Impact of Fenestration on Outcomes of the Fontan Procedure: A Systematic Review and Meta-Analysis

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Abstract

Background: The Fontan procedure remains the definitive surgical intervention for single-ventricle congenital heart defects. The effectiveness of fenestration in the Fontan procedure has been debated, with numerous studies reporting inconsistent outcomes. However, its routine implementation remains controversial, with studies presenting conflicting results regarding its clinical efficacy and associated complications. Methods: A systematic review and meta-analysis were conducted in adherence to the PRISMA guidelines. A comprehensive literature search was performed across PubMed, ScienceDirect, and ResearchGate for studies published between 1992 and 2022. Inclusion criteria encompassed clinical trials comparing fenestrated and non-fenestrated Fontan procedures and reporting outcomes such as cardiopulmonary bypass (CPB) time, oxygen saturation, ICU stay, hospital length of stay, pleural effusion, Fontan failure, survival, and mortality. A total of 16 studies involving 6,282 participants were included. Statistical analysis was performed using Review Manager 5.4.1, and pooled effect sizes were presented using odds ratios (OR) or mean differences (MD), with heterogeneity assessed using the I^2 statistic. Results: The meta-analysis revealed a significant reduction in CPB time in the fenestrated group (MD, 12.66; 95% CI, [2.87, 22.46]; p = 0.01; I^2 = 36%). Oxygen saturation was significantly lower postoperatively in fenestrated patients (MD, -3.46; 95% CI, [-5.96, -0.96]; p = 0.007; I^2 = 89%). Prolonged pleural effusion was less frequent in the fenestrated group (OR, 0.47; 95% CI, [0.24, 0.93]; p = 0.03; I^2 = 84%). However, no significant differences were observed in ICU stay, hospital length of stay, Fontan failure, survival rate, or mortality between the groups. Conclusion: While fenestration in the Fontan procedure demonstrates certain hemodynamic benefits, such as reduced pleural effusion and CPB time, it is associated with postoperative desaturation and does not significantly impact critical outcomes like survival or Fontan failure. These findings underscore the importance of individualized patient selection for fenestration to balance its benefits against potential risks. Further research is warranted to refine the criteria for fenestration use in the Fontan procedure.

Keywords: Fontan procedure, fenestration, congenital heart defects, surgical outcomes, meta-analysis

Significance | This study evaluates the benefits and limitations of fenestration in the Fontan procedure, providing critical insights for surgical decision-making.

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Introduction

The Fontan procedure, initially described by Francis Fontan in 1971, represents a landmark surgical approach for addressing the physiological challenges of single-ventricle congenital heart defects. Originally devised as a palliative measure for tricuspid atresia, this technique has evolved significantly over the past five decades, adapting to address a broader range of single-ventricle pathologies (Marcelletti et al., 1988). Despite substantial advances in technique and postoperative care, Fontan patients continue to face

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notable challenges, particularly those with preoperative risk factors such as elevated pulmonary artery pressures, valvular abnormalities, or pulmonary vascular resistance. These patients remain at risk of complications, including increased systemic venous pressure and reduced cardiac output, contributing to elevated postoperative morbidity and mortality rates (Atz et al., 2011).

One significant advancement in the evolution of the Fontan procedure is the introduction of fenestration within the intracardiac lateral tunnel (ILT) technique, which permits controlled right-to-left shunting. This modification facilitates preload augmentation and potentially reduces central venous pressure, improving early recovery outcomes (Bridges et al., 1992). However, the adoption of fenestration is not without its controversies. Although fenestration appears to reduce complications such as prolonged pleural effusion and Fontan circuit failure, concerns about cyanosis, desaturation, and potential long-term effects remain (Fiore et al., 2014). The transition to the extracardiac conduit (ECC) Fontan procedure, described by Marcelletti et al. (1988), introduced further complexities, including difficulties in maintaining fenestration patency, which prompted some surgical centers to favor non-fenestrated approaches with comparable early outcomes.

Despite the theoretical benefits of fenestration, debate persists regarding its routine implementation in all Fontan patients. Proponents argue that fenestration mitigates complications associated with Fontan physiology, including high central venous pressure and low cardiac output, thereby reducing the risk of postoperative complications such as effusion and circuit failure (Lemler et al., 2002). However, detractors highlight the lack of conclusive evidence demonstrating significant long-term survival benefits or reductions in Fontan takedown rates (Salazar et al., 2010). Additionally, fenestration has been associated with drawbacks, including prolonged cardiopulmonary bypass times and the potential for hypoxemia and metabolic imbalances (Fan et al., 2017; Fiore et al., 2014).

Given the ongoing controversy surrounding fenestration, a comprehensive comparison of fenestrated versus non-fenestrated Fontan procedures is essential to inform clinical decision-making. This study conducts a meta-analysis to evaluate these two approaches, focusing on key outcomes such as cardiopulmonary bypass time, postoperative oxygen saturation, pleural effusion, ICU and hospital stays, Fontan failure, survival, and mortality rates. By synthesizing evidence from diverse studies conducted across the globe, this analysis aims to provide clarity on the relative benefits and risks of fenestration, ultimately guiding surgical strategies for optimizing outcomes in Fontan patients.

2. Methodology

2.1 Data Sources and Search Strategies

This study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines to conduct a comprehensive literature search. A single reviewer systematically identified eligible studies using databases such as PubMed, ScienceDirect, and ResearchGate. The search focused on literature published in English between 1992 and 2022. Keywords included "Fenestrated Fontan," "Non-Fenestrated Fontan," "Fontan Procedure," "Single Ventricle," and "Total Cavopulmonary Connection." A PRISMA flow diagram was constructed to visually represent the search process and study selection.

2.2 Inclusion and Exclusion Criteria

Studies were selected based on predefined inclusion and exclusion criteria. Eligible studies met the following conditions:

Participants had undergone a Fontan procedure.

Studies compared outcomes between fenestrated and non-fenestrated Fontan procedures.

Reported outcomes included at least one of the following:

- Cardiopulmonary bypass (CPB) time
- Post-operative oxygen saturation
- Hospital length of stay
- ICU stay duration
- Prolonged effusion
- Fontan failure
- Survival rate
- Mortality

Excluded studies included letters, literature reviews, systematic reviews, and in vivo animal studies, as well as studies focusing solely on a single intervention. All included studies provided participants' baseline characteristics and clinical trial data.

2.3 Data Extraction

One reviewer independently extracted relevant data from the selected studies. Extracted information included the first author, year of publication, patient demographics, intervention details, number of participants, age, gender, and follow-up duration. The Newcastle-Ottawa Scale (NOS) was used to assess the risk of bias in each study.

2.4 Statistical Analysis

Data analysis was performed using Review Manager (version 5.4.1). The random-effects model (Der Simonian-Laird) was employed to calculate pooled effect sizes. Statistical significance was determined using a p-value of <0.05, and heterogeneity was assessed using the I^2 statistic (≥50% indicating significant heterogeneity). Binary data were summarized using odds ratios (OR), while continuous data were analyzed using mean differences. Results were presented in Forest plots. Publication bias was evaluated using Egger's and Begg's tests, with findings summarized in Table 1, Table 3.

3. Results

3.1 Characteristics of Eligible Studies

A total of 581 articles were initially identified across the three databases. After removing duplicates and articles that did not meet the inclusion criteria, 122 articles remained. Following title and abstract screening, 84 articles were excluded. One full-text article could not be retrieved, leaving 37 articles for full-text review. Of these, 21 articles were excluded for not meeting the inclusion criteria. Ultimately, 16 articles were included in the meta-analysis. The PRISMA flowchart (Figure 1) provides a detailed illustration of the study selection process.

The meta-analysis included a total of 6,282 participants, with 3,502 in the fenestrated group and 2,780 in the non-fenestrated group. Studies were geographically distributed as follows: six from the USA, one from Canada, one from Brazil, two from Germany, one from Austria, one from Greece, one from China, two from India, one from South Korea, and one jointly conducted in Australia and New Zealand. Several studies reported whether the Fontan technique was extracardiac or intracardiac, while others did not specify these details (Table 2).

3.2 Meta-Analysis

3.2.1 Cardiopulmonary Bypass (CPB) Time

A significant difference was observed in CPB time between the two groups, with the fenestrated group showing a shorter time (MD, 12.66; 95% CI, [2.87, 22.46]; $p = 0.01$, $I^2 = 36\%$; Figure 2).

3.2.2 Post-Operative Oxygen Saturation

Post-operative oxygen saturation was significantly lower in the fenestrated group compared to the non-fenestrated group (MD, -3.46; 95% CI, [-5.96, -0.96]; $p = 0.007$, $I^2 = 89\%$; Figure 3).

3.2.3Prolonged Pleural Effusion

The fenestrated group had a significantly lower risk of prolonged pleural effusion (OR, 0.47; 95% CI, [0.24, 0.93]; $p = 0.03$, $I^2 = 84\%$; Figure 4).

3.2.4 ICU Stay and Hospital Length of Stay

There was no significant difference in ICU stay between the two groups (MD, -0.51; 95% CI, [-0.51, 0.68]; $p = 0.77$, $I^2 = 45\%$; Figure 5). Although the fenestrated group showed a trend toward shorter hospital stays, this difference was not statistically significant (MD, -1.30; 95% CI, [-3.79, 1.18]; $p = 0.05$, $I^2 = 0\%$; Figure 6).

3.2.5 Fontan Failure and Mortality

No significant difference was found in Fontan failure between the two groups (OR, 0.69; 95% CI, [0.42, 1.13]; $p = 0.14$, $I^2 = 60\%$; Figure 7). Similarly, mortality rates did not differ significantly (OR, 1.13; 95% CI, [0.55, 2.31]; $p = 0.74$, $I^2 = 31\%$; Figure 8).

3.2.6 Survival Rate

The survival rate was comparable between the two groups, with no statistically significant difference observed (OR, 1.04; 95% CI, [0.84, 1.30]; $p = 0.70$, $I^2 = 0\%$; Figure 9).

4. Discussion

Since its introduction by Bridges et al. in 1989, fenestration during the Fontan procedure has gained widespread acceptance, particularly for high-risk patients. Despite its theoretical benefits, the routine implementation of fenestration remains controversial due to varying clinical outcomes. The creation of a right-to-left shunt in fenestrated Fontan was initially designed to augment preload, thereby enhancing stroke volume and cardiac output via the Frank-Starling mechanism (Daley et al., 2022; Fiore et al., 2014). However, these hemodynamic advantages come at the cost of mild cyanosis due to systemic desaturation (Atz et al., 2011).

The findings of this meta-analysis align with the proposed benefits of fenestration, such as reduced central venous pressure and potentially improved hemodynamics. However, these improvements did not translate into significant reductions in early mortality or the need for Fontan takedown (Bouhout et al., 2020). This disconnect may stem from patient selection bias or the intrinsic limitations of fenestration in addressing critical outcomes like survival and Fontan failure.

4.1 Hemodynamic Impacts

One of the significant findings was the reduction in cardiopulmonary bypass (CPB) time in the fenestrated group (Figure 2). While fenestration theoretically extends operation duration, prior studies have reported no significant differences in CPB time between the two approaches (Fiore et al., 2014; Salazar et al., 2010). The shorter CPB time observed in this analysis could reflect variations in surgical protocols or patient-specific factors, such as younger age or higher pulmonary artery pressures in fenestrated cases.

4.2 Postoperative Oxygen Saturation

The fenestrated group exhibited lower postoperative oxygen saturation than the non-fenestrated group (Figure 3). This finding aligns with studies that reported early desaturation following fenestration, particularly when larger fenestrations were used (Atz et al., 2011). Although some studies noted spontaneous closure of fenestrations over time, which increased long-term saturation levels, this was not universally observed (Fiore et al., 2014). Hypoxemia-related acid-base imbalances, pulmonary vasoconstriction, and increased pulmonary vascular resistance are potential contributors to desaturation in fenestrated patients (Fan et al., 2017; Atz et al., 2011).

4.3 Pleural Effusions and ICU Stay

Fenestration was associated with a reduced risk of prolonged pleural effusions (Figure 4), consistent with the expected decrease in systemic venous pressure. However, this benefit did not translate into shorter ICU or hospital stays (Figures 5 and 6). This contrasts with studies by Lemler et al. (2002), which reported shorter ICU

Table 1. Newcastle-Ottawa Scale for Risk of Bias of Included Non-RCTs

No.	Study (Author, year)	Selection					Outcomes			Total		
		Representativeness of Exposed Cohort a) Truly representative **(one star)** b) Somewhat representative **(one star)** c) Selected group d) No description of the derivation of the cohort	**Selection of Non-Exposed Cohort** a) Drawn from the same community as the exposed cohort **(one star)** b) Drawn from a different source c) No description of the derivation of the non-exposed cohort	**Ascertainment of Exposure** a) Secure record (e.g., surgical record) **(one star)** b) Structured interview **(one star)** c) Written self-report d) No description e) Other	**Outcome not Present at the Start of the Study** a) Yes **(one star)** b) No	**Comparability** a) The study controls for age, sex and marital status **(one star)** b) Study controls for other factors (list) **(one star)** c) Cohorts are not comparable on the basis of the design or analysis controlled for confounders	**Assessment of Outcomes** a) Independent blind assessment **(one star)** b) Record linkage **(one star)** c) Self report d) No description e) Other	**Length of Follow-up** a) Yes **(one star)** b) No	**Adequacy of Follow-up** a) Complete follow up- all subject accounted for **(one star)** b) Subjects lost to follow up unlikely to introduce bias-number lost less than or equal to 20% or description of those lost suggested no different from those followed. **(one star)** c) Follow up rate less than 80% and no description of those lost d) No statement	**Selection**	**Comparability**	**Outcomes**
1	Airan, 2000	1	1	1	1	1	1	1	1	4	1	3
2	Atik, 2002	1	1	1	1	1	1	1	1	4	1	3
3	Atz, 2011	1	1	1	1	1	1	1	1	4	1	3
4	Bridges, 1992	1	1	1	1	1	1	1	1	4	1	3
5	Daley, 2022	1	1	1	1	1	1	1	1	4	1	3
6	Fan, 2017	1	1	1	1	1	1	0	1	4	1	2
7	Fiore, 2014	1	1	1	1	1	1	1	1	4	1	3
8	Fu, 2019	1	1	1	1	1	1	0	1	4	1	2
9	Heal, 2017	1	1	1	1	1	1	1	1	4	1	3
10	Kim, 2008	1	1	1	1	1	1	1	1	4	1	3
11	Knez, 1999	1	1	1	1	1	1	1	1	4	1	3
12	Lemler, 2002	1	1	1	1	1	1	0	1	4	1	2
13	Ono, 2006	1	1	1	1	1	1	1	1	4	1	3
14	Talwar, 2020	1	1	1	1	1	1	1	1	4	1	3
15	Salazar, 2010	1	1	1	1	1	1	1	1	4	1	3
16	Sfyridis, 2010	1	1	1	1	1	1	1	1	4	1	3
17	Steward, 2012	1	1	1	1	1	1	0	1	4	1	2

Table 2. Baseline Characteristics of Included Studies

Author, Study	Study Design	Study Period	Research Center	Sample		Total	Fontan Type
				Fenestrated	Non-Fenestrated		
Airan, 2000[3]	Cohort Retrospective	January 1988 to December 1997	Cardiothoracic Sciences Center, All India Institute of Medical Science, India	126	222	348	NR
Atik, 2002[4]	Cohort Retrospective	August 23, 1988 and December 1, 1999	Instituto do Coração, Brazil	41	21	62	Fenestrated LT=30; EC=11 Non-Fenestrated LT=17; EC=4
Atz, 2011[1]	Cross Sectional Study	NR	National Institutes of Health/National Heart, Lung, and Blood Institute–funded PHN Fontan Cross-Sectional Study, USA and Canada	361	175	536	NR
Bridges, 1992[5]	Cohort Retrospective	October 1987-June 1991	USA	91	56	147	NR
Daley, 2022[6]	Cohort Retrospective	June 1975 – January 2020	Australia and New Zealand	621	822	1443	Fenestrated LT=151; EC=470 Non-Fenestrated LT=137; EC=685
Fan, 2017[7]	Cohort Retrospective	January 2004 to June 2013	Fu Wai Hospital, China	49	44	93	NR
Fiore, 2014[8]	Cohort Retrospective	1995-2010	James Whitcomb Riley Children's Hospital at Indiana University, Indianapolis, Indiana, and Cardinal Glennon Children's Hospital at St. Louis University, St. Louis, Missouri, USA	61	54	115	NR
Song, 2019[9]	Cohort Retrospective	1996 to July 2007	Department of Children Heart Center, Justus Liebig—University Giessen Germany	71	24	95	NR
Kim, 2008[10]	Cohort Retrospective	1996 and August 2006	Sejong General Hospital, South Korea	85	115	200	NR
Knez, 1999[11]	Cohort Retrospective	March 1989 to September 1997	Austria	21	26	47	NR
Lemler, 2002[12]	Cohort Retrospective	May 1997 through September 2000	Children's Medical Center of Dallas, USA	25	24	54	NR
Ono, 2006[13]	Cohort Retrospective	1984 and 2004	Germany	21	50	71	NR
Salazar, 2010[14]	Cohort Retrospective	January 1, 2002, and December 31 2008	Texas Children's Hospital, USA	95	131	226	EC=157; LT=69

Table 2. Continuous

Sfyridis, 2010[15]	Cohort Retrospective	1997 and 2009	Onassis Cardiac Center and Mitera Children's Hospital, Greece	26	32	58	Fenestrated LT=4; EC=22 Non Fenestrated LT=4; EC=54
Stewart, 2012[16]	Cohort Retrospective	2010-2009	The Society of Thoracic Surgeons Congenital Heart Surgery Database (STSCHSD), USA	1788	959	2747	NR
Talwar, 2020[17]	Randomized Control Trial	September 2018 and December 2019	India Institute of Medical Sciences, New Delhi, India	20	20	40	NR

EC: extracardiac; LT: lateral tunnel

Table 3. Publication Bias Assessment for Outcomes of Included Study

Parameters	**Egger's Test**	**Begg's Test**
Cardiopulmonary Bypass Time	0.4191	1.0000
Post-Operative Oxygen Saturation	0.0422	1.0000
Prolonged Pleural Effusion	0.8204	0.7105
ICU Stay	0.2673	0.8065
Hospital Stay	0.5129	0.2105
Fontan Failure	0.1412	0.3082
Mortality	0.3766	0.4524
Survival Rate	0.4633	0.7341

stays with fenestration, and Salazar et al. (2010), which found shorter durations in non-fenestrated cases. The lack of significant differences in hospitalization length may reflect the higher prevalence of preoperative risk factors in the fenestrated group, such as pulmonary artery distortion and elevated pulmonary resistance (Atik et al., 2002; Kim et al., 2008).

4.4 Fontan Failure, Mortality, and Survival

No significant differences were observed in Fontan failure, mortality, or survival rates between the two groups (Figures 7–9). This finding suggests that fenestration may not have a definitive impact on these critical outcomes, particularly in the context of modern surgical techniques and patient management. Notably, the fenestrated group included patients with higher preoperative risk profiles, such as younger age, elevated pulmonary pressures, and anatomical distortions. These factors may amplify the influence of fenestration on outcomes (Marcelletti et al., 1999; Bridges et al., 1992).

4.5 Complications and Clinical Implications

While fenestration provides theoretical hemodynamic benefits, it also introduces risks, including persistent desaturation and potential complications from shunt size. Hypoxemia-related vasoconstriction and low cardiac output syndrome remain significant concerns, contributing to morbidity after the Fontan procedure (Song et al., 2009; Thompson et al., 1999). Additionally, subclinical infections may disrupt the Fontan circuit's delicate balance, exacerbating complications like prolonged pleural effusions (Talwar et al., 2020).

The decision to fenestrate should consider patient-specific factors, including age, pulmonary resistance, and anatomical distortions. For high-risk patients, fenestration may provide a safety net by reducing central venous pressure and improving early postoperative outcomes. However, in lower-risk patients, the risks of fenestration, such as prolonged desaturation and potential complications, may outweigh its benefits.

4.6 Study Limitations and Future Directions

This meta-analysis highlights several limitations in the existing literature. Variability in study design, surgical techniques, and reporting standards complicates direct comparisons between fenestrated and non-fenestrated groups. Additionally, the long-term effects of fenestration remain poorly understood, particularly regarding spontaneous closure and its impact on hemodynamics and oxygenation. Future studies should focus on standardized reporting and long-term follow-up to elucidate fenestration's role in improving patient outcomes (Ono et al., 2006; Stewart et al., 2012).

5. Conclusion

The findings of this meta-analysis underscore the nuanced role of fenestration in the Fontan procedure. While fenestration offers hemodynamic benefits, such as reduced central venous pressure and shorter CPB times, these advantages do not consistently translate into improved survival or reduced complications. The decision to fenestrate should be individualized, balancing the theoretical benefits against potential risks and considering patient-specific factors. Further research is needed to refine patient selection criteria and optimize surgical techniques to maximize the benefits of fenestration while minimizing its drawbacks.

Author contributions

P.A.A. conceptualized the study, designed the methodology, and supervised the research process. A.R.H. conducted data collection and analysis, prepared visualizations, and contributed to manuscript drafting. Both authors reviewed and approved the final version of the manuscript.

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Competing financial interests

The authors have no conflict of interest.

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