Longevity of homograft conduits for infant right ventricular outflow tract reconstruction in the modern era

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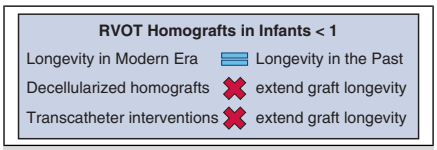
ABSTRACT

Background: Homograft conduits are widely used for right ventricular outflow tract (RVOT) reconstruction. The literature reports a 50% 2-year freedom from reoperation for infants age <1 year. Recently, decellularized homografts and transcatheter interventions have been purported to prolong conduit longevity. This study evaluated homograft longevity in the modern era.

Methods: All infants (age <1 year) receiving a homograft RVOT conduit at a single institution between 2006 and 2024 were reviewed. The cumulative incidence function was used to estimate the cumulative probability of reoperation within 2 years, accounting for the competing risk of death. A Fine-Gray regression model with subdistribution hazard ratios (sHRs) identified predictors for reoperation within 2 years. Data on transcatheter interventions also were collected to aid the analysis.

Results: A total of 74 patients met the inclusion criteria, who had a median age of 1.8 months (interquartile range [IQR], 0.3-5.5 months) and median weight of 4.2 kg (IQR, 3.2-5.8 kg) at homograft implantation. The cumulative incidence was 44.1% for surgical reintervention within 2 years and 12.3% for death before reoperation. Younger age, lower weight, smaller homograft size, and lower homograft *z*-score were associated with increased early reoperation. Nineteen patients (25.7%) had a transcatheter intervention, including 6 (31.6%) before a surgical reoperation, 6 (31.6%) after a surgical reoperation, and 7 (36.8%) without a surgical reintervention.

Conclusions: Compared with the literature, time to operative reintervention after homograft RVOT reconstruction in infants age <1 year has not changed significantly in the modern era, despite the expanded use of decellularized homografts and catheter-based interventions. (JTCVS Open 2025;28:469-78)



Modern advances have not extended homograft longevity in infants age <1 year.

CENTRAL MESSAGE

For infants age <1 year, right ventricular outflow tract homograft longevity has not increased in the modern era with decellularized homografts and transcatheter interventions.

PERSPECTIVE

Homograft conduit longevity has not increased in the modern era for infants age <1 year requiring right ventricular outflow tract reconstruction, despite such advances as decellularized homografts and transcatheter interventions. Future efforts to understand and mitigate the need for surgical reoperation in this young population are warranted.

Cryopreserved homograft valved conduits are the most common conduits used for reconstruction of a right ventricular outflow tract (RVOT) in neonates and infants with congenital heart disease.[1] Homograft conduits lack the capacity for additional growth. Additionally, accelerated immune-mediated deterioration has been observed in young recipients.[2] These factors contribute to decreased RVOT homograft longevity in younger patients, with an approximate 50% 2-year freedom from reoperation in infants age <1 year reported in a study that examined outcomes from 1985 to 1999.[3] Since then, biomedical developments, such as the advent of decellularized homografts and transcatheter interventions, have been purported to extend homograft longevity in the modern era.

A common mode of failure in homograft conduits is stenosis due to an early postoperative inflammatory reaction.[4] To mitigate this effect, starting in 2001, decellularized homografts have been used in hopes of prolonging homograft longevity.[5] Since then, decellularized RVOT homografts have demonstrated lower rates of reoperation in both

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Abbreviations and Acronyms
CI = confidence interval
CIF = cumulative incidence function
IQR = interquartile range
RVOT = right ventricular outflow tract
sHR = subdistribution hazard ratio

children and adult patients.[4-6] For homografts that do fail, either transcatheter or surgical reintervention is needed. The use of transcatheter interventions, such as conduit stenting, balloon angioplasty, and valve replacement, has increased in recent years as an alternative to reoperation for some patients.[7]

Although these advances show promise, how they have impacted homograft longevity in the uniquely vulnerable patient population of infants age <1 year remains unclear. This study aimed to evaluate homograft longevity and 2-year freedom from surgical reoperation for infants age <1 year in the modern era, as well as to identify risk factors associated with the need for reoperation and characterize the impact of transcatheter interventions in this population.

METHODS

The Institutional Review Board or equivalent Ethics Committee of the Vanderbilt University Medical Center approved the study protocol and publication of data (Protocol 240,290, approved on March 15, 2024). Patient written consent for publication of the study data was waived by the owing to the study's retrospective nature.

Study Population

All infants under age <1 year who underwent homograft RVOT conduit implantation at a single institution between January 2006 and January 2024 were reviewed. Patients who first received a nonhomograft and later received a homograft conduit replacement while still under age 1 year were also included. All RVOT homograft conduits were obtained from Artivion (formerly CryoLife), except for 2 conduits obtained from the University of Alabama Tissue Biorepository. All homograft conduits in this study were decellularized grafts.

Data Definitions and Outcomes

The main outcome of this study was surgical replacement for RVOT conduit failure within 2 years after initial homograft implantation, with a competing risk of death due to any cause. Other outcomes of interest included rates and types of transcatheter reinterventions and reason for reintervention, including conduit failure modes and branch pulmonary artery (PA) stenosis. Conduit failure modes were characterized as conduit stenosis, conduit insufficiency, both, or other (conduit pseudoaneurysm). Quantitative data indicating a need for reintervention included a pressure gradient ≥40 mm Hg and an right ventricular end-diastolic volume index >150 mL/m^2. Other signs of right ventricular dysfunction or symptoms also may necessitate a reintervention, but specific indications and measurements vary, and the decision for transcatheter versus surgical reintervention is determined on a case-by-case basis. However, several potential clinical indications call for surgical reoperation over transcatheter intervention. These include the presence of other pathologies necessitating concomitant surgical intervention, proximity of coronaries that increase the risk for transcatheter interventions, and the clinical determination that the patient has simply outgrown the conduit as opposed to other causes of stenosis/regurgitation.

A z-score for homograft conduit sizing was calculated using the difference between the actual diameter of the implanted homograft and the predicted pulmonary valve diameter based on patient weight, using previously validated formulas.[8] Higher z-score absolute values indicate larger deviation of implanted homograft size from predicted size, with negative z-scores indicating undersized homografts.

Statistical Analyses

Demographic data were shown as absolute number (percentage) for categorical variables, and median (interquartile range [IQR]) for continuous variables. The cumulative incidence function (CIF) was used to estimate the cumulative probability of reoperation within 2 years of initial homograft implant, accounting for the competing risk of death. Univariate Fine-Gray regression models with subdistribution hazard ratio (sHR) were used to quantify the effects of each variable on the hazard for operative reintervention within 2 years. Variables of interest included age, weight, homograft type (aortic vs pulmonary), homograft size, and homograft z-score. Variables significantly associated with reoperation within 2 years on univariate analysis were input into a multivariate Fine-Gray regression model. A sensitivity analysis was performed by excluding patients with early postoperative death (within 30 days of homograft implant) not attributable to homograft failure. A subset analysis of all patients requiring surgical reoperation at any time was conducted. Characteristics of patients requiring reoperation within 2 years versus after 2 years were compared using the Fisher exact test for categorical variables and the Wilcoxon rank-sum test for continuous variables. A significance level of $P < .05$ was used throughout. All analyses was conducted using R version 4.3.3 (R Core Team).

RESULTS

Initial Homograft Implantation

A total of 74 patients met the study inclusion criteria. The median age at first homograft implant was 1.8 (IQR, 0.3-5.5) months, and the median weight was 4.2 (IQR, 3.2-5.8) kg (Table 1). A wide range of etiologies necessitating RVOT reconstruction were represented, with the most common being Tetralogy of Fallot (n = 23; 31.1%), truncus arteriosus (n = 74; 27.0%), and pulmonary atresia with ventricular septal defect (n = 20; 27.0%). There were 42 aortic homografts (56.8%) and 32 pulmonary homografts (43.2%), with a median diameter of 11 (IQR, 10-14) mm. Compared to the predicted pulmonary orifice diameter using equations based on infant weight described by Rowlatt and colleagues,[8] 1 (2.4%) implanted homograft was undersized. The median z-score of the implanted homograft compared to the predicted diameter was 1.15 (IQR, 0.81-1.56). Among these patients, 3 (4.1%) had a prior nonhomograft RVOT conduit (all Gore-Tex nonvalved conduits) that had been replaced with a homograft within 1 year of age.

Throughout the complete follow-up, 15 patients (20.3%) died, with a median time from initial homograft implantation to death of 59 (IQR, 25-235) days. Ten of the patients who died (13.5%) did so before a second RVOT conduit operation (surgical or transcatheter). There were 5 (6.8%) early deaths, none of which due to homograft failure. A

TABLE 1. Demographics data of all infants age <1 year receiving an RVOT homograft conduit implant between 2006 and 2024 (N = 74)

Variable	Value
Age at surgery, mo, median (IQR)	1.8 (0.3-5.5)
Weight at surgery, kg, median (IQR)	4.1 (3.2-5.8)
Primary diagnosis, n (%)	
TOF/DORV, PS	23 (31.1)
Truncus arteriosus	20 (27.0)
Pulmonary atresia, VSD	20 (27.0)
TGA, VSD, PS/L-TGA	6 (8.1)
AS/AI (Ross)	3 (4.1)
Pulmonary atresia, IVS	1 (1.4)
Ebstein anomaly	1 (1.4)
Homograft type, n (%)	
Aortic	42 (56.8)
Pulmonary	32 (43.2)
Homograft diameter, mm, median (IQR)	11 (10-14)
z-score, median (IQR)	1.15 (0.81-1.56)
Undersized, n (%)	1 (2.4)
Nonhomograft explanted, n (%)	3 (4.1)

IQR, Interquartile range; *TOF*, tetralogy of Fallot; *DORV*, double-outlet right ventricle; *PS*, pulmonary stenosis; *VSD*, ventricular septal defect; *TGA*, transposition of the great arteries; *L*, left *AS*, aortic stenosis; *AI*, aortic insufficiency; *IVS*, intact ventricular septum.

schematic summarizing the clinical courses of our patient cohort was shown in Figure 1.

CIF and Predictors of Reoperation

Using a CIF to evaluate incidence of surgical reoperation with death as a competing risk, we found a cumulative incidence of 44.1% for surgical reintervention within 2 years and of 12.3% for death before reoperation (Figure 2). Our univariate Fine-Gray subdistribution hazards model identified that younger age (subdistribution hazards ratio [sHR] 0.80 per month increase; 95% confidence interval [CI], 0.70-0.92), lower weight at homograft implantation (sHR, 0.76 per kg increase; 95% CI, 0.60-0.97), smaller homograft size (sHR, 0.81 per mm increase, 95% CI, 0.71-0.93), and lower homograft size *z*-score (sHR, 0.60 per unit increase; 95% CI, 0.38-0.93) were each significantly associated with increased hazard for reoperation within 2 years (Table 2). Use of a pulmonary homograft (relative to aortic homograft) was not associated with hazard for reoperation. When adjusting for age, weight, homograft size, and *z*-score in a multivariate regression model, none of these variables remained independently significant (Table E1).

In our sensitivity analysis after excluding the 5 early deaths, the cumulative incidence was 47.4% for reoperation within 2 years and 5.9% for death before reoperation (Figure E1). Similar to above, younger age, lower weight at initial homograft implantation, smaller homograft size, and lower homograft size *z*-score were each associated with increased hazard for reoperation in univariate analysis (Table E2).

Subset Requiring Surgical Reoperation

Of the 74 patients in this study, 47 (63.5%) required a second surgery, with a median time to surgical reintervention of 250 (IQR, 143-1464) days. Of these 47 patients, 32 (68.1%) underwent reoperation within 2 years of their initial surgery, and 15 (31.9%) did so after 2 years (Table 3). Patients who underwent reoperation within

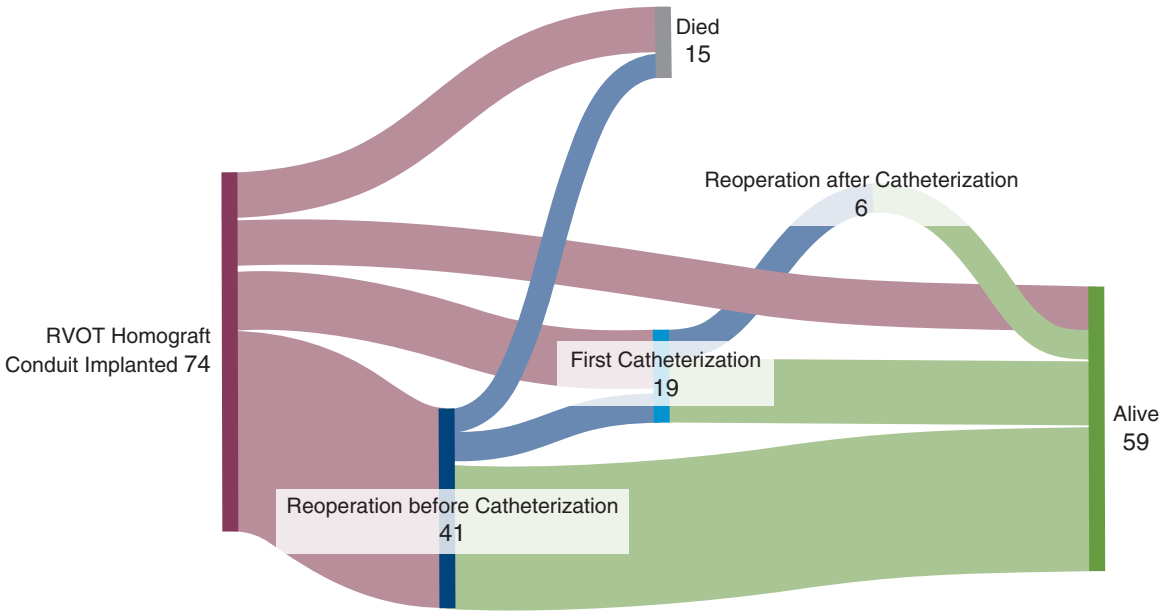


FIGURE 1. Schematic summarizing clinical courses for patients receiving a right ventricular outflow tract (RVOT) homograft conduit at age <1 year.

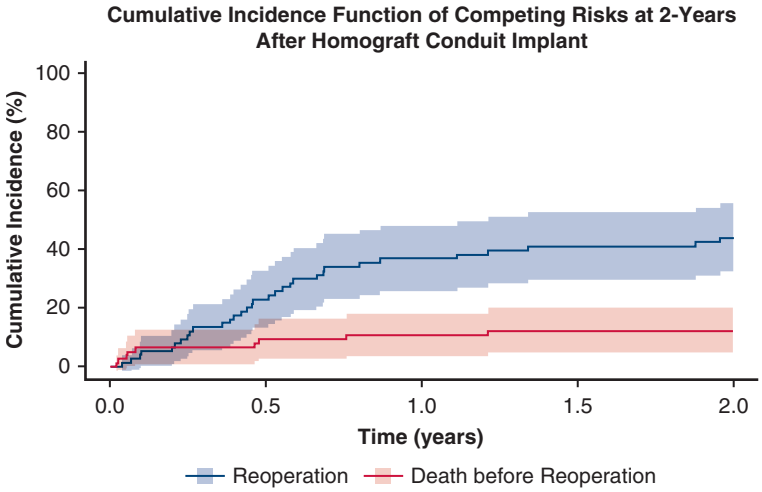


FIGURE 2. Cumulative incidence function plot of the probability of reoperation within 2 years of initial homograft conduit implantation, with death before reoperation as a competing risk. We found an incidence of reoperation within 2 years of 44.1% and an incidence of death before reoperation of 12.3%. The shaded area represents the 95% confidence interval.

2 years were more likely to receive an aortic homograft at their second surgery (43.8% vs 0%; $P = .002$), were more likely to receive a smaller second homograft (median diameter, 15 mm vs 22 mm; $P < .001$), and had a smaller increase in homograft size relative to their initial homograft (median, +4.5 mm vs +9.5 mm; $P = .007$). Patients were more likely to present with either conduit stenosis or conduit insufficiency as the reason for reoperation within 2 years, and more likely to have both stenosis and insufficiency when presenting for reoperation after 2 years ($P = .004$). Although statistically insignificant, a trend toward increased overall mortality among patients requiring reoperation within 2 years was seen (15.6% vs 0%; $P = .16$).

Catheter Reinterventions

Among the 74 patients in the study cohort, 19 (25.7%) had a transcatheter intervention, with a median time to first catheter intervention of 385 (IQR, 259-865) days (Table 4). These first catheter interventions included 8 balloon expansions, 10 conduit stenting procedures, and 1 Medtronic Melody valve implantation. Indications for transcatheter interventions included conduit stenosis (n = 16; 84.2%), conduit insufficiency (n = 1; 5.3%), and both (n = 2; 10.5%). Regarding the timing of catheterization, 6 (31.6%) occurred before a second surgical reoperation, 6 (31.6%) occurred after a second surgical reoperation, and 7 (36.8%) occurred without a surgical reintervention.

Among the 19 patients receiving a transcatheter intervention, 8 required a second transcatheter intervention, which included 2 balloon angioplasties, 2 conduit stenting procedures, and 4 Melody valve implantations. The indication for repeat transcatheter intervention was conduit stenosis in all 8 patients. Regarding the timing of follow-up catheterization, 1 (12.5%) was done prior to surgical reoperation, 4 (50.0%) were done after a surgical reoperation, and 3 (37.5%) were done without a surgical reintervention.

TABLE 2. Univariate sHR for patient and homograft characteristics on the hazard for surgical reoperation within 2 years

Variable	sHR (95% CI)	*P* value
Age, mo	0.80 (0.70-0.92)	**.002**
Weight, kg	0.76 (0.60-0.97)	**.026**
Pulmonary homograft	0.89 (0.44-1.80)	.75
Homograft size, mm	0.81 (0.71-0.93)	**.002**
z-score	0.60 (0.38-0.93)	**.021**

Significant values are in bold type. *sHR*, Subdistribution hazard ratio; *CI*, confidence interval.

DISCUSSION

Cryopreserved homograft conduits are widely used for RVOT reconstruction in infants, and modern advances such as decellularization and transcatheter interventions have been purported to extend homograft longevity. Historically, infants receiving a homograft at age <1 year have represented a unique population, with a reoperation rate within 2 years close to 50%.[3] This study reevaluated RVOT homograft longevity in the modern era among this vulnerable population. The main findings are that (1) modern rates of RVOT conduit surgical reintervention are close to historical rates among infants age <1 year, (2) certain patient demographics and initial homograft characteristics may favor prolonged homograft longevity, and (3) transcatheter interventions do not appear to prolong the time to surgical reoperation in this cohort.

The factors that we identified as associated with decreased homograft longevity—younger age, lower

TABLE 3. Subset analysis of patients who received a second surgical intervention on the initial homograft conduit (N = 47)

Variable	Within 2 y (N = 32; 68.1%)	After 2 y (N = 15; 31.9%)	*P* value
First surgery			
Age at surgery, mo, median (IQR)	0.4 (0.2-3.8)	4.2 (1.0-6.5)	**.026**
Weight at surgery, kg, median (IQR)	3.3 (3.1-4.8)	5.5 (3.7-6.1)	**.033**
Diagnosis, n (%)			.53
TOF/DORV	8 (25.0)	6 (40.0)	
Truncus	13 (40.6)	5 (33.3)	
Pulmonary atresia, VSD	9 (28.1)	2 (13.3)	
TGA, VSD, PS/L-TGA	1 (3.1)	1 (6.7)	
AS/AI (Ross)	1 (3.1)	1 (6.7)	
Homograft type, n (%)			>.99
Aortic	19 (59.4)	9 (60.0)	
Pulmonary	13 (40.6)	6 (40.0)	
Homograft diameter, mm, median (IQR)	10.0 (9.0-11.0)	13.0 (10.0-14.5)	**.013**
z-score, median (IQR)	1.1 (0.8-1.2)	1.3 (0.8-1.6)	.22
Nonhomograft explanted, n (%)	1 (3.1)	1 (6.7)	.54
Second surgery			
Catheter intervention prior to second surgery, n (%)	4 (12.5)	2 (13.3)	>.99
Time to second surgery, d, median (IQR)	167 (93-250)	1770 (1556-2610)	<**.001**
Age at second surgery, mo, median (IQR)	6.9 (5.1-11.4)	60.2 (55.8-91.7)	<**.001**
Conduit type, n (%)			**.002**
Aortic	14 (43.8)	0 (0)	
Pulmonary	16 (50.0)	13 (86.7)	
Nonhomograft	2 (6.3)	1 (6.7)	
Conduit removed	0 (0)	1 (6.7)	
Conduit diameter, mm, median (IQR)	15.0 (13.8-18.2)	22.0 (20.2-23.0)	<**.001**
Change from first conduit, mm, median (IQR)	4.5 (3.0-8.0)	9.5 (5.2-11.0)	**.007**
Conduit indications, n (%)			**.004**
Stenosis	13 (40.6)	5 (33.3)	
Insufficiency	11 (34.4)	1 (6.7)	
Both stenosis and insufficiency	4 (12.5)	9 (60.0)	
Pseudoaneurysm	4 (12.5)	0 (0)	
PA indications, n (%)			>.99
None	11 (34.4)	5 (33.3)	
Left PA stenosis	5 (15.6)	3 (20.0)	
Right PA stenosis	4 (12.5)	2 (13.3)	
Bilateral PA stenosis	2 (6.3)	1 (6.7)	
Bilateral branch PA stenosis	10 (31.2)	4 (26.7)	
Overall mortality, n (%)	5 (15.6)	0 (0)	.16

Significant values are in bold type. PA stenosis was diagnosed based on preoperative diagnostic catheterization. Reintervention targeting PA stenosis were determined on a case-by-case basis. *IQR*, Interquartile range; *TOF*, tetralogy of Fallot; *DORV*, double-outlet right ventricle; *VSD*, ventricular septal defect; *TGA*, transposition of the great arteries; *AS*, aortic stenosis; *AI*, aortic insufficiency; *PA*, pulmonary artery.

weight, smaller absolute homograft size, and lower homograft *z*-score—also have been reported in previous studies.[3,9,10] However, those studies found that use of an aortic homograft was associated with shorter time to reoperation, whereas we found no differences between pulmonary and aortic homografts. Given that these prior studies included patient cohorts older than our present cohort, this difference between aortic and pulmonary homograft longevity may exist only in older patients. It is also important to note that the predictors we report were identified only in univariate analysis; after adjustments in multivariate regression, no statistically significant associations were found. We believe that this is due to a combination of our small sample size and possible collinearity between these variables. Therefore, we believe that our findings are still useful for guiding clinical care, especially in regard to the adjustable variables (homograft size and *z*-score).

TABLE 4. Summary of transcatheter interventions performed on the homograft conduit

Variable	Value
Total number requiring transcatheter interventions (N = 19)	
First intervention, n (%)	
Balloon	8 (42.1)
Stent	10 (52.6)
Melody valve	1 (5.3)
Time to catheterization, d, median (IQR)	385 (259-865)
Catheterization before surgical reoperation, n (%)	6 (31.6)
Catheterization after surgical reoperation, n (%)	6 (31.6)
Catheterization without surgical reoperation, n (%)	7 (36.8)
Conduit indications, n (%)	
Stenosis	16 (84.2)
Insufficiency	1 (5.3)
Both	2 (10.5)
PA indications, n (%)	
Right PA stenosis	1 (5.3)
Bilateral PA stenosis	2 (10.5)
Bilateral branch PA stenosis	2 (10.5)
Total number requiring second transcatheter intervention (N = 8)	
Second intervention, n (%)	
Balloon	2 (25.0)
Stent	2 (25.0)
Melody valve	4 (50.0)
Time to second catheterization, d, median (IQR)	3304 (1564-3788)
Catheterization before surgical reoperation, n (%)	1 (12.5)
Catheterization after surgical reoperation, n (%)	4 (50.0)
Catheterization without surgical reoperation, n (%)	3 (37.5)
Conduit indications, n (%)	
Stenosis	8 (100)
Insufficiency	0 (0)
Both	0 (0)

PA stenosis was diagnosed based on preoperative diagnostic catheterization. Reintervention targeting PA stenosis was determined on a case-by-case basis.

As Niemantsverdriet and colleagues[9] also have argued, we believe that one should choose the largest possible conduit when sizing RVOT homografts. Our current practice already entails choosing the largest homograft conduit that can safely fit in position, so this may be easier said than done. Furthermore, logistical considerations, such as conduit availability and distance from our center, also could have affected whether or not the theoretical largest safe homograft size was used.

Decellularized homografts have been presented as another strategy for prolonging homograft longevity. Several studies analyzing adult patients undergoing the Ross procedure with an RVOT homograft conduit implant have shown that decellularized homografts prolong conduit longevity.[4,5,11,12] Other studies looking at all indications for RVOT reconstruction also found a similar benefit from using decellularized homografts, but the studies included primarily adolescent/young adult patients.[6,13,14] Although we did not have an internal comparison cohort using non-decellularized homografts, our 2-year freedom from reoperation rates were similar to those reported by Tweddell and colleagues in 2000,[3] before the advent of decellularized homografts. Therefore, our data may suggest that decellularized homografts do not have the same benefit in our much younger patient population compared to studies in older cohorts. It is also possible that homograft failure in older patients is driven more by the inflammatory response, whereas patient growth is the primary driver in young infants. However, further investigation is needed to validate this hypothesis.

Finally, transcatheter interventions are another promising method to prolong homograft longevity. Transcatheter interventions have demonstrated safety even when performed in the early postoperative period after congenital heart surgery.[15] Several studies have shown that in young children (~5-7 years), endovascular stenting across a RVOT homograft conduit is a successful method of prolonging the time to surgical reoperation on the conduit.[16-18] Another study examining patients age <1 year with truncus arteriosus undergoing RVOT homograft implantation found a freedom of reintervention rate of 48% at 2 years, although they included both surgical and transcatheter interventions in this calculation.[10] In general, there is a lack of data examining how transcatheter interventions have affected homograft longevity among the young, vulnerable patient population included in our study. Our results suggest that while transcatheter interventions are an option, they do not seem to prolong the time to the need for repeat surgery for RVOT conduit replacement in infants age <1 year.

The rate of transcatheter interventions also was low in our cohort, with only 19 of the 74 patients (25.7%) ever receiving a transcatheter intervention. Furthermore, among these 19 patients, 6 (31.6%) received a transcatheter intervention only after undergoing a second surgery. However, it is important to note that the majority of our patients (n = 41; 55.4%) underwent repeat surgery as their first reintervention, and 30 of these 41 (73.2%) are alive without needing another reintervention, either surgical or transcatheter. Whether these findings simply reflect the difficulty in prolonging homograft longevity in our young patient population, or whether transcatheter interventions are underutilized in this cohort, is unclear. This remains an area for robust discussion, and future work is needed to elucidate scenarios in which transcatheter intervention would effectively prolong homograft longevity versus when surgical reoperation provides the greater probability of long-term clinical stability.

Throughout our institution's experience and as demonstrated by this study, we have learned that care for this young, unique cohort is complex and requires deliberate multidisciplinary collaboration and decision making. While

we have found that modern advances have increased the available options for the care of older patients (such as the choice between bioprosthetic vs mechanical valves in surgical reoperation or between Melody valve implantation vs stenting in transcatheter reinterventions), we also have found that this increased flexibility does not fully extend to young infants/neonates.

We also have learned that the infant's anatomy often dictates the decision of transcatheter versus surgical reintervention. Outgrowing a first homograft conduit also will necessitate a surgical reoperation, which is something that cannot be easily delayed. Investigations of biologically active valves that can grow with the patient may address this need in young patient populations someday, but only time will tell. In conclusion, care for these young patients often comes down to shared decisions made on a case-by-case basis between the care teams and family, with both short-term clinical benefit and long-term patient quality of life considered.

Limitations

The main limitations of our study are its retrospective nature and extended enrollment period, during which some patients may have been lost to follow-up and the most updated clinical course might not be available for some patients. Changing clinical practices and the lack of specific criteria for surgical versus transcatheter reintervention may limit the generalizability of our findings. Care for these complex patients is very practice-dependent, with the course of care may vary due to patient/family wishes, physician preference, and different institutional standards, which may further limit this study's generalizability. Nonetheless, our findings are consistent with those of previous studies, and practical takeaways such as maximizing initial conduit size could still help guide clinical decision making. Finally, we did not have an internal comparison group and used a historical study to extrapolate the potential effects (or lack thereof) of decellularization and transcatheter interventions on homograft longevity in patients under age <1 year. However, it is impractical to directly compare these advances in a prospective manner, as both decellularized homografts and transcatheter interventions have become standard of care in the modern era.

We believe that this does not change our overall message that infants age <1 year are a uniquely vulnerable population for whom advances shown to prolong homograft longevity in older patients do not have a similar effect.

CONCLUSIONS

For infants age <1 year requiring a homograft implantation for RVOT reconstruction, rates of the need for surgical reoperation within 2 years have not decreased in the modern era compared to the literature. Decellularized homografts, while shown to be effective in older patients, do not appear to prolong homograft longevity in this younger cohort. Transcatheter interventions similarly may not extend homograft longevity, but this could reflect an underuse of transcatheter interventions in this cohort.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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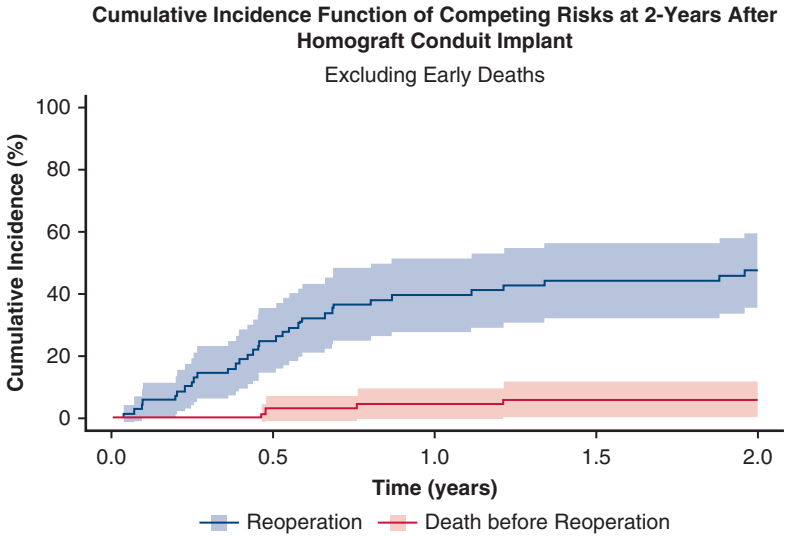


FIGURE E1. Sensitivity analysis showing the cumulative incidence function plot of probability for reoperation within 2 years of initial homograft conduit implant with death before reoperation as a competing risk, after excluding early (<30 days from implant) deaths. We found an incidence of 47.3% for reoperation within 2 years and 5.9% for death before reoperation. The shaded are represents the 95% confidence interval.

TABLE E1. Multivariate sHR for patient and homograft characteristics on the hazard for surgical reoperation within 2 years

Variable	sHR (95% CI)	*P* value
Age, mo	0.79 (0.62-1.01)	.065
Weight, kg	1.46 (0.74-2.88)	.28
Homograft size, mm	0.71 (0.37-1.36)	.30
z-score	2.06 (0.22-19.32)	.53

CI, Confidence interval; *sHR*, subdistribution hazard ratio.

TABLE E2. Sensitivity analysis after excluding early (<30 days from initial implantation) deaths, with sHRs for patient and homograft characteristics on the hazard for surgical reoperation within 2 years

Variable	sHR (95% CI)	*P* value
Age, mo	0.81 (0.71-0.93)	**.002**
Weight, kg	0.76 (0.56-0.96)	**.020**
Pulmonary homograft	0.88 (0.43-1.78)	.72
Homograft size, mm	0.82 (0.72-0.93)	**.002**
z-score	0.58 (0.37-0.90)	**.016**

Significant values are in bold type. *sHR*, Subdistribution hazard ratio; *CI*, confidence interval.