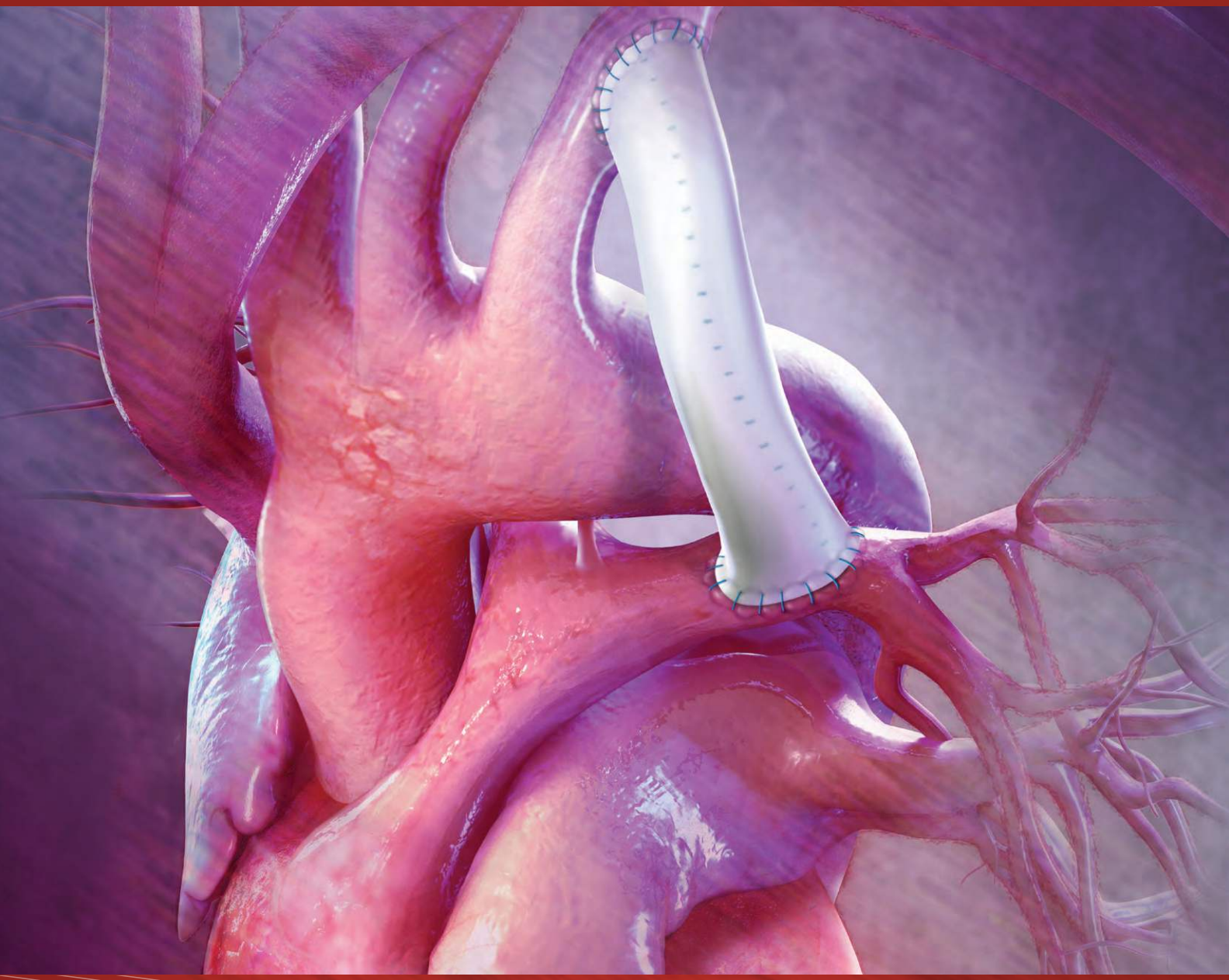
Literature Summary:
Clinical Use of ePTFE Pediatric Shunts



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Pediatric shunts are small diameter (3 – 6 mm) vascular connections (native vessels or synthetic vascular grafts) between systemic and pulmonary circulations. The shunts provide additional blood flow to the lungs as a palliative procedure in patients with cyanotic congenital heart disease (CCHD). Expanded polytetrafluoroethylene (ePTFE) vascular grafts are routinely used as pediatric shunts due to their superior performance and ease of use compared to native vessels. As surgical technique and post-operative care has improved, pediatric cardiac surgeons are palliating and repairing increasingly complex lesions which, not long ago, were considered uniformly fatal conditions. The alternatives for these infants are limited. Complications associated with the surgical procedures and the use of prosthetic shunts in these complex defects are multivariate and have not been completely eliminated. These complications, including shunt thrombosis, are experienced by all pediatric cardiac surgeons at all hospitals throughout the world. Although the use of ePTFE shunts is not without complications, to date it is reported in the literature as the best surgical strategy available.

PALLIATIVE PEDIATRIC SHUNT PROCEDURES

Systemic-to-pulmonary artery shunts are palliative procedures performed in the neonatal period for patients with severe CCHD associated with diminished or absent pulmonary blood flow. Shunts are almost invariably used as staging procedures to increase pulmonary blood flow, improve tissue oxygenation, and promote normal development of pulmonary arteries in the interim prior to further palliative or definitive reconstruction. In most neonates, subsequent stages of cardiac repair are performed between three months and two years after the primary shunting stage, dependent upon the primary diagnosis and procedure undertaken.

Systemic-to-pulmonary artery shunts were first described by Blalock-Taussig (BT) in 1945 [1] (subclavian to pulmonary artery shunt), Potts in 1946 [2] (descending aorta to left pulmonary artery shunt), and Waterston-Cooley in 1962 [3] and 1966 [4] (ascending aorta to right pulmonary artery shunt). Complications of these surgical procedures included:

- Shunt thrombosis [5 – 7]
- Distortion or kinking of the subclavian[4] and pulmonary arteries [8 – 11]
- Sacrifice of the subclavian artery leading to ischemic sequelae in the ipsilateral upper limb [12 – 14]
- Lack of control over the size of the subclavian artery which is often too small in newborns to provide adequate shunting [1, 4, 7]
- Limited control of the shunt diameter resulting in excessive flow and ensuing pulmonary hypertension or congestive heart failure [10, 15 – 17]
- Preferential flow to a single lung [9, 10, 18 – 20]
- Phrenic nerve injury [21]
- Excessive or difficult dissection at the time of definitive open revision or repair [4, 17, 22]

COMPARATIVE STUDIES USING CLASSIC BLALOCK-TAUSSIG SHUNTS (CBTS) VERSUS MODIFIED BLALOCK-TAUSSIG SHUNTS (MBTS)

The development of tubular prosthetic grafts was intended to reduce shunt complications. Prosthetic grafts are used as an interposition graft between the subclavian and pulmonary arteries, a procedure referred to as the MBTS [23]. In the mid 1980s to 2000, the performance of CBTS (native vessels) and MBTS (ePTFE grafts) were evaluated. In a comparative study of 12 CBTS and 27 MBTS, combined early and late shunt failure was 33% for CBTS and 41% for MBTS [24]. One shunt related death occurred in a patient with a CBTS. In another comparative study of 23 CBTS and 35 MBTS, Moulton *et al*. reported that combined early and late shunt failure occurred in 39% of CBTS and 11% of MBTS [6]. Shunt related death was 9% for CBTS and 0% for MBTS. A comparative study of 29 CBTS and 24 MBTS demonstrated that combined early and late shunt failure occurred in 52% of CBTS and 21% of MBTS [11]. Shunt related death was 14% in CBTS and 4% in MBTS. The authors also noted that tenting / kinking of the pulmonary artery was more common in CBTS (75%) than MBTS (36%) in a select number of patients analyzed. In a larger comparative study of 128 CBTS and 418 MBTS, combined early and late shunt failure occurred in 14% of CBTS and 8% of MBTS[25]. There were no shunt related deaths. Overall, the combined data from four studies show the superior performance of MBTS made of ePTFE (Table 1).

Table 1. Comparison between CBTS (native vessels) and MBTS (ePTFE grafts) performance.

Shunt	Number of Shunts	Early Failure	Late Failure	Shunt Related Death
Native Vessels*	192	7.3%	16.7%	3.6%
ePTFE*	504	2.0%	8.5%	0.2%
Comparative Study References	5, 10, 23, 24			

* Average of the events reported in corresponding references.
(Early failure defined as 0 – 30 days; late failure defined as > 30 days)

ePTFE SHUNTS IN CCHD REPAIR

The first reported clinical use of ePTFE grafts for palliation of CCHD in infants was in 1976 [26] and has since become routine based on its superior performance and ease of use. Nanton *et al*. indicated that ePTFE shunts are easy to manipulate, and can be implanted and taken down more easily than a traditional shunt because the pericardium does not have to be opened [27]. McKay *et al*. demonstrated a shunt patency rate of 97% for 29 ePTFE MBTS between a 5 and 29 month follow-up [28]. In another study of 63 ePTFE MBTS, patency was 85% at three years [29]. Opie *et al*. [30] demonstrated an overall two year 89% patency rate in 47 ePTFE shunts, and Sakai *et al*. [31] also showed a patency rate of 89% at three and five year follow-ups in 40 MBTS. In a different

study of 100 ePTFE MBTS, patency was 90% at one year [32]. Although Fermanis *et al.* demonstrated a similar shunt patency of 87% at one year in 53 MBTS, the two year patency rate was 62% [33]. Nonetheless, the ePTFE MBTS has been noted as the procedure of choice for increasing blood flow to the lungs in newborns or small infants with CCHD [27, 32, 34].

NORWOOD PROCEDURE

As surgical techniques and post-operative care have improved, there has been a move towards early primary repair of CCHD which eliminates the need for shunts. However, in certain cases, due to the severity of the cardiac condition (e.g., hypoplastic left heart syndrome; HLHS) or lack of donor hearts for transplantation, a palliative shunt procedure is still a required therapy [35 – 38]. Once considered a uniformly fatal condition, HLHS is characterized by severe hypoplasia or absence of the left ventricle, and it is now considered one of the most challenging CCHD to repair. The current surgical strategy requires a three-stage repair [35]. The first stage, the Norwood procedure,[39] is performed within the first 30 days of life and requires the implantation of an ePTFE systemic-to-pulmonary shunt along with the reconstruction of the aorta and atrial septectomy.

The Norwood procedure poses the greatest risk of mortality for staged repair of single ventricle heart malformations with associated systemic outflow obstruction. It has been reported that between 7 – 47% of infants die before the second palliative procedure [36, 37, 40 – 42]. Some of the events often associated with high mortality of the Norwood procedure are diastolic runoff and coronary steal, and the compromised balance between pulmonary and systemic blood flows associated with implantation of MBTS. In 2003, Sano *et al.* described a new technique that entailed the construction of a non-valved ePTFE shunt between the right ventricle and the pulmonary artery (RV-PA shunt) with the aim of reducing pulmonary overcirculation and hemodyamic instability[43]. Although Sano *et al.* has demonstrated that the RV-PA shunt simplifies postoperative management and enhances survival of HLHS infants,[38, 43 – 45] other studies have shown that outcomes are similar to the conventional Norwood procedure [46 – 48]. Nonetheless, survival rates have improved over the years, attributing to pre-selection of patients, improvement in perioperative and postoperative patient management, and the general approach to care for these patients [42, 49, 50].

Cardiac transplantation is a favorable alternative to surgical intervention. Studies indicate that although the survival rates of transplanted patients are equivalent to those for staged surgical reconstruction, the quality of life and physical development is superior [51]. However, approximately 25% of the infants died on the waiting list in these studies, which resulted in a lower overall survival rate than staged reconstruction. Although the quality of life argument is compelling, transplantation limits the future surgical options when the transplanted heart begins to fail and a significant shortage of suitable donor hearts restricts the applicability of transplantation for most newborns.

FREQUENCY AND CAUSES OF ePTFE SHUNT OCCLUSION

Prosthetic shunt obstruction is not uncommon [25, 33, 52 – 54]. Causes of ePTFE shunt failures include thrombosis,[23, 25, 32, 52, 55 – 57] neointimal proliferation at the anastomosis,[34, 54, 58] and pulmonary artery distortion or stenosis related to the fixed length of a prosthetic tube [8, 11, 23, 29, 53, 55, 59]. Shunt thrombosis is the most common complication associated with pediatric shunts. Incidence of thrombotic occlusions in ePTFE shunts has been reported to range from 0 – 13%, [23, 32, 52, 55, 57, 60, 61] and may occur early (0 – 30 days) or late (> 30 days). A review of 22 cases showed that median time to shunt occlusion was five days (0 – 1080 days) [62]. Kulik *et al.* concluded that ePTFE shunt closure occurs within the first two months of operation [53]. However, Tomizawa *et al.* noted that thrombus formation and intimal hyperplasia were common in explanted ePTFE pediatric shunts removed from 11 months to 5 years and 7 months implantation [58]. In a series of 169 patients, Fenton *et al.* reported a 6% shunt thrombosis with higher occurrence in smaller shunts (13% for 3 – 3.5 mm shunts vs. 2.4% for 4 and 5 mm shunts) [52]. Of the 21 interim deaths, five were attributed to shunt thrombosis all in patients with single ventricle anatomy. Lower body weight, younger age,[8, 32] smaller graft size,[23, 28, 32, 34, 54, 63-65] and single ventricle physiology[32, 66] have all been found to be predictors of early and late shunt failure.

SHUNT THROMBOSIS THERAPY

Current methods to address shunt thrombosis are preventative (anti-platelet or anti-coagulant therapy) [56, 61] and corrective (surgical or catheter-based shunt revisions) [62, 67]. Anti-platelet therapy includes long-term postoperative administration of aspirin [56] or clopidogrel [61]. Anti-coagulants such as intravenous heparin [25] has also been used to lower the risk of shunt thrombosis. Although helpful, aspirin treatment still results in over 12 – 13% thrombosis rates in higher risk conditions [54, 56]. Heparin was also proven to have a beneficial but limited effect on shunt thrombosis. In a study of 546 CBTS and MBTS procedures, Al Jubair *et al.* reported an overall 9.1% failure rate in heparinized patients versus 13.6 % when heparin was not used [25]. In the same study, administration of aspirin during follow-up reduced the failure rate from 11% to 6.7%. Despite these preventative strategies, shunt thrombosis remains a significant cause of morbidity and mortality. Corrective procedures for chronic shunt thrombosis may involve a second planned or unplanned intervention with surgery, thrombolysis, mechanical thrombectomy, balloon angioplasty, or stent implantation [62, 67].

CONCLUSIONS

The clinical use of ePTFE shunts for palliation of CCHD has become a standard and preferred practice based on its superior performance, ease of use, and reduction in morbidity and mortality in neonates. Challenges with prosthetic grafts are shunt thrombosis, neointimal proliferation, and shunt stenosis or distortion related to patient growth. The use of any shunt, whether surgical or prosthetic, requires consideration of future procedures and possible open definitive repair of the defect. This is especially true in the neonatal population given the rapid growth and development during infancy and childhood.

REFERENCES

1. Blalock A, Taussig HB. Landmark article May 19, 1945: The surgical treatment of malformations of the heart in which there is pulmonary stenosis or pulmonary atresia. By Alfred Blalock and Helen B. Taussig. *Journal of the American Medical Association* 1984;27;251(16):2123-2138.
2. Potts WS, Smith S, Gibson S. Anastomosis of the aorta to a pulmonary artery: certain types in congenital heart disease. Certain types in congenital heart disease. *Journal of the American Medical Association* 1946;132(11):627-631.
3. Waterston DJ. [Treatment of Fallot's tetralogy in children under 1 year of age.]. *Rozhledy v Chirurgii* 1962;41:181-183.
4. Cooley DA, Hallman GL. Intrapericardial aortic-right pulmonary arterial anastomosis. *Surgery, Gynecology & Obstetrics* 1966;122(5):1084-1086.
5. Brandt B III, Camacho JA, Mahoney LT, Heintz SE. Growth of the pulmonary arteries following Blalock-Taussig shunt. *Annals of Thoracic Surgery* 1986 Dec;42(6)Supplement:S1-S4.
6. Moulton AL, Brenner JI, Ringel R, *et al.* Classic versus modified Blalock-Taussig shunts in neonates and infants. *Circulation* 1985 Sep;72(3)Part 2:II35-II44.
7. Edmunds LH Jr, Stephenson LW, Gadzik JP. The Blalock-Taussig anastomosis in infants younger than 1 week of age. *Circulation* 1980;62(3):597-603.
8. Godart F, Qureshi SA, Simha A, *et al.* Effects of modified and classic Blalock-Taussig shunts on the pulmonary arterial tree. *Annals of Thoracic Surgery* 1998;66(2):512-518.
9. Reitman MJ, Galioto FM Jr, el-Said GM, Cooley DA, Hallman GL, McNamara DG. Ascending aorta to right pulmonary artery anastomosis. Immediate results in 123 patients and one month to six year follow-up in 74 patients. *Circulation* 1974;49(5):952-957.
10. Tay DJ, Engle MA, Ehlers KH, Levin AR. Early results and late developments of the Waterston anastomosis. *Circulation* 1974;50(2):220-229.
11. Ullom RL, Sade RM, Crawford FA Jr, Ross BA, Spinale F. The Blalock-Taussig shunt in infants: standard versus modified. *Annals of Thoracic Surgery* 1987;44(5):539-543.
12. Geiss D, Williams WG, Lindsay WK, Rowe RD. Upper extremity gangrene: a complication of subclavian artery division. *Annals of Thoracic Surgery* 1980;30(5):487-489.
13. Lodge FA, Lamberti JJ, Goodman AH, *et al.* Vascular consequences of subclavian artery transection for the treatment of congenital heart disease. *Journal of Thoracic & Cardiovascular Surgery* 1983;86(1):18-23.
14. Mearns AJ, Deverall PB, Kester RC. Revascularization of an arm for incipient gangrene after Blalock-Taussig anastomosis. *British Journal of Surgery* 1978;65(7):467-468.
15. Bernhard WF, Jones JE, Friedberg DZ, Litwin SB. Ascending aorta-right pulmonary artery shunt in infants and older patients with certain types of cyanotic congenital heart disease. *Circulation* 1971;43(4):580-584.
16. Paul MH, Miller RA, Potts WJ. Long-term results of aortic-pulmonary anastomosis for tetralogy of Fallot. An analysis of the first 100 cases eleven to thirteen years after operation. *Circulation* 1961;23(4):525-533.
17. Truccone NJ, Bowman FO Jr, Malm JR, Gersony WM. Systemic-pulmonary arterial shunts in the first year of life. *Circulation* 1974;49(3):508-511.
18. Albers WH, Nadas AS. Unilateral chronic pulmonary edema and pleural effusion after systemic-pulmonary artery shunts for cyanotic congenital heart disease. *American Journal of Cardiology* 1967;19(6):861-866.
19. Ebert PA, Gay WA Jr, Oldham HN. Management of aorta-right pulmonary artery anastomosis during total correction of tetralogy of Fallot. *Surgery* 1972;71(2):231-234.
20. Oldham HN Jr, Simpson L, Jones RH, Goodrich JK, Sabiston DC Jr. Differential distribution of pulmonary blood flow following aortopulmonary anastomosis. *Surgical Forum* 1970;21:201-202.
21. Mickell JJ, Oh KS, Siewers RD, Galvis AG, Fricker FJ, Mathews RA. Clinical implications of postoperative unilateral phrenic nerve paralysis. *Journal of Thoracic & Cardiovascular Surgery* 1978;76(3):297-304.
22. Jennings RB Jr, Innes BJ, Brickman RD. Use of microporous expanded polytetrafluoroethylene grafts for aorta-pulmonary shunts in infants with complex cyanotic heart disease. A report of seven cases. *Journal of Thoracic & Cardiovascular Surgery* 1978;76(4):489-494.
23. de Leval MR, McKay R, Jones M, Stark J, Macartney FJ. Modified Blalock-Taussig shunt. Use of subclavian artery orifice as flow regulator in prosthetic systemic-pulmonary artery shunts. *Journal of Thoracic & Cardiovascular Surgery* 1981;81(1):112-119.
24. Lamberti JJ, Carlisle J, Waldman JD, *et al.* Systemic-pulmonary shunts in infants and children. Early and late results. *Journal of Thoracic & Cardiovascular Surgery* 1984;88(1):76-81.
25. Al Jubair KA, Al Fagih MR, Al Jarallah AS, *et al.* Results of 546 Blalock-Taussig shunts performed in 478 patients. *Cardiology in the Young* 1998;8(4):486-490.
26. Gazzaniga AB, Lamberti JJ, Siewers RD. Arterial prosthesis of microporous expanded polytetrafluoroethylene for construction of aorta-pulmonary shunts. *Journal of Thoracic & Cardiovascular Surgery* 1976;72(3):357-363.
27. Nanton MA, Roy DL, Murphy DM, *et al.* Polytetrafluoroethylene shunts in congenital heart disease. *Canadian Journal of Surgery* 1982;25(2):134-138.
28. McKay R, de Leval MR, Rees P, Taylor JFN, Macartney FJ, Stark J. Postoperative angiographic assessment of modified Blalock-Taussig shunts using expanded polytetrafluoroethylene (GORE-TEX). *Annals of Thoracic Surgery* 1980;30(2):137-145.
29. Wright J, Albrecht H, Beveridge J. Palliation in cyanotic congenital heart disease. Fifteen years' experience of various shunt procedures. *Medical Journal of Australia* 1986;144(4):178- 182.
30. Opie JC, Traverse L, Hayden RI, Ho CY, Culham JAG, Ashmore PG. Experience with polytetrafluoroethylene grafts in children with cyanotic congenital heart disease. *Annals of Thoracic Surgery* 1986;41(2):164-168.
31. Sakai K, Goh K, Gohda T, *et al.* Modified versus classical Blalock-Taussig shunts for congenital cyanotic heart diseases: a comparison of long-term results. *Japanese Journal of Surgery* 1987;17(6):470-477.
32. Tsai KT, Chang CH, Lin PJ. Modified Blalock-Taussig shunt: statistical analysis of potential factors influencing shunt outcome. *Journal of Cardiovascular Surgery* 1996;37(2):149-152.
33. Fermanis GG, Ekangaki AK, Salmon AP, *et al.* Twelve year experience with the modified Blalock-Taussig shunt in neonates. *European Journal of Cardiothoracic Surgery* 1992;6(11):586-589.
34. Woolf PK, Stephenson LW, Meijboom E, *et al.* A comparison of Blalock-Taussig, Waterston, and polytetrafluoroethylene shunts in children less than two weeks of age. *Annals of Thoracic Surgery* 1984;38(1):26-30.
35. Backer CL, Bove EL, Zales VR, Mavroudis C. Hypoplastic left heart syndrome. In: Mavroudis C, Backer CL, eds. *Pediatric Cardiac Surgery*. St Louis, MO: Mosby Year Book Inc; 1994;30:444-448.
36. Breymann T, Kirchner G, Blanz U, *et al.* Results after Norwood procedure and subsequent cavopulmonary anastomoses for typical hypoplastic left heart syndrome and similar complex cardiovascular malformations. *European Journal of Cardiothoracic Surgery* 1999;16(2):117-124.
37. Daebritz SH, Nollert GD, Zurakowski D, *et al.* Results of Norwood stage I operation: comparison of hypoplastic left heart syndrome with other malformations. *Journal of Thoracic & Cardiovascular Surgery* 2000;119(2):358-367.
38. Sano S, Huang SC, Kasahara S, Yoshizumi K, Kotani Y, Ishino K. Risk factors for mortality after the Norwood procedure using right ventricle to pulmonary artery shunt. *Annals of Thoracic Surgery* 2009;87(1):178-186.
39. Norwood WI, Kirklin JK, Sanders SP. Hypoplastic left heart syndrome: experience with palliative surgery. *American Journal of Cardiology* 1980;45(1):87-91.
40. Ishino K, Stümper O, De Giovanni JJ, *et al.* The modified Norwood Procedure for hypoplastic left heart syndrome: early to intermediate results of 120 patients with particular reference to aortic arch repair. *Journal of Thoracic & Cardiovascular Surgery* 1999;117(5):920-930.
41. Malec E, Januszewska K, Kołz J, Pajak J. Factors influencing early outcome of Norwood procedure for hypoplastic left heart syndrome. *European Journal of Cardiothoracic Surgery* 2000;18(2):202-206.
42. Tweddell JS, Hoffman GM, Mussatto KA, *et al.* Improved survival of patients undergoing palliation of hypoplastic left heart syndrome: lessons learned from 115 consecutive patients. *Circulation* 2002;106(12)Supplement 1:I82-I89.
43. Sano S, Ishino K, Kawada M, *et al.* Right ventricle-pulmonary artery shunt in first-stage palliation of hypoplastic left heart syndrome. *Journal of Thoracic & Cardiovascular Surgery* 2003;126(2):504-510.
44. Pizarro C, Malec E, Maher KO, *et al.* Right ventricle to pulmonary artery conduit improves outcome after stage I Norwood for hypoplastic left heart syndrome. *Circulation* 2003;108(Supplement 1):II155-II60.
45. Sano S, Ishino K, Kawada M, Honjo O. Right ventricle-pulmonary artery shunt in first-stage palliation of hypoplastic left heart syndrome. *Seminars in Thoracic & Cardiovascular Surgery: Pediatric Cardiac Surgery Annual* 2004;7:22-31.
46. Azakie A, Martinez D, Sapru A, Fineman J, Teitel D, Karl TR. Impact of right ventricle to pulmonary artery conduit on outcome of the modified Norwood procedure. *Annals of Thoracic Surgery* 2004;77(5):1727-1733.
47. Mahle WT, Cuadrado AR, Tam VK. Early experience with a modified Norwood procedure using right ventricle to pulmonary artery conduit. *Annals of Thoracic Surgery* 2003;76(4):1084-1089.
48. Tabbutt S, Dominguez TE, Ravishankar C, *et al.* Outcomes after the stage I reconstruction comparing the right ventricular to pulmonary artery conduit with the modified Blalock Taussig shunt. *Annals of Thoracic Surgery* 2005;80(5):1582-1591.
49. Azakie T, Merklinger SL, McCrindle BW, *et al.* Evolving strategies and improving outcomes of the modified norwood procedure: a 10-year single-institution experience. *Annals of Thoracic Surgery* 2001;72(4):1349-1353.
50. Checchia PA, Larsen R, Sehra R, *et al.* Effect of a selection and postoperative care protocol on survival of infants with hypoplastic left heart syndrome. *Annals of Thoracic Surgery* 2004;77(2):477-483.
51. Hehrlein FW, Yamamoto T, Orime Y, Bauer J. Hypoplastic left heart syndrome: "which is the best operative strategy?". *Annals of Thoracic & Cardiovascular Surgery* 1998;4(3):125-132.
52. Fenton KN, Siewers RD, Rebovich B, Pigula FA. Interim mortality in infants with systemic-to-pulmonary artery shunts. *Annals of Thoracic Surgery* 2003;76(1):152-157.
53. Kulik TJ, Foker JE, Lucas RV Jr, Anderson RW, Lock JE. Postoperative hemodynamics in children with polytetrafluoroethylene shunts. *Circulation* 1981;64(2)Part 2:II123-II30.
54. Motz R, Wessel A, Ruschewski W, Bürsch J. Reduced frequency of occlusion of aorto-pulmonary shunts in infants receiving aspirin. *Cardiology in the Young* 1999;9(5):474-477.
55. Alkhulaifi AM, Lacour-Gayet F, Serraf A, Belli E, Planché C. Systemic pulmonary shunts in neonates: early clinical outcome and choice of surgical approach. *Annals of Thoracic Surgery* 2000;69(5):1499-1504.
56. Li JS, Yow E, Berezny KY, Rhodes JF, *et al.* Clinical outcomes of palliative surgery including a systemic-to-pulmonary artery shunt in infants with cyanotic congenital heart disease: does aspirin make a difference? *Circulation* 2007;116(3):293-297.
57. Miyamoto K, Zavanella C, Lewin AN, Subramanian S. Aorta-pulmonary artery shunts with expanded polytetrafluoroethylene (PTFE) tube. *Annals of Thoracic Surgery* 1979;27(5):413-417.
58. Tomizawa Y, Takanashi Y, Noishiki Y, Nishida H, Endo M, Koyanagi H. Evaluation of small caliber vascular prostheses implanted in small children: activated angiogenesis and accelerated calcification. *ASAIO Journal* 1998;44(5):M496-M500.
59. Gladman G, McCrindle BW, Williams WG, Freedom RM, Benson LN. The modified Blalock-Taussig shunt: clinical impact and morbidity in Fallot's tetralogy in the current era. *Journal of Thoracic & Cardiovascular Surgery* 1997;114(1):25-30.
60. Bove EL, Sondheimer HM, Kavey RE, Byrum CJ, Blackman MS, Parker FB Jr. Subclavian-pulmonary artery shunts with polytetrafluorethylene interposition grafts. *Annals of Thoracic Surgery* 1984;37(1):88-91.
61. Li JS, Yow E, Berezny KY, *et al;* PICOLO Investigators. Dosing of clopidogrel for platelet inhibition in infants and young children: primary results of the Platelet Inhibition in Children On cLOpidogrel (PICOLO) trial. *Circulation* 2008;29;117(4):553-559.
62. Kogon B, Villari C, Shah N, *et al.* Occlusion of the modified Blalock-Taussig shunt: unique methods of treatment and review of catheter-based intervention. *Congenital Heart Disease* 2007;2(3):185-190.
63. Fenchel G, Steil E, Seboldt H, Quintenz R, Apitz J, Hoffmeister HE. Early and late results of the modified Waterston shunt with PTFE grafts for palliation of complex congenital cyanotic heart disease in neonates. *Thoracic & Cardiovascular Surgery* 1991;39(5):268-272.
64. Karpawich PP, Busch CP, Antillon JR, Amato JJ, Marbey ML, Agarwal KC. Modified Blalock-Taussig shunt in infants and young children. *Journal of Thoracic & Cardiovascular Surgery* 1985;89(2):275-279.
65. Tamisier D, Vouhé PR, Vernant F, Lecá F, Massot C, Neveux JY. Modified Blalock-Taussig shunts: results in infants less than 3 months of age. *Annals of Thoracic Surgery* 1990;49(5):797-801.
66. Rao MS, Bhan A, Talwar S, *et al.* Modified Blalock-Taussig shunt in neonates: determinants of immediate outcome. *Asian Cardiovascular & Thoracic Annals* 2000;8(4):339-343.
67. Gillespie MJ, Rome JJ. Transcatheter treatment for systemic-to-pulmonary artery shunt obstruction in infants and children. *Catheterization & Cardiovascular Interventions* 2008;71(7):928-935.

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