Polytetrafluoroethylene conduits versus homografts for right ventricular outflow tract reconstruction in infants and young children: An institutional experience

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ABSTRACT

Objective: Our institution uses a valved polytetrafluoroethylene conduit as an alternative to homografts. The objective of this study was to investigate the performance of bicuspid valved polytetrafluoroethylene conduits used for right ventricular outflow tract reconstruction in children aged less than 2 years and to evaluate risk factors for earlier conduit explant.

Methods: We performed an Institutional Review Board–approved retrospective chart review of all patients aged less than 2 years who underwent surgical right ventricular outflow tract reconstruction with a bicuspid valved polytetrafluoroethylene conduit or homograft conduit from July 2004 to December 2014. The end points of the study were defined as conduit explant, conduit explant or re-intervention, conduit stenosis, and conduit insufficiency.

Results: Fifty-four patients underwent 65 right ventricular outflow tract reconstructions with a bicuspid valved polytetrafluoroethylene conduit ($n = 39$) or a homograft conduit ($n = 26$, 23 pulmonary, 3 aortic). The majority of diagnoses were truncus arteriosus ($n = 28$) and tetralogy of Fallot with pulmonary atresia ($n = 19$). Median age of patients at surgery was 134 (8–323) days and 128 (7–384) days in the PTFE and homograft groups, respectively. There was no difference in demographic data between the 2 groups. Time-to-event analysis demonstrated no difference in time to explant ($P = .474$) or time to explant or re-intervention ($P = .206$) between the 2 conduit types. Younger age at surgery was the only independent risk factor for conduit explant (subdistribution hazard ratio 1.104 per 30 days younger, $P < .001$). There was no significant influence of conduit type on the development of moderate conduit stenosis ($P = .931$) or severe conduit insufficiency ($P = .880$). Larger conduit z score was protective for the development of moderate conduit stenosis (subdistribution hazard ratio, 0.46; $P = .001$).

Conclusions: Bicuspid valved polytetrafluoroethylene conduits are a satisfactory choice for right ventricular outflow tract reconstruction in patients aged less than 2 years. Their availability, low cost, and lack of potential sensitization make them an appealing alternative to homograft conduits. (*J Thorac Cardiovasc Surg* 2018;155:2082–91)

Time-to-event analysis of time to conduit explantation between homografts and PTFE conduits.

Central Message

Valved PTFE conduits have a comparable performance to homograft conduits in terms of time to conduit explantation and development of conduit stenosis or insufficiency.

Perspective

Homograft conduits are frequently used for RVOT reconstruction; however, they have limited availability, a high cost, and the potential for allosensitization. Valved PTFE conduits are inexpensive, easy to construct, readily available, and lack potential sensitization. Their comparable performance makes them a satisfactory alternative to homografts.

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Abbreviations and Acronyms

LOS = length of stay
PG = peak gradient
PTFE = polytetrafluoroethylene
RVOT = right ventricular outflow tract

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Nearly all conduits used for right ventricular outflow tract (RVOT) reconstruction require replacement because of stenosis or insufficiency, especially in infants and young children. Since the mid-1980s, cryopreserved homografts have been the conduit of choice in the United States for RVOT reconstruction.¹⁻³ Young patient age and small conduit size have been shown to be risk factors for decreased conduit durability.^{1,2,4,5} Because of less than ideal performance,^{1,6,7} the potential for immunogenicity,⁸ the cost, and the limited availability of homografts, alternate prosthetic conduits have been developed over the years, including the Contegra (Medtronic, Minneapolis, Minn) (bovine jugular venous valve), Dacron conduits, porcine xenografts, and valved and nonvalved polytetrafluoroethylene (PTFE) tubes. The search is ongoing for safe, long-lasting, and cost-effective homograft alternatives. Since 2008, our institution has been using handmade bicuspid valved PTFE conduits using standard-stretch PTFE graft and 0.1 mm-thick PTFE membrane for RVOT reconstruction. PTFE has the advantage of being a relatively cheap material, readily available, and biologically inert. With this in mind, our aim was to investigate the performance of these bicuspid valved PTFE conduits compared with homografts at our own institution and to evaluate risk factors for decreased conduit durability in patients aged less than 2 years.

MATERIALS AND METHODS

All occurrences of RVOT reconstruction with a valved conduit in children aged less than 2 years at Children's Hospital of Pittsburgh from July 2004 to December 2014 were included in this retrospective study. Patients were identified through a query of the cardiothoracic surgery database. Patients were excluded if they received a nonvalved conduit, underwent univentricular repair, or had a modified or "bicuspidalized" homograft. Valved conduits implanted included pulmonary homografts, aortic homografts, and bicuspid valved PTFE conduits. Medical records, demographic data, operative reports, echocardiographic data, and catheterization data were reviewed through May 2016.

The primary end point of the study was "conduit explant." Conduit explant was defined as a surgical intervention that removed and replaced the right ventricle-pulmonary artery conduit for any reason. A secondary end point of "conduit explant or major reintervention" was also analyzed. Interval reinterventions were classified as major (surgery or catheter-based intervention involving the conduit, ie, stenting, ballooning) or minor (surgery or catheter-based intervention not involving the conduit, ie, branch pulmonary artery ballooning or stenting, truncal valve repair). Early (<30 days) and late (≥30 days) mortality were evaluated, as well as hospital length of stay (LOS) and postoperative LOS. This study was approved by the University of Pittsburgh Institutional Review Board, and the need for patient consent was waived because of its retrospective nature.

Polytetrafluoroethylene Conduit Construction and Operative Data

All conduits implanted in patients between 2004 and 2008 were homografts, with a shift to predominantly PTFE conduits in 2009. Type of conduit implanted was at the discretion of the surgeon, with valved PTFE conduits becoming available in 2009. Homograft conduits were cryopreserved pulmonary or aortic homografts. PTFE conduits were constructed in the operating room at the time of surgery, as previously described in our initial article.⁹ Video 1 demonstrates valved conduit construction and can be viewed at <https://www.dropbox.com/s/v29kvvfq1hxm8e8/PTFE%20Conduit%20JTCVS%202017.mp4?dl=0>. Operative data, bypass time, and aortic crossclamp time were analyzed. Z scores for conduit size were assigned from the conduit diameter and body surface area, according to published nomograms for pulmonary valve annulus size.¹⁰ Z scores for conduit size at explant were also determined on the basis of the patients' body surface area at the time of explant and original conduit size.

Echocardiographic Analysis

Echocardiographic indices of conduit performance were evaluated by analyzing conduit stenosis and conduit insufficiency over time. These additional end points were defined as "development of moderate conduit stenosis" and "development of severe conduit insufficiency." Conduit stenosis was defined according to published American Society of Echocardiography guidelines as follows¹¹: mild stenosis = peak gradient (PG) less than 36 mm Hg, moderate stenosis = PG 36 mm Hg to less than 64 mm Hg, severe stenosis = PG greater than 64 mm Hg. Conduit insufficiency was graded as none to mild, moderate, or severe according to published guidelines.^{12,13} Moderate pulmonary insufficiency was defined as a jet width to annulus ratio greater than 50%. Severe pulmonary insufficiency was

VIDEO 1. Video demonstration showing the construction of a bicuspid valved PTFE conduit. Video available at: <https://www.dropbox.com/s/v29kvvfq1hxm8e8/PTFE%20Conduit%20JTCVS%202017.mp4?dl=0>.

defined as a jet width to annulus ratio greater than 70% plus diastolic flow reversal in the branch pulmonary arteries. Short deceleration time in the pulmonary regurgitation spectral Doppler was also used as an adjunct to determine severe pulmonary insufficiency. All postoperative echocardiograms were reviewed. The first occurrences of moderate conduit stenosis and severe conduit insufficiency, as defined earlier, were used as the end points regardless of whether subsequent echocardiograms continued to meet criteria.

Statistical Analysis

Statistical analysis was performed using Stata 14 (StataCorp LP, College Station, Tex). Descriptive data for categorical variables are presented as relative frequencies, and continuous variables are presented as means and standard deviations or medians with interquartile ranges, depending on the normality of distribution. Linear regression was performed to test the association between continuous variables and conduit type groups; univariate logistic regression was performed to test the association between categorical variables and conduit type groups. We used univariate regression analysis instead of independent sample *t* test or chi-square tests because of several patients being included multiple times for having more than 1 conduit. Events were analyzed for each individual conduit, not for each patient. Clustered standard error was used to account for the dependence in the data for all analyses. Propensity score matching was not performed because of small sample sizes. All time to event end points were measured from the date of surgery. Cox proportional hazards regression with competing risks were performed for all time-to-event analysis comparing the PTFE group with the homograft group. For “explant” and “explant or major reintervention” events, death was treated as a competing risk; for “moderate conduit stenosis” and “severe conduit insufficiency” events, death and major reintervention were treated as competing risks. Risk factors for conduit exchange and conduit stenosis were analyzed via linear univariate and multivariate Cox regression models.

RESULTS

During the study period, 65 valved conduits were placed in 54 patients for RVOT reconstruction. Twenty-six homografts were implanted in 24 patients (3 aortic and 23 pulmonary). Homograft sizes used were 8 mm (3), 9 mm (8), 10 mm (4), 11 mm (1), 12 mm (1), 13 mm (3), 14 mm (3), 16 mm (1), 17 mm (1), and 18 mm (1). Mean homograft size was 11.2 ± 2.9 mm. Thirty-nine bicuspid valved PTFE conduits were implanted in 35 patients. PTFE conduits came in sizes 8 mm (3), 10 mm (12), 12 mm (13), 14 mm (7), and 16 mm (4), with a mean conduit size of 11.8 ± 2.2 mm. Nine patients had 2 conduits implanted, and 1 patient had 3 conduits implanted. Sixty-seven percent of PTFE conduits and 65% of homografts were placed as the patient's initial conduit. Forty conduits (62%) were implanted in male patients. The most common diagnosis was truncus arteriosus in 28 conduits (43%) and tetralogy of Fallot with pulmonary atresia in 19 conduits (29%). A total of 10 patients (12 conduit occurrences) had a diagnosis of DiGeorge syndrome. There was no difference in demographic data between patients receiving homografts versus PTFE conduits. Patient characteristics are presented in Table 1.

Mean follow-up time was 2.7 years. Follow-up was complete in all but 3 patients who moved after surgery or

TABLE 1. Patient characteristics at time of conduit implantation

	PTFE, n = 39	Homograft, n = 26	P value
Age (d)	134 [8-323]	128 [7-384]	.999
Sex (male)	25 (64%)	15 (57%)	.583
Weight (kg)	5.7 $\pm$ 2.9	5.6 $\pm$ 2.9	.860
Height (cm)	60.9 $\pm$ 12.3	59.1 $\pm$ 11.8	.558
BSA (m ²)	0.31 $\pm$ 0.11	0.30 $\pm$ 0.11	.775
First time conduit (yes)	26 (67%)	17 (65%)	.921
Diagnosis			.584
Truncus arteriosus	17 (44%)	11 (42%)	
TOF/PA	11 (28%)	8 (31%)	
Other	11 (28%)	7 (27%)	
Aortic stenosis	5 (13%)	2 (8%)	
CCTGA/VSD	1 (3%)	0 (0%)	
DOLV, LVOTO	0 (0%)	1 (4%)	
DORV/MGA	2 (5%)	1 (4%)	
IAA	2 (5%)	1 (4%)	
TGA/VSD	1 (3%)	0 (0%)	
TOF	0 (0%)	1 (4%)	
TOF/absent PV	0 (0%)	1 (4%)	

PTFE, Polytetrafluoroethylene; BSA, body surface area; TOF, tetralogy of Fallot; PA, pulmonary atresia; CCTGA, congenitally corrected transposition of the great arteries; VSD, ventricular septal defect; DOLV, double-outlet left ventricle; LVOTO, left ventricular outflow tract obstruction; DORV, double-outlet right ventricle; MGA, malposed great arteries; IAA, interrupted aortic arch; TGA, transposition of the great arteries; PV, pulmonary valve.

followed up with outside cardiologists. These patients were censored at the time of their most recent echocardiogram. Thirty-four of the 65 conduits (52%) were explanted and replaced by the end of follow-up. Reasons for conduit replacement included conduit stenosis and insufficiency in 25 patients, isolated stenosis in 2 patients, isolated insufficiency in 1 patient, pseudoaneurysm in 1 patient, congestive heart failure from residual ventricular septal defect in 1 patient, primary branch pulmonary artery stenosis without conduit stenosis in 3 patients, and unknown in 1 patient. Overall mortality was 6% with 2 early deaths (<30 days, 1 patient who had a pulmonary homograft and 1 patient with a PTFE conduit) and 2 late deaths (>30 days, both pulmonary homografts and both occurring at home). None of the deaths were primarily related to conduit failure. There were no additional late deaths in patients after their conduit explant.

Conduit size, conduit *z* score, cardiopulmonary bypass time, and aortic crossclamp time were similar between the 2 groups. There was a statistically significant difference in total hospital LOS between the 2 groups, favoring a decreased LOS in the PTFE group versus the homograft group. Median hospital LOS for the PTFE group was 14 days (6-30), and median hospital LOS for the homograft group was 24.5 days (17-46) (*P* = .013). Although postoperative LOS showed a similar trend toward a decreased LOS

TABLE 2. Operative data

	PTFE, n = 39	Homograft, n = 26	P value
RACHS score	3.5 ± 0.71 (n = 25)	3.6 ± 0.98 (n = 18)	.631
Bypass time (min)	107 ± 36	113 ± 43	.611
Aortic crossclamp time (min)	46.5 [25-63]	33 [22-54]	.727
Hospital LOS (d)	14 [6-30]	24.5 [17-46]	.013
Postoperative LOS (d)	10 [6-18]	18.5 [13-29]	.063
Conduit size (mm)	11.8 ± 2.2	11.2 ± 2.9	.322
Conduit z score at implant	+0.95 ± 0.52	+0.58 ± 1.07	.107
Conduit z score at exchange	−0.92 ± 1.14 (n = 21)	−1.6 ± 1.61 (n = 13)	.185

Bold indicates statistically significant *P* values. *PTFE*, Polytetrafluoroethylene; *RACHS*, Risk Adjustment for Congenital Heart Surgery; *LOS*, length of stay.

in the PTFE group (10 days [6-18]) versus the homograft group (18.5 days [13-29]), this was not statistically significant (*P* = .063). Operative data are presented in Table 2.

There was no difference in time to conduit explantation between the 2 groups (*P* = .474) (Figure 1). Cumulative incidence of conduit explant at 1, 3, and 5 years was 17%, 52%, and 55% for PTFE conduits and 23%, 43%, and 56% for homograft conduits, respectively. There were 52 total reinterventions in 38 conduits before explant. Twenty reinterventions were considered “major.” Nine PTFE conduits and 3 homografts had stents placed before explant. There was no difference in time to conduit explant or major reintervention (*P* = .206) between the 2 groups (Figure 2). Time to development of at least moderate conduit stenosis and severe conduit insufficiency was similar between the 2 groups (*P* = .931 and .880, respectively) (Figures 3 and 4). Separate competing risk figures for each of the time-to-event analyses are presented in Figures E1 to E4.

On univariate and multivariate Cox regression analyses for the entire cohort, the only independent risk factor for conduit explant was younger age at surgery (subdistribution

hazard ratio 1.104 for every 30 days younger, *P* < .001) (Table 3). Conduit z score was not associated with timing to conduit exchange; however, it was associated with the development of conduit stenosis. A larger conduit z score at implant was protective for developing moderate conduit stenosis (subdistribution hazard ratio, 0.46; *P* = .001).

Although our study population was defined as patients aged less than 2 years, we did perform subgroup analysis on patients aged less than 1 year. This also demonstrated no difference between the 2 conduit groups in regard to time to conduit explant (*P* = .550), time to conduit explant or major reintervention (*P* = .316), time to moderate conduit stenosis (*P* = .485), or time to severe conduit insufficiency (*P* = .675). There remained no difference in patient characteristics when excluding patients aged more than 1 year.

DISCUSSION

Although homografts have been the most used conduits for RVOT reconstruction to date, they have less than ideal performance in children,^{1,6,7} especially in neonates and

FIGURE 1. Time-to-event analysis showing cumulative incidence of conduit explantation over time between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene; *CI*, confidence interval.

FIGURE 2. Time-to-event analysis showing cumulative incidence of conduit explantation or major reintervention over time between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene; *CI*, confidence interval.

FIGURE 3. Time-to-event analysis showing cumulative incidence of moderate conduit stenosis by echocardiography between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene; *CI*, confidence interval.

infants.^{6,14} In non-Ross patients, allograft performance was poor in infants with a 5-year freedom from conduit failure of 42%, with a diagnosis of truncus arteriosus and smaller conduit size being risk factors for conduit dysfunction.¹ Along with poor performance, decreasing availability of homografts has necessitated a search for alternative conduits.

Our study suggests that bicuspid valved PTFE conduits are an appropriate alternative for RVOT reconstruction in children aged less than 2 years. We found no difference in time to explant or time to explant or major reintervention between the homograft group and the PTFE group. Also, there was no difference in the timing of development of conduit stenosis or insufficiency by echocardiography. There are few studies specifically evaluating conduits in

FIGURE 4. Time-to-event analysis showing cumulative incidence of severe conduit insufficiency by echocardiography between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene; *CI*, confidence interval.

patients aged less than 2 years; however, this age group has been shown to be high risk for the development of homograft failure.^{2,15} Two separate multi-institutional Congenital Heart Surgeons' Society studies in patients aged less than 2 years have evaluated conduit type and size in association with durability, each study comparing homografts, the Contegra, and porcine xenografts.^{4,6} Karamlou and colleagues⁶ showed that conduit explantation was undertaken in 20% of the patients at 2 years after initial conduit implant. Risk factors were determined to be younger age and smaller conduit *z* score, whereas there was no difference in conduit type. Poynter and colleagues⁴ reported a conduit durability of 63% at a median follow-up of 6 years. They noted a decreased durability of homografts compared with Contegras (although Contegras were not available in sizes <12 mm) and found that a smaller *z* score at implant was associated with earlier replacement or explantation.

The Contegra conduit is a bovine jugular venous valved conduit that has been established as an appropriate choice for RVOT reconstruction in infants and children.^{6,16-19} Hickey and colleagues¹⁶ evaluated infant truncus repair and concluded that the Contegra matched allograft performance and exhibited a trend toward slower progression of conduit stenosis and insufficiency, although this was not statistically significant. Another study in patients aged less than 1 year comparing homografts, Contegras and Hancock valves also showed equal durability between the types, but earlier development of conduit stenosis and insufficiency with the Contegra.⁵ Although this conduit has shown promising results, it may not be an option in very small infants because the smallest diameter Contegra is limited to 12 mm.

PTFE is a biologically inert, nonimmunogenic material that is relatively inexpensive. The cost of the materials needed for construction of the valved PTFE conduit are one tenth the cost of a similarly sized pulmonary homograft conduit at our institution. Before being used as a valved conduit, PTFE has been used as a prosthetic valve since the early 1990s. Brown and colleagues²⁰ reported excellent long-term results using PTFE as a monocusp valve within the RVOT, significantly reducing early and midterm pulmonary insufficiency without causing significant stenosis. Quintessenza and colleagues^{21,22} have also been using PTFE to construct valves within the RVOT in children and young adults since 2000 with good results and have recently adopted their technique to incorporate these valves within PTFE conduits as well.²³ Ando and Takahashi²⁴ described their 10-year experience with trileaflet PTFE valves within Dacron conduits and demonstrated an 88% freedom from conduit explantation at 10 years. In Japan, where homograft conduits are unavailable in parts of the country, valved PTFE conduits have been described in differing variations, including bicuspid, tricuspid, and

TABLE 3. Risk factors for conduit exchange: Univariate and multivariate analyses

	SHR	Univariate 95% CI	P value	SHR	Multivariate 95% CI	P value
Age (d)	0.997	0.995-0.998	<.001	0.995	0.993 - 0.997	<.001
Conduit size (mm)	0.802	0.679-0.948	.010	1.004	0.754-1.336	.978
Conduit z score	0.859	0.535-1.381	.531	0.829	0.474-1.447	.509
Weight (kg)	0.795	0.691-0.913	.001			
Height (cm)	0.954	0.927-0.982	.001			
BSA (m ²)	0.003	0.0001-0.101	.001			
Conduit type	1.285	0.646-2.555	.474			

Bold indicates statistically significant *P* values for multivariate regression. *SHR*, Subdistribution hazard ratio; *CI*, confidence interval; *BSA*, body surface area.

with and without bulging sinuses. Miyazaki and colleagues^{25,26} and Yamashita and colleagues²⁷ have developed fan-shaped PTFE valved conduits with and without bulging sinuses and have shown promising midterm outcomes. Shinkawa and colleagues²⁸ compared valved PTFE conduits with other types of conduits at their institution and found that the valved PTFE conduits had an improved freedom from conduit reoperation at 5 years of 92.1% compared with 76.8% for pulmonary homografts.

We have previously described our initial experience with a bicuspid valved PTFE conduit in 2011,⁹ and since that time, these have been conduit of choice for most RVOT reconstructions at our institution. We initially used these bicuspid valved conduits even in older children and adults, but have now modified our technique to use trileaflet valves in all conduits 16 mm or larger, because these are likely more physiologic and allow more complete coaptation of the valve leaflets. So far, our clinical experience with these larger trileaflet conduits has been excellent. With the recent impressive results of our Japanese colleagues,²⁵⁻²⁷ incorporation of bulging sinuses may be a future modification to our technique.

The inevitability of conduit replacement in infants and young children is in part related to somatic outgrowth of the conduit; however, dysfunction due to valve incompetence and stenosis is an important factor leading to adverse outcomes or need for earlier reintervention. Regarding somatic outgrowth, some authors recommend upsizing conduits to a *z* score greater than +2⁷ or between +1 and +3.^{4,6} This conclusion is somewhat controversial however, as others determined that somatic outgrowth was not a significant factor for conduit exchange. Vitanova and colleagues⁵ found no association with conduit *z* score and conduit explant, and the mean conduit *z* score at explant was only −0.78. Another study by Wells and colleagues²⁹ concluded that only 8% of 40 patients exhibited somatic outgrowth and recommended placement of an initial conduit with a *z* score of 0, as oversized conduits may predispose the patient to external compression and lead to earlier repair. Karamlou and colleagues³⁰ showed no

advantage in the durability of oversized homografts in young patients. Our study did not demonstrate a significant association between initial conduit *z* score and conduit explant or reintervention, with the mean conduit *z* score at explant being −1.18. Conduit *z* score at implantation was a significant factor, however, in the development of conduit stenosis by echocardiography, with larger conduit *z* scores being protective. Yamashita and colleagues²⁷ also demonstrated this similar finding of conduit *z* score being associated with the development of conduit stenosis while not being associated with the rate of conduit replacement. On the basis of this finding, and knowing anecdotally that conduit stenosis remains the primary reason for conduit exchange in this population, we would tend to agree with upsizing the conduit at implant when feasible.

Although the exact mechanism of PTFE conduit failure was not documented at the time of explant because this was a retrospective review, our surgeons have not noticed calcification or shrinkage of the PTFE grafts, which is a well-known complication of homograft conduits. The primary mode of failure with the valved PTFE conduits appears to be fibrosis or narrowing at the distal anastomosis over time. There is no apparent formation of fibrous tissue within the conduit; however, they have noticed a few patients with fibrosis of the valve leaflets resulting in stenosis. Also, there have been a few instances of the leaflets becoming “stuck” in the open position, which would result in conduit insufficiency.

Of clinical relevance, we found a significant difference in hospital LOS between the 2 groups, with the PTFE group having approximately one half the LOS of the homograft group. The reasons for this are likely multifactorial, but the primary determinants are the factors that influenced preoperative LOS, which may include severity of illness or era confounders. An exaggerated anti-inflammatory or immune response to homografts postoperatively could be hypothesized to affect the postoperative LOS because our institution uses primarily nondecellularized homografts; however, there was no statistical difference in postoperative LOS between the homografts and the PTFE conduits.

This suggests that the overall LOS difference is not explained by conduit type.

Study Limitations

This study was subject to the limitations inherent in its retrospective design. Although the time period of 2004 to 2014 starts with the arrival of our current senior surgeon, there may be a potential era effect because there was a shift in conduit selection in 2009, when PTFE conduits were first implanted in our children aged less than 2 years. After this date, selection of conduit was at the discretion of the surgeon, so it is possible that selection bias was a factor. Sicker patients (with small distal pulmonary arteries or elevated pulmonary vascular resistance, and those in whom a competent pulmonary valve was thought to be necessary) may have been selected to receive homografts as opposed to PTFE conduits, even though there was no difference in measured demographic parameters or diagnosis between the 2 groups. To maximize our total numbers, we looked at all diagnoses that included different surgical repairs with conduits placed in both the heterotopic and orthotopic positions, as well as included patients multiple times for each conduit that they received while aged less than 2 years. Also, the decision to proceed with conduit replacement was not uniform, and each patients' surgical- and catheterization-based reintervention was individualized, and institutional preference may have changed over the years. For this reason, we also evaluated echocardiographic predictors of conduit function, including conduit insufficiency and conduit stenosis. These are also not perfect measures for conduit function, because conduit insufficiency is sometimes difficult to grade and not well standardized. Conduit stenosis was a primary reason for conduit exchange in our cohort. This evaluation can be imprecise as well, depending on the echocardiographic windows, potential contamination from branch pulmonary stenosis, and varying loading conditions (hypertension, agitation, pulmonary insufficiency), which all can largely influence the estimations of Doppler velocities, and all were not necessarily taken into account.

CONCLUSIONS

The performance of bicuspid valved PTFE conduits are comparable to that of homografts at our institution. There is no difference in time to conduit explant or in the timing of development of conduit stenosis or insufficiency. Younger age at surgery was found to be a risk factor for conduit explantation, and larger conduit z score is protective against the development of conduit stenosis. Their low cost, availability, ease of construction, and lack of potential allo-sensitization make valved PTFE conduits an appealing alternative to homograft conduits.

Webcast

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Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Discussion

Dr J. Quintessenza (Lexington, Ky). Dr Mercer and the group from Children's Hospital of Pittsburgh report their retrospective review of expanded PTFE conduits compared with homografts in children aged less than 2 years, with 55 patients having 39 PTFE conduits and 26 with homografts. They found no significant difference

between the 2 conduits with regard to the variables, including conduit explant or major interventions. Similar to other studies in the literature, multivariable analysis show that younger age was a risk factor for early explant, as we all know. Also, in general, conduits in small children, irrespective of the material they are made of, have a significant failure rate of approximately 40% to 50% failure at 3 to 5 years.

My first question relates to the mode of failure of the PTFE grafts. Was there proximal or distal suture line fibrosis, which we have seen in other conduit types, leaflet thickening, or a diameter reduction in the tube, so-called shrinkage, like we have seen with some homografts?

Dr C. Mercer (Pittsburgh, Pa). With this study, we didn't specifically evaluate the reasons for explantation. I did look back, and I saw that 75% of the conduits were explanted for a combination of stenosis and insufficiency. There were 3 that were explanted where the conduits were not stenotic, but they went in anyway for branch pulmonary artery stenosis and the conduit was replaced at the same time.

In regard to shrinkage, we don't measure the size of the conduit at explantation. We did look at the conduit Z score at explantation, but that is based solely on the initial size of the conduit. So anecdotally, I don't know of any that have shrunk. I am a cardiology fellow, so I catheterize these patients and haven't really noticed that when we are measuring the size of the conduits that they are much different.

Dr Quintessenza. By inference, one might say if you looked at Z values at implant and there was no significant difference and then Z values at explant, the delta in that number might infer that there was some relative decreased diameter over time. That analysis wasn't done, but it might add some value to the analysis.

Dr Mercer. The delta between the 2 groups was similar. The PTFE group started out a bit bigger than the homograft group, and then when they were explanted, their Z score was slightly more negative.

Dr Quintessenza. Was there calcification of the leaflets or conduits?

Dr Mercer. These don't calcify; there was no calcification that we have seen. Sometimes the leaflets will get a little fibrosis, but no calcification like we usually see with homografts.

Dr Quintessenza. There seems to be an advantage with larger Z scores at implant with regard to developing moderate stenosis but not at explant. Can you tell us what you would recommend now for an optimal Z score at implant at your institution? I see Dr Morell is right behind you, so you can ask him for help.

Dr Mercer. I think we would all tend to agree with upsizing when reasonable as long as there is not going to be any concern for compression. We didn't see an association with Z score and conduit explant, but anecdotally knowing that conduit stenosis in this group is the primary reason for conduit explant, I would tend to agree with upsizing.

Dr Quintessenza. It wasn't really mentioned in the article about patients who had elevated pulmonary artery pressures. I was just wondering what the experience might be at the institution. I know with some other valves, the Contegra especially, I have had early dilatation, acute regurgitation from a hypertensive-type patient. Did you see anything like that or can you make any comments about the pulmonary hypertensive patient with the PTFE conduits?

Dr Mercer. We didn't specifically evaluate that either. I know Dr Morell will make some comments here after you about what his personal experience was with patients with high right ventricle pressures or pulmonary artery pressures. He tells me there is some bias that if he wants to have a competent pulmonary valve in those situations, he would probably choose a homograft. But there have been several patients who unexpectedly had elevated pulmonary artery pressures, and the valve initially performed fine.

Dr Quintessenza. I wonder if he still has that bias.

Dr Mercer. We will see.

Dr Quintessenza. Overall, I think your conclusions are valid, and the PTFE conduits are a satisfactory choice for valved conduits in these younger children. They are lower cost and nonimmunogenic, and their availability makes them an attractive conduit as long as you have somebody who will build them for you.

Dr V. Morell (Pittsburgh, Pa). I want to answer a few of the questions that Jim brought up. First, the mode of failure. I have never explanted one of these conduits and found that there was neointima to the point that there was obstruction of the conduit. These conduits are inert, they don't shrink, so shrinkage is not an issue. There is not massive formation of fibrous tissue inside the conduit. But I have found a couple of patients in whom at the level of the valve leaflets there was fibrosis of the leaflets, and that was part of the obstruction, just at the level of the leaflets. I have also found that at the distal anastomosis, at times fibrous tissue forms and kind of narrows that distal anastomosis over time. But as a whole, those conduits don't shrink, and, at least in my experience, they perform excellently.

We started this in 2009 simply because we had a Japanese influence in our institution; we had a Japanese fellow who had a lot of experience with these conduits in Japan. So he came over and said, Victor, why don't we use these? I had experience in Tampa using Gore-Tex (WL Gore & Associates,

Inc, Flagstaff, Ariz) pulmonary valves, and it made sense.

I had a suspicion that these valves were not going to work well under systemic pressures for the long term. I had a bias that if I am doing a test for pulmonary atresia in a patient with major aortopulmonary collateral arteries, I am going to do unifocalization. I am expecting high pressures distally, and I am going to use a homograft, hoping that that valve is going to work better. In reality, I had a few patients who ended up with systemic pulmonary artery pressures basically with what we call the Mazza valve or a PTFE valve, and those valves have worked fine. Obviously, we are not using it to replace aortic valves, and I am not suggesting that anybody should, but even under high pressure they seem to work okay.

On the basis of these data, which we just collated and received recently, I feel comfortable putting a PTFE valved conduit in, and we do it routinely in most patients. Now with these data, I rarely will use a homograft.

I will also mention that when you do a redo sternotomy to go back, we are always cautious to get close to that homograft, because sometimes it could be quite thin when you go back in and you don't want to get into the right ventricle before you are on pump. With the level of safety that the PTFE conduit also provides, it is a thicker material, you really aren't going to sew through it, and it makes your redo sternotomy that much easier knowing that you have a Gore-Tex conduit in place as opposed to a homograft.

Dr R. Hopkins (Kansas City, Mo).

Victor, you may be able to recall or you may have run across this, but it is a specific question per your review. It did catch my eye, as it did you, that the hospital stay was longer in the homografts. One of our observations over the years has been that patients

who received homografts have a more frequent presentation of postpericardiectomy syndrome—type factors, fever, laboratory signs of inflammatory response, and serositis, which may explain your prolonged hospitalization.

Do you recall or did you pick up on your case review that there was an increased clinical diagnosis of postpericardiectomy syndrome in the homograft group? It would make sense. In the one case, one is an autoimmune response, and in the other case, it would be an allotransplant antibody response.

Dr Mercer. Nothing specifically that we saw. We have been thinking about this, too, what is the reason for the difference in LOS. I would like to think that it is, because the homografts cause an inflammatory and immune response, and they don't tolerate it early on. But postoperative LOS wasn't significant.

I think it is multiple factors why we had a different LOS, the era factor, the homografts earlier, and a lot of those patients had a long preoperative LOS, and then the selection bias with the later half, picking maybe sicker patients for a homograft.

Dr Hopkins. Nonetheless, for years we put these patients on nonsteroidal anti-inflammatory drugs postoperatively.

Dr C. Knott-Craig (*Memphis, Tenn*). In your presentation, the inference was placing a larger homograft would be better in terms of reimplantation. My own bias is the worst being the opposite. My feeling is that if you have a larger homograft, the valve leaflets don't have enough volume to actually close completely, and so they tend to have more pulmonary regurgitation, and early on pulmonary regurgitation, as opposed to a smaller homograft. So I was wondering when you analyzed your patients and looked at the pulmonary regurgitation, did you find that the larger homografts leaked more often or earlier than the smaller ones?

Dr Mercer. No, we didn't see any significant factors associated with pulmonary insufficiency; age was the only thing.

Dr G. Stellin (*Padova, Italy*). Were the homografts you used xenografts from CryoLife (Kennesaw, Ga)? What type of homografts did you use?

Dr Mercer. They were nondecellularized mostly.

Moderator. I think it is an important point that the decellularization may change the blanket statement that allosensitization is a big deal with homografts. I am not sure to what degree. But despite that, we can't ignore cost anymore, and cost is a huge difference between homografts. Whether allosensitization is something or not, it is really heartening to see all these alternatives being developed that are going to be very cost-effective.

FIGURE E1. Competing risk analysis shown for the primary end point of time to conduit explantation. Death is shown as a competing risk between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene.

FIGURE E3. Competing risk analysis shown for the end point of moderate conduit stenosis. Death and conduit explantation or major reintervention are shown as competing risks between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene.

FIGURE E2. Competing risk analysis shown for the primary end point of time to conduit explantation or major reintervention. Death is shown as a competing risk between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene.

FIGURE E4. Competing risk analysis shown for the end point of severe conduit insufficiency. Death and conduit explantation or major reintervention are shown as competing risks between homograft conduits and PTFE conduits. *PTFE*, Polytetrafluoroethylene.