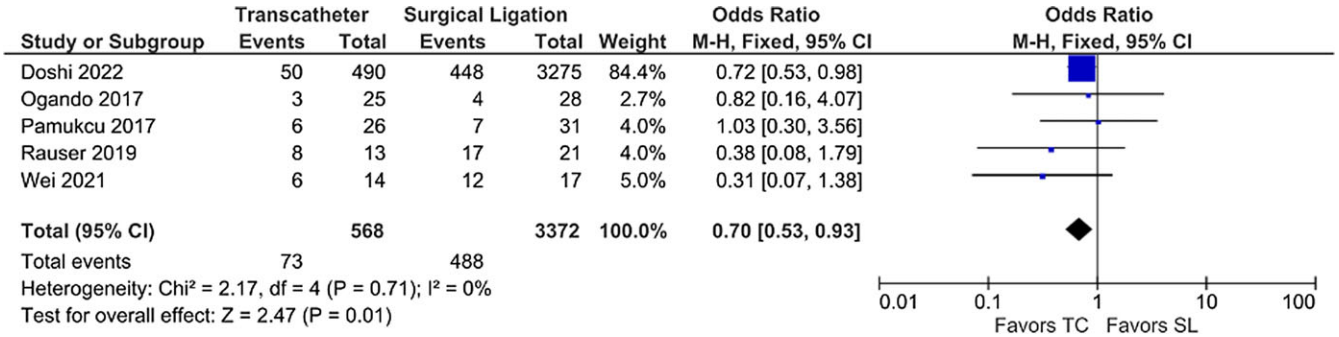

Figure 9. Retinopathy of prematurity was significantly reduced in the transcatheter closure group.

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Table 2. Risk of bias summary for non-randomised studies (ROBINS-I)

Study	Bias due to confounding	Bias in selection of participants	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of the reported result	Overall risk of bias judgement
Tabb Jr 2023	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate
Doshi 2022	Serious	Moderate	Moderate	Low	Low	Low	Low	Serious
Lefort 2022	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate
Lenoir 2021	Serious	Moderate	Moderate	Low	Low	Low	Low	Serious
McLean 2020	Serious	Serious	Moderate	Low	Low	Moderate	Low	Serious
Ogando 2018	Moderate	Moderate	Moderate	Low	Low	Moderate	Low	Moderate
Pamukcu 2017	Serious	Moderate	Moderate	Low	Low	Low	Low	Serious
Phillip 2019	Moderate	Moderate	Moderate	Low	Low	Low	Low	Moderate
Rauser 2019	Serious	Moderate	Moderate	Low	Low	Low	Low	Serious
Sathanandam 2019	Serious	Moderate	Moderate	Serious	Low	Low	Low	Serious
Serrano 2019	Serious	Moderate	Moderate	Low	Low	Low	Low	Serious
Wei 2021	Moderate	Moderate	Low	Low	Low	Low	Low	Moderate

studies, they were subject to confounding factors, particularly related to clinical severity. Six studies reported a tendency of sicker infants to be allocated into the transcatheter closure group, due to a perception of high surgical risk.[10–16]

Discussion

To our knowledge, this is the first meta-analysis comparing percutaneous transcatheter for patent ductus arteriosus closure with surgical ligation. Transcatheter percutaneous closure was associated with reduced all-cause mortality and lower haemodynamic instability. In addition, we discovered that transcatheter percutaneous closure protected against retinopathy of prematurity and periventricular leukomalacia.

There was no significant difference in bronchopulmonary dysplasia, severe complications, and related morbidities such as necrotising enterocolitis and intraventricular haemorrhage between groups. Despite the differences in group size, the more stringent inclusion criteria (preterm birth, weighing less than 2,500 g) allowed both groups to be reasonably homogeneous and comparable (see Table 1).

Different publications define post-ligation syndrome differently based on clinical evaluations, therapies, and echocardiographic findings. For example, the Tennessee group considers post-ligation syndrome clinically significant if four of seven criteria are met during the first 24 hours after the procedure: a) a peak inotrope score of >15, b) a ten mmHg decrease in mean blood pressure from baseline, c) evidence for new-onset pulmonary venous congestion chest X-ray, d) a 30% increase in respiratory severity score, e) a 20% absolute decrease in ejection fraction, f) left ventricular output 200 ml/kg/min, and g) a >20% decrease in tissue Doppler-derived lateral and medial E').[17] To simplify the definition and analysis process, we describe post-ligation syndrome as hypotension requiring inotropic support and failure of oxygenation and ventilation, which may occur 6–12 hours following ligation due to left ventricular systolic and diastolic failure, respectively. This decompensation is primarily driven by increased afterload.[18]

The definition of a haemodynamically unstable patent ductus arteriosus needs to be clarified, and there is no consensus.[19] Currently, most doctors decide to intervene based on clinical evidence and echocardiographic criteria to define a haemodynamically significant ductus arteriosus better.[20] However, there is variation between groups regarding the specific criteria. In this review, most articles consider a ductus arteriosus to be haemodynamically unstable when it is larger than 2 mm, with criteria of haemodynamic instability, such as using vasoactive drugs.

Pulmonary congestion and low systemic circulation, in the context of a patent ductus arteriosus, can lead to compromised perfusion to the bowel, kidney, and brain. This pathophysiology justifies prolonged assisted ventilation, higher mortality rates, bronchopulmonary dysplasia, necrotising enterocolitis, impaired renal function, intraventricular haemorrhage, periventricular leukomalacia, and cerebral palsy.[21]

We found no difference in the outcome of major complications. However, there was less retinopathy and leukomalacia in the

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transcatheter percutaneous closure group. This result is likely due to the need for greater haemodynamic changes associated with surgery. Importantly, with technological advancements, complications of device transcatheter percutaneous closure implantation can now be minimised, particularly in extremely low-birth-weight infants. New implant techniques have been developed to reduce device malposition or protrusion in this population.[22] However, it is important to interpret our findings cautiously as evaluating comorbidities was not our primary objective.

The optimal timing for closing the ductus arteriosus remains a subject of ongoing debate. Acting promptly correlates with a reduced likelihood of associated health complications.[23] Historically, catheterisation for ductal closure was reserved for more severe clinical scenarios, often arising from delayed closure (beyond 15 days). With the FDA's approval of the innovative "Amplatzer Piccolo Occluder" device, extending its use to premature infants weighing >700 g, recent investigations have suggested that early closure may be a viable option, given the risks of comorbidities associated with delayed closure.[24]

Recent studies indicate that early closure is considered safe and may be a preferred option for preterm babies with low birth weight.[25] These contemporary insights propose that initiating treatment before the duct becomes clinically significant may prevent damage to surrounding tissues. Furthermore, this approach may reduce reliance on nonsteroidal anti-inflammatory drugs, minimise associated side effects, and contribute to shorter hospital stays – a proposition consistent with earlier findings highlighted in a Cochrane review.[21]

This study has limitations. We faced challenges evaluating respiratory impairment due to a lack of standardisation.[22,26–30] It was not possible to assess ventilation time as an outcome due to insufficient data. We only used observational studies, which are prone to confounding factors. Multivariable adjusted analyses in the individual studies to correct for severity of clinical presentation were not performed. Of note, confounding by illness severity would most likely favour the surgical group, if present. In other words, if more severe patients are excluded from the surgical group, this would typically lead to worsened outcomes among the sicker population of the transcatheter group. Nevertheless, we observed the opposite result, increasing the confidence in the findings. Finally, although most papers used clinical and echocardiographic parameters to determine which ductus arteriosus was haemodynamically significant, no definitive and uniform diagnostic criteria existed. Similarly, the criteria for respiratory impairment and the definition of post-ligation syndrome varied between different studies. Future research may benefit from the standardisation of outcome definitions.

Conclusion

In conclusion, our findings indicate that transcatheter patent ductus arteriosus closure in low-birth-weight premature infants is associated with lower all-cause mortality and haemodynamic instability than surgical treatment, with no significant difference in safety outcomes. We also found that transcatheter closure protects against retinopathy of prematurity and periventricular leukomalacia compared with surgical treatment.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S1047951123004353.

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Competing interests. None of the authors have any conflict of interest to disclose. All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

Registration. Registered in PROSPERO Database (CRD42023389847).

Conception and design of the research and statistical analysis. Conception and design of the research: SE; acquisition, analysis, and interpretation of the data: MP, SE, CM, GN, BO, ACT, JL; writing manuscript: MP, SE, CM, GN, BO, ACT, JL; critical revision of the manuscript for intellectual content: CM, MP, SE.

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