

Blalock-Taussig Shunt versus Ductal Stent in the Palliation of Duct Dependent Pulmonary Circulation; A Systematic Review and Metanalysis

Antoine Fakhry AbdelMassih, MD^a,
Rahma Menshawey, MD^b, Esraa Menshawey^b,
Ahmed Emad El-Maghraby, MD^b,
Ahmed O. Sabry, MD^b, Aya Kamel^b,
Mahmoud Yassin Seyam^b, Passant Elshawarbi^b,
Sama Nagmeldin Ahmed, MD^b, Seif S. Salem^b,
Shahd Ragab^b, Youssef Nada^b, and Hala Agha, MD^a

From the ^a Pediatric Cardiology unit, Pediatrics' Department, Faculty of Medicine, Cairo University, Egypt and ^b Research Accessibility Team, Student and Internship research program Faculty of Medicine, Cairo University, Egypt.

Abstract: In infants with ductal dependent pulmonary blood flow, Blalock-Taussig (BT) shunt and Patent Ductus Arteriosus (PDA) stent, are two palliative procedures aimed to restore circulation. A systematic review and metanalysis was performed on studies comparing PDA stents and BT shunts, in accordance with PRISMA guidelines. Meta-analysis revealed the following; (1) a reduced risk of mortality [RR = 0.585 [0.399-0.859], ($P = 0.006$)], (2) a reduced risk of complications [RR = 0.523 [0.318-0.860], ($P = 0.011$)], and (3) a reduced risk of ECMO use [R = 0.267 [0.101-0.706] ($P = 0.008$)], all in the stent group. Additionally, stent group showed higher post procedure oxygen saturation [SMD = 1.307 [95% CI 1.065-1.550], ($P < 0.001$)],

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and Nakata index [SMD = 0.679 95% CI [0.513 to 0.845], ($P < 0.001$)]. PDA stenting presents a viable alternative to BT shunt procedure with better post procedure stability. (Curr Probl Cardiol 2021;00:100885.)

Introduction

Ductal dependent circulation is a life threatening emergency in neonates. Survival of these patients depends on a Patent Ductus Arteriosus (PDA), which serves to maintain circulation for some time until staged surgical repair can take place.¹ Classically, palliation is achieved by a Blalock-Taussig shunt procedure; a systemic to pulmonary artery shunt which aims to increase pulmonary blood flow, promoting growth of the pulmonary arteries and lungs until the time of corrective repair.² However, mortality rates, found to be 15% in single ventricle and 3% to 5% in double ventricle patients,³ as well as post procedural complications such as shunt blocking as a result of clotting or kinking,^{4,5} have indicated the need for an alternative procedure.

Ductal stenting appears to be an attractive alternative to shunt procedures, though not as widely accepted for those with ductal dependent circulation. DS avoids procedural related risks involved with shunt procedures such as thoracotomy, as well as avoidance of cardiopulmonary bypass. DS is also used as rescue for late BT shunt occlusion. However, some concerns arise over the variability of the morphological features of the ductus, which can render stent implantation impossible. As well, there are concerns for serious and fatal complications such as acute stent thrombosis.⁶ Between the two techniques, rigorous and proper case selection is needed to choose the optimum procedure that best meets the needs of palliation for each patient.

Nonetheless, the BT shunt procedure still remains the procedure due of choice due to factors such as, low incidence of pulmonary overperfusion, high patency rate, and higher systemic oxygenation.⁷ BT shunting is also the preferred choice for patients with more complex intracardiac anatomy, as well as those who will proceed to a single ventricle pathway.⁸

A systematic review and meta-analysis is needed to compare DS and BT shunt procedures. The aim of this review is to determine the risks of certain outcomes between ductal stenting and BT shunt procedures in neonates with ductal dependent pulmonary circulation when used as first palliation until the time of definitive corrective surgery. These outcomes

include mortality, interventions, complications, ECMO use post op, Nakata index, and post procedure oxygen saturation.

Methods

Study Registration

The protocol of this study has been registered in PROSPERO (CRD42020178837).

This review was prepared in accordance to Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA).

Search Strategies

A comprehensive search of the literatures was performed on July 2020, for two armed studies comparing DS and BT shunt procedures as palliation for patients with duct dependent pulmonary circulation in the following databases; PubMed/MEDLINE, Web of Science, Scopus, and Google Scholar. Reference lists of included studies were searched by hand for any additional studies. English only studies were considered.

Inclusion criteria for study selection

Study Selection. Full length articles comparing ductal stent and BT shunt procedures were included. No grey literature was included in the form of abstracts or conference papers. We included retrospective and prospective studies examining the two interventions. Studies must be reporting on the use of these interventions as first palliation for neonate patients with ductal dependent circulation. Studies must have clearly defined distinctions between the outcomes to be included in metanalysis, especially those pertaining to BT shunt procedures. Studies comparing ductal stent procedure to shunt procedures in general, ie grouped BT shunt results with other shunt results such as central shunt or Sano shunt, were not included. Multicenter and single center data is included.

Types of participants. Neonates with ductal dependent pulmonary circulation where ductal stenting or BT shunt is performed as first palliation, until the time of definitive corrective surgery.

Types of interventions and comparator. The two interventions to be compared are stenting of the patent ductus Arteriosus and BT shunt.

Types of outcome measures. Primary outcomes included mortality (all cause), complications (counted until the time of corrective surgery), interventions (acute and or related to cyanosis). Secondary outcomes included Nakata index and post procedure oxygen saturation, and use of ECMO post op.

Two authors (R.M & E.M) independently screened titles and abstracts for inclusion and exclusion criteria. Any disagreements were resolved by discussion, or the opinion of a third author (A.F.A).

Data Extraction and Quality Assessment

Quality of the studies was assessed using a modified version of the New-Castle Ottawa Scale. Studies with a NOS score ≥ 6 were deemed high quality. Quality of the evidence was assessed using ROBINS-I tool which is a risk of bias assessment tool designed for non-randomized studies for interventions. Any disagreements were resolved through discussion, or the opinion of a third judge (A.F.A).

Meta-analysis

Data from the studies that reported on any of the following outcomes was included in meta-analysis; mortality, complications, re-intervention, ECMO use post-op, post procedure oxygen saturation, and Nakata index. Meta-analysis was performed for outcomes reported by at least two studies, irrespective of sample size of each patient group.

Data was determined to be either continuous or dichotomous. Relative risk was used for the statistical analysis of dichotomous data. Standardized Mean Difference was used for the statistical analysis of continuous data. All of the studies were weighted, which reflects the value of evidence of each particular study.⁹ Additionally, some outcomes (Nakata index, and post procedure oxygen saturation) were reported using mean and standard deviation, or as median and interquartile range. Values that were provided as median and IQR were converted to mean and standard deviation using the method described by Hozo et al.¹⁰ Data was pooled using a random effects model for dichotomous variables, and fixed effects model for continuous variables. Effect estimates were reported with 95% Confidence Intervals. Results were presented as forest plots. Cochran's Q was used to detect heterogeneity. I^2 was used to determine the percentage variation due to true heterogeneity.

All statistical analysis was performed using MedCalc for Windows, version 19.1 (MedCalc Software, Ostend, Belgium).

Results

Initial search of databases using select key words revealed a total of 818 studies. After duplication and screening based on title and abstract and language, 29 full text articles remained to be assessed for eligibility (see Fig 1). At the end, 6 studies met our inclusion and exclusion criteria and were part of the qualitative and quantitative data synthesis. 5 studies assessed BT shunt versus DS procedures retrospectively, 1 was performed prospectively (see Table 1).

Quality Assessment

A modified version of NOS was used to determine the quality of the studies. For our purposes, a max score of 8 was possible and we considered a score of more than or equal to 6 to be a high quality study. All of the studies included in this review were high quality.

ROBINS-1 tool was used to assess the quality of the evidence of each study. ROBINS -1 is a tool used to determine the risk of bias in non-randomized studies of interventions. 83% (5/6) of studies were considered to have moderate bias (see Fig 2). One study had serious bias.

This study by Nasser et al¹¹ assessed patients prospectively which gave room for reporting bias, where they mentioned DS was the preferred procedure in their institution, as well as some serious risk of bias due to deviation of from intended intervention. In this particular study, some patients initially designated for stent procedure failed and were moved to the shunt group instead. Nonetheless, risk of bias assessment for all other studies was moderate except for the Nasser study which was serious.

Sensitivity analysis was performed to see if inclusion or exclusion of this particular study would affect results of any of our outcomes of interest. Analysis revealed that inclusion did not make a significant difference in any of the results, and so Nasser et al results were included in metanalysis.

Outcomes

1) Outcomes for Dichotomous Variables

Mortality – Analysis revealed that between DS and BT shunt procedures, the relative risk for the outcome of mortality was $RR = 0.578$ [0.391 to 0.854] ($P = 0.006$). This finding was significant. In other words,

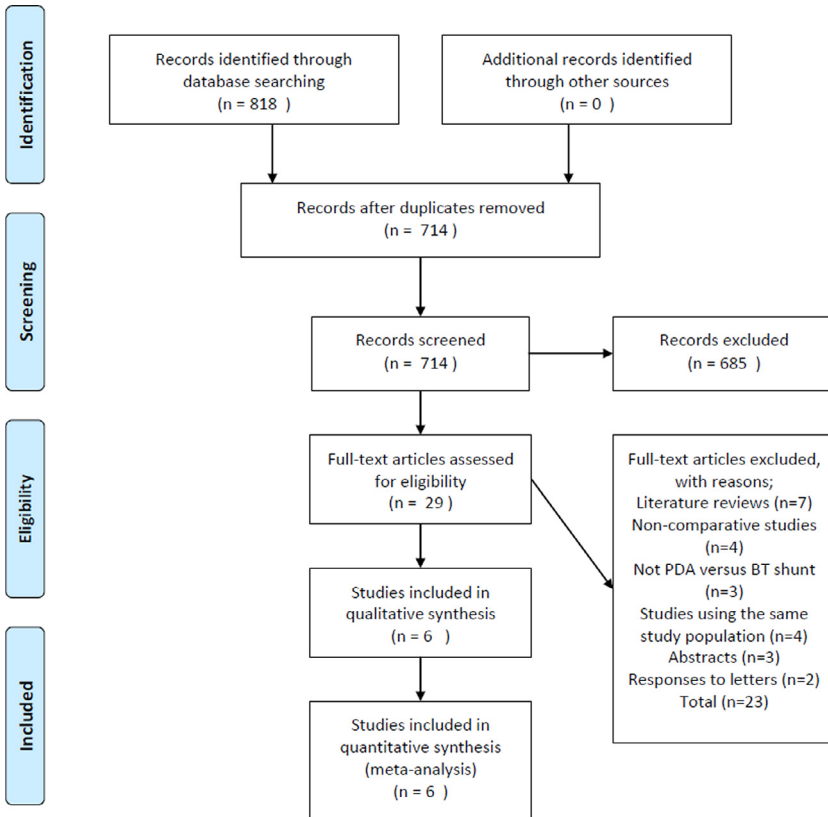


FIG 1. PRISMA flow diagram for systematic review and meta-analysis.

patients in ductal stent groups had a 42.2% lower risk of mortality compared to BT shunt group patients. These findings suggest that patients who had undergone ductal stenting were less likely to experience mortality (see [Table 2](#)).

Complications – Analysis revealed that between DS and BT shunt groups, the relative risk for the outcome of complications was $RR = 0.565$ [0.338 to 0.945] ($P = 0.030$). This finding was significant. In other words, patients in ductal stent groups had a 43.5% lower risk of complications compared to BT shunt group patients. These findings suggest that patients who have undergone ductal stenting were less likely to experience complications (see [Table 3](#)).

Re-interventions – Analysis revealed that between DS and BT shunt procedures, the relative risk for the outcome of needing re-intervention was $RR = 0.960$ [0.446 to 2.066] ($P = 0.917$). This would imply that patients who had undergone ductal stenting were at a 4% lower risk for

TABLE 1. Summary of studies comparing outcomes in BT shunt and Ductal Stent procedures.

Author	Type of Study	Year	Country	PDA Stent patients	BT shunt patients	Mortality	Complications	Re-intervention	ECMO	Nakata Index	Post-procedure O2 Sat	NOS Score
Glatz et al	Retrospective	2017	USA	106	251	7 vs 26	14 vs 54	12 vs 52	2 vs 14	158(115-214) vs 131(81-200)		8
Amoozgar et al	Retrospective	2012	IRAN	15	15	3 vs 5	0 vs 3			177.7±12.5 vs 183.8±12.5		6
Nasser et al	Prospective	2019	Saudia Arabia	33	10	4 vs 0	1 vs 1	1 vs 0		162±26 vs 194.7±48	84.9±1.7% vs 83±1.9%	6
Bentham et al	Retrospective	2018	United Kingdom	83	171	15 vs 61		33 vs 41	2 vs 83	210.2(165.7-313.3) vs 208.9(139.2-302)	87%(82-91) vs 85%(80-88)	8
McMullan et al	Retrospective	2013	USA	13	42	1 vs 1	0 vs 3	3 vs 11			87%(68-95) vs 83%(72-97)	6
Santoro et al	Retrospective	2009	Italy	45	87	0 vs 3					87±5% vs 86±3%	6

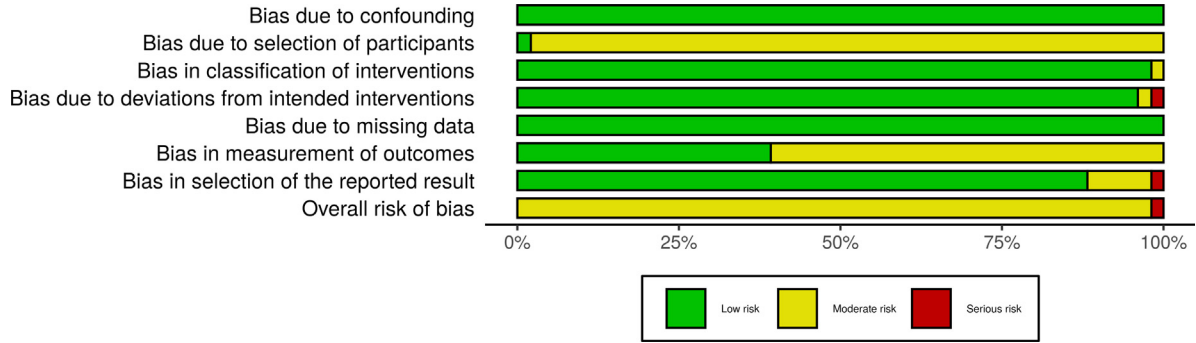


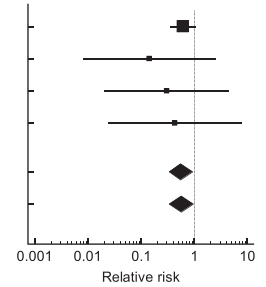
FIG 2. PRISMA flow diagram for systematic review and meta-analysis.

TABLE 2. Forest plot for relative risk of mortality in Stent vs. Shunt.

	Stent	Shunt	Relative risk	95% CI	z	P	Weight (%)			
							Fixed	Random		
Glatz 2018	7/106	26/251	0.638	0.286 to 1.423			23.59	23.59		
Amoozgar 2010	3/15	5/15	0.600	0.174 to 2.073			9.90	9.90		
Nasser 2019	4/33	0/10	2.912	0.170 to 49.917			1.88	1.88		
Bentham 2017	15/83	61/171	0.507	0.307 to 0.836			60.78	60.78		
McMullan 2014	1/13	1/42	3.231	0.217 to 48.128			2.09	2.09		
Santoro 2009	0/45	3/87	0.273	0.0144 to 5.178			1.76	1.76		
Total (fixed effects)	30/295	96/576	0.585	0.398 to 0.860	-2.725	0.006	100.00	100.00		
Total (random effects)	30/295	96/576	0.578	0.391 to 0.854	-2.755	0.006	100.00	100.00		
Test for heterogeneity										
Q	3.3837									
DF	5									
Significance level	P = 0.6411									
I ² (inconsistency)	0.00%									
95% CI for I ²	0.00 to 63.58									

TABLE 3. Forest plot for relative risk of complications in Stent vs. Shunt.

Study	Stent	Shunt	Relative risk	95% CI	z	P	Weight (%)	
							Fixed	Random
Glatz 2018	14/106	54/251	0.614	0.357 to 1.056			89.99	89.99
Amoozgar 2012	0/15	3/15	0.143	0.00801 to 2.548			3.19	3.19
Nasser 2019	1/33	1/10	0.303	0.0208 to 4.420			3.68	3.68
McMullan 2014	0/13	3/42	0.439	0.0241 to 7.984			3.14	3.14
Total (fixed effects)	15/167	61/318	0.551	0.331 to 0.918	-2.288	0.022	100.00	100.00
Total (random effects)	15/167	61/318	0.565	0.338 to 0.945	-2.176	0.030	100.00	100.00



Test for heterogeneity

Q	1.2104
DF	3
Significance level	P = 0.7505
I ² (inconsistency)	0.00%
95% CI for I ²	0.00 to 68.00

needing re-intervention. However, this finding was not significant (see [Table 4](#)).

ECMO – Analysis revealed that between DS and BT shunt procedure, the relative risk for the outcome of needing ECMO use post-op was $RR = 0.256$ [0.0921 to 0.711] ($P = 0.009$). In other words, patients who had ductal stenting had a 74.4% lower risk of requiring ECMO post procedure. Ductal stent patients were less likely to require ECMO (see [Table 5](#)).

1) Outcomes of Continuous Variables

Nakata Index – Analysis revealed that between DS and BT shunt procedure, neonates that underwent ductal stenting had higher Nakata index scores than those who underwent BT shunt procedure [SMD = 0.679 95% CI [0.513 to 0.845], ($P < 0.001$)]. This is a medium effect. (see [Table 6](#))

Post procedure oxygen saturation – Analysis revealed that between DS and BT shunt procedures, neonates that underwent ductal stenting had higher post procedure oxygen saturation [SMD = 1.307 [95% CI 1.065-1.550], ($P < 0.001$)]. This is a large effect. (see [Table 7](#))

Discussion

The aim of palliative techniques, in the setting of ductal dependent pulmonary circulation in neonates, is to alleviate cyanosis by increasing pulmonary blood flow. This is conventionally achieved by a BT shunt, which is the first line option for critical neonates not able to undergo initial corrective surgery.¹² The procedure meets the purposes of increasing blood flow to the lungs, as well as maintaining preload and afterload.¹³⁻¹⁵ However, there are reports of outcomes that suggest high morbidity and mortality among neonates. In our metanalysis, patients who had undergone BT shunt were at significant higher risk of mortality, complications, and the need for ECMO post op. While neonates that had undergone ductal stenting as an alternative, were less likely to experience these outcomes.

Criteria of an ideal shunt include; that it is technically simple to perform, provide long term patency, provide adequate pulmonary blood flow but to so much that it increases the risk of pulmonary hypertension or congestive heart failure. In place of the classic BT shunt technique, a modified BT shunt procedure is performed which utilizes a graft inter positioned between the subclavian and pulmonary artery; the subclavian artery is not sacrificed.² However, in neonates there are known morbidity

TABLE 4. Forest plot for relative risk of reintervention in Stent vs. Shunt.

Study	Stent Event/Total	Shunt Event/Total	RR [95% CI]	Weight (fixed)	Weight (random)
Glatz 2018	12/106	52/251	0.546 [0.304 to 0.981]	26.79	33.97
Nasser 2019	1/33	0/10	0.971 [0.0425 to 22.149]	0.94	5.26
Bentham 2017	33/83	41/171	1.658 [1.139 to 2.415]	64.89	38.44
McMullan 2014	3/13	11/42	0.881 [0.289 to 2.687]	7.38	22.34
Total Fixed	49/235	104/474	1.047 [0.776 to 1.413]	100.00	100.00
Total Random	49/235	104/474	0.960 [0.446 to 2.066]	100.00	100.00

Total fixed ($z=0.300$) ($P=0.764$)

Total random ($z=0.104$) ($P=0.917$)

Heterogeneity [$Q= 10.5833$, $DF= 3$, Significance Level $P = 0.0142$, $I^2= 71.65\%$, 95% CI for $I^2= [19.41$ to $90.03]$]

TABLE 5. Forest Plot for relative risk of ECMO in Stent vs. Shunt.

Study	Stent	Shunt	Relative risk	95% CI	z	P	Weight (%)	
							Fixed	Random
Glatz 2018	2/106	14/251	0.338	0.0782 to 1.463			48.70	48.70
Bentham 2017	2/83	21/171	0.196	0.0471 to 0.817			51.30	51.30
Total (fixed effects)	4/189	35/422	0.250	0.0904 to 0.690	-2.675	0.007	100.00	100.00
Total (random effects)	4/189	35/422	0.256	0.0921 to 0.711	-2.615	0.009	100.00	100.00

Test for heterogeneity	
Q	0.2748
DF	1
Significance level	$P = 0.6001$
I^2 (inconsistency)	0.00%
95% CI for I^2	0.00 to 0.00

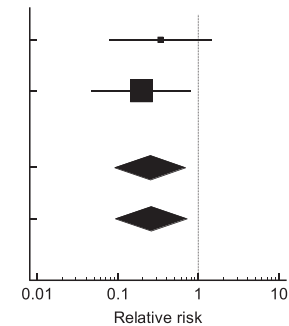


TABLE 6. Forest Plot for difference of Nakata index in patients with stent vs. shunt.

Study	SMD	SE	95% CI	t	P	Weight (%)	
						Fixed	Random
Bentham	0.388	0.134	0.123 to 0.653			39.40	21.82
Santoro	-0.00669	0.373	-0.776 to 0.762			5.11	18.67
Nasser	-0.977	0.370	-1.724 to -0.231			5.21	18.73
Amoozgar	-0.475	0.361	-1.213 to 0.264			5.48	18.88
Glatz	1.347	0.126	1.099 to 1.596			44.80	21.89
Total (fixed effects)	0.679	0.0844	0.513 to 0.845	8.046	<0.001	100.00	100.00
Total (random effects)	0.106	0.396	-0.672 to 0.883	0.267	0.790	100.00	100.00

Test for heterogeneity	
Q	66.4663
DF	4
Significance level	$P < 0.0001$
I ² (inconsistency)	93.98%
95% CI for I ²	88.81 to 96.76

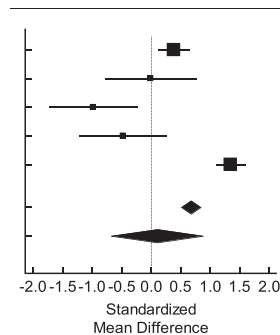
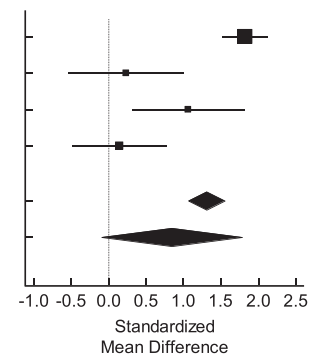


TABLE 7. Forest Plot for difference in Post procedure Oxygen Saturation in stent vs shunt.

Study	SMD	SE	95% CI	t	P	Weight (%)	
						Fixed	Random
Bentham	1.822	0.156	1.515 to 2.129			62.65	27.18
Santoro	0.237	0.375	-0.535 to 1.009			10.84	23.89
Nasser	1.068	0.373	0.316 to 1.821			10.98	23.93
McMullan	0.149	0.313	-0.480 to 0.777			15.53	25.00
Total (fixed effects)	1.307	0.123	1.065 to 1.550	10.591	<0.001	100.00	100.00
Total (random effects)	0.845	0.479	-0.0974 to 1.787	1.763	0.079	100.00	100.00

Test for heterogeneity	
Q	33.1216
DF	3
Significance level	$P < 0.0001$
I^2 (inconsistency)	90.94%
95% CI for I^2	79.89 to 95.92



risks including, thrombosis, leaking through the graft, pseudoaneurysms, diaphragmatic paralysis, pleural effusion, excessive pulmonary blood flow, as well as complications due to thoracotomy.⁶ These complications may prolong the stay in intensive care units.^{1,16}

In the studies we examined, complications were more likely to occur in the BT shunt group. However, while stenting obviates some of the complications of shunt procedures, there are known complications specific to stenting procedures including perforations of the right ventricular wall and pulmonary artery, dislodgement, and suboptimal positioning of the stent.^{17,18} Additionally, stenting procedure may require cut down of the axillary artery which is invasive, as well more than one stent may be needed to cover the length of the PDA; uncovered segments of the PDA carry a risk of constriction.⁷ Other complications include; (1) acute thrombosis, where if the guide wire still remains, a small balloon may be passed and inflated several times in an attempt to break the thrombus manually, or may require thrombolytic therapy,⁷ and (2) spasm of the ductus during manipulation of the guidewire through the ductus, and if recurs it may require referral for surgery. These drawbacks may explain the preference for shunt procedure instead. On the other hand, those treated with PDA stenting may have a lower risk of procedural complications, lesser ICU stay, less need for diuretics, and more symmetrical pulmonary arteries.¹⁹

There are some subsets of patients where BT shunt appears to be more preferred, and these groups tend to have more complicated intracardiac lesions than those selected for ductal stenting.² Patient selection for BT shunt depends on factors including age, weight, maturity, coexisting non-cardiac, congenital diseases, RV function, respiratory infection, and others. In the studies we examined BT shunt was preferred over stenting for diagnostic indications including double outlet right ventricle, tetralogy of fallot, Ebstein anomaly, tricuspid atresia, and complex atrial transposition.⁸ Additionally, patient selection strategy for stented patients requires echocardiographic and angiographic evidence of ductal morphology including information about its size, length, origin, and tortuosity.^{8,11,7} Moreover, patients may have been selected for stent group if they were believed to be at higher risk for surgical complications. Therefore, patient selection bias is apparent in the studies we examined. In one study, there was a preference for ductal stenting over shunt procedures, and this study was prospective in nature where patients with failed stent attempt were referred to shunting.¹¹ In the study performed by Glatz et al,¹⁹ there was significant differences in the distribution of treatment strategies among centers. Patients with pulmonary atresia, intact septum,

and isolated pulmonary stenosis were more likely selected for ductal stenting, as well as those with two ventricle circulation, and antegrade pulmonary blood flow.¹⁹

Extracorporeal membrane oxygenation is a supportive therapy used as a type of cardiopulmonary life support where blood is drained from the vascular system, circulated outside the body where it is saturated with oxygen and CO₂ is removed, and then re-infused into the circulation. In the studies we analyzed, neonates that underwent ductal stenting were less likely to require ECMO post op. It is important to note that ECMO use itself is associated with common complications, as well as significant increase in morbidity and mortality.^{20,21} These outcomes may be due to the underlying pathologies that necessitated the need for ECMO, or are specific to ECMO. The influence of ECMO on mortality outcomes in BT shunt groups should be elucidated in future studies.

The Nakata index is the sum of the cross-sectional areas of the right and left pulmonary arteries divided by the body surface area ($N = >200$ mm²/m²). Nakata index may be used as a predictor for the success of definitive surgical repair.²² Pulmonary artery size is a major factor that impacts post-operative early outcomes, however one study showed that even in very small PA's (< 100 mm²/m²) were not associated with a higher risk of longer mechanical ventilation or longer hospital stay. In our analysis, Nakata index was higher in neonates belonging to ductal stent groups; this effect size was medium. Some studies suggest that pulmonary artery growth is equal to and even superior in stented patients compared to shunted patients.^{8,23} Santoro et al mention that given the short term of palliation, and the general favor for surgical repair, variables relating to pulmonary vascular development may not be as influent.²⁴ Moreover, surgical shunt may have been left in situ for duration longer than the stented duct, and this may have amplified differences between left-to-right growth.²⁴

Conclusion

Although primary repair is the preferred management for neonates with ductal dependent pulmonary circulation, BT shunt and ductal stent procedures remain viable alternatives as first stage palliation. Stented patients appear to be at lower risk of outcomes such as mortality, complications and the need for ECMO post op. Additionally, stented patients showed higher post procedure oxygenation and higher Nakata index scores. Early post procedure stability is apparent with ductal stenting

compared to BT shunt procedures, and may be a safer and more effective option to palliative surgery in high-risk patients.

Acknowledgements

As authors we would love to dedicate this paper to the late Prof. HALA hamza, one of the pioneers of pediatric cardiology in MENA and one of the first pediatric cardiologist to bring the technique of PDA stent in developing countries in the region.

Author Contributions

All of the listed authors have met the authorship criteria recommended by ICJME standards. A.F.A and H.A conceived the idea. R.M, E.M. A.E. E, A.O.S, A.K, M.Y.S, P.E, S.N.A, S.S.S, S.R, Y.N, performed the search of databases and data collection and data extraction. R.M, E.M, Y.N performed statistical analysis. R.M, E.M performed the final review and analysis of outcomes. A.F.A acted as a third judge when needed. Final revision of the manuscript was performed by R.M, E.M, A.F.A. A.F.A, and H.A supervised.

Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors.

Limitations

Non-english studies and grey literature was not included in this review. Additionally, the non-randomized nature of the studies, and retrospective nature of most (5/6) studies included poses some biases. Patient selection bias within the studies examined may have favored more stable patients for stenting as compared to BT shunt procedures. Keeping minimal patient risk as a main priority, randomized studies are needed to minimize this selection bias. It has been suggested that to account for these factors, a randomized trial of large magnitude and design similar to a study comparing shunts in Norwood procedures would be needed.^{25,26}

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