# Reconstruction of right ventricular outflow tract in neonates and infants using valved cryopreserved femoral vein homografts

Ofer Schiller, MD,[a] Pranava Sinha, MD,[b] David Zurakowski, PhD,[c] and Richard A. Jonas, MD[b]

**Objectives:** Aortic or pulmonary homografts (A/PHs) are common biomaterials used for restoration of right ventricle to pulmonary artery continuity for repair of various congenital heart defects. The smaller sized homografts required for early primary repair in neonates and infants are prone to early failure and are in short supply. Due to these limitations, since 2008 it has been our preference to use valved segments of cryopreserved femoral vein homograft (cFVH) for right ventricle to pulmonary artery reconstruction. This study was undertaken to assess the performance of cFVH compared with A/PH in neonates and infants.

**Methods:** A retrospective review of all infants and neonates who underwent biventricular early primary repair with right ventricle to pulmonary artery reconstruction using homograft conduits at a single center was conducted. Patients who received cFVH constituted the study group, whereas all other patients received A/PH and formed the control group. Patients with pulmonary atresia, ventricular septal defect, and major aortopulmonary collaterals who had conduits placed to promote pulmonary artery growth or to unifocalized pulmonary vasculature were excluded from the study because they have different clinical indications for reoperation and reintervention. Demographic, anatomical, perioperative, and follow-up variables were compared between the groups using univariate and multivariable Cox regression analyses. Kaplan-Meier analysis and log-rank tests were used to identify intergroup differences in freedom from catheter intervention, reoperation, or overall freedom from reintervention (catheter and/or surgical).

**Results:** A total of 36 patients (20 cFVH and 16 A/PH) were included in the study. There were no intergroup differences in the demographic, anatomic, and perioperative variables, except for significantly shorter aortic crossclamp time in the cFVH group. Univariate analysis revealed a higher catheter reintervention rate as well as higher reoperation rate in the A/PH group. Multivariate Cox regression correcting for the intergroup differences in the length of follow-up revealed comparable freedom from catheter intervention, freedom from reoperation, or freedom from either intervention in the cFVH and the A/PH groups.

**Conclusions:** Valved femoral vein homografts have comparable short- and intermediate-term performance to A/PHs for right ventricular outflow tract reconstruction and are an attractive alternative to other small conduits for use in neonates and infants. (J Thorac Cardiovasc Surg 2014;147:874-9)

Consistent with the general trend toward early primary repair, right ventricular outflow tract (RVOT) reconstruction with a conduit is increasingly used in neonates and infants.[1,2] Current surgical options for conduits for these small patients with complex disease include aortic[3] or pulmonary homografts[4] (A/PHs) and bovine jugular vein grafts (Contegra; Medtronic Inc, Minneapolis, Minn), all of which have the drawback of early failure, especially in the small size range required for this patient population.[5-7] A/PHs are also in short supply in the small size ranges required for neonates and infants and are considerably more expensive than cryopreserved femoral vein homografts (cFVHs). Pericardial conduits can be limited by the availability of suitable autologous pericardium and the need for additional personnel and operative time for fabrication, and do not offer better conduit durability.[8]

For all of the above reasons it has been our preference to use cFVH for RVOT reconstruction since 2008.[9] Here we report our intermediate-term cumulative experience in neonatal and infant RVOT reconstruction with this novel alternative conduit.

## METHODS

A waiver of documented consent was granted by the Children's National Medical Center Institutional Review Board due to the retrospective nature of the study. Data on all neonates and infants (aged <1 year) who underwent a single-stage biventricular repair of congenital heart disease using cFVH as a valved right valve to pulmonary artery (RV-PA) conduit between July 2008 and December 2012 (cFVH group) were retrospectively reviewed. The control group consisted of children with similar heart

From the Division of Cardiology,[a] and Division of Cardiac Surgery,[b] Children's National Medical Center, Washington, DC; and Departments of Anesthesia and Surgery,[c] Boston Children's Hospital, Harvard Medical School, Boston, Mass.

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Address for reprints: Richard A. Jonas, MD, Division of Cardiac Surgery, Children's National Heart Institute, Children's National Medical Center, 111 Michigan Ave, NW, Washington, DC 20010 (E-mail: lyoung@cnmc.org).

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**Abbreviations and Acronyms**
A/PH = aortic or pulmonary homograft
cFVH = cryopreserved femoral vein homograft
RVOT = right ventricular outflow tract
RV-PA = right ventricle to pulmonary artery

defects, matched by age and weight, who had A/PH used for RV-PA reconstruction before July 2008 (A/PH group). Patients with pulmonary atresia, ventricular septal defect, and major aortopulmonary collaterals who had conduits placed to promote pulmonary artery growth or unifocalized pulmonary vasculature were excluded from the study because they have different clinical indications for reoperation and reintervention. Demographic, preoperative, intraoperative, postoperative, and follow-up data were recorded and compared between the 2 groups. The primary end points were conduit catheter reinterventions (percutaneous intervention on the conduit), conduit reoperations (surgical replacement/revision), or both. Intraoperative and immediate postoperative variables constituted the secondary end points.

### Operative Technique

All patients underwent biventricular complete intracardiac repair and RVOT reconstruction via a median sternotomy with hypothermic cardiopulmonary bypass support. Deep hypothermic circulatory arrest was performed only when aortic arch reconstruction was required. RVOT reconstruction was performed using a valved segment of cFVH (cFVH group) or A/PH (A/PH group). The operative technique has been described in our previous report.[9] After selecting an appropriately sized segment with a competent valve, maintaining antegrade orientation, the distal anastomosis to the pulmonary artery bifurcation was fashioned using continuous 6-0 polypropylene sutures. The proximal end of the graft was spatulated posteriorly and anastomosed to the right ventriculotomy using a running 5-0 polypropylene suture. No hoods were necessary to augment the proximal anastomosis. Primary sternal closure was performed whenever possible.

In the A/PH group, A/PHs were used to reconstruct the RVOT using standard techniques, including a pericardial hood at the proximal anastomosis. Additional procedures were performed as indicated by the cardiac anatomy.

The indication for catheter- or surgical-based reintervention was severe conduit stenosis, insufficiency, or a combination of moderate stenosis and moderate conduit insufficiency as determined either by echocardiogram or hemodynamic cardiac catheterization, and was similar for both groups.

### Statistical Analysis

Univariate analysis was performed to compare demographic, perioperative, and follow-up data between the 2 groups. Continuous data are presented as median (interquartile range) and were compared using the Mann-Whitney *U* test. Proportions were compared using the Fisher exact test and categorical data by the $\chi^2$ test. Follow-up data were analyzed for freedom from catheter intervention, reoperation (surgical conduit revision/replacement), or overall freedom from any reintervention (catheter and/or surgical) using Kaplan-Meier analysis with the log-rank test to identify intergroup differences. Multivariate Cox regression was applied to compare time to catheter intervention or surgical reintervention controlling for conduit diameter and length of follow-up as covariates. Data was analyzed using IBM SPSS Statistics version 19.0 (IBM-SPSS Inc, Armonk, NY).

## RESULTS

Between July 1998 and July 2012, 36 patients younger than age 1 year underwent 1 stage complete biventricular repair using a RV-PA conduit. Twenty patients (mean weight, 3.4 kg; mean age, 36 days) underwent RVOT reconstruction using a cFVH, whereas 16 infants (mean weight, 3.4 kg; mean age, 24 days) underwent placement of aortic (n = 5) or pulmonary (n = 11) homograft for restoration of RV-PA continuity. Demographic, operative, and postoperative data are detailed in Table 1. We switched to using the cFVH in 2008; therefore, all patients in the study group were operated on between 2008 and 2012, whereas the control group underwent surgery before 2008. The 2 groups were comparable for demographic, anatomic, and perioperative variables, except for a significantly shorter mean aortic crossclamp time for the cFVH group (cFVH group, 64 minutes; A/PH group, 81 minutes; $P = .04$). There were 2 operative mortalities (defined as occurring on the same admission or <30 postoperative days) in the cFVH group, 1 due to a stroke >2 weeks after conduit placement in a patient with truncus arteriosus with interruption of the aortic arch, and the other secondary to refractory postoperative low cardiac output and hypoxic ischemic encephalopathy in a patient with truncus arteriosus with interrupted aortic arch and severe truncal valve insufficiency who underwent complete repair. There were no operative deaths in the control group (Table 1). There were 2 late deaths in the cFVH group, both of them unrelated to the conduit. One patient with double outlet right ventricle, subpulmonic ventricular septal defect, aortic stenosis, severely hypoplastic ascending aorta, and interrupted aortic arch who underwent a Yasui repair died due to respiratory arrest of unknown etiology 9 months after surgery. The other patient had pulmonary atresia with ventricular septal defect and multiple extracardiac anomalies, and died of late complications from esophageal stenosis after tracheoesophageal fistula repair 8 months after the cardiac procedure. No late mortality occurred in the A/PH group.

One of 18 patients was lost to follow-up in cFVH group for a follow-up rate of 94% (17 out of 18), whereas follow-up was 100% in the A/PH group (16 out of 16). The length of follow-up was significantly longer in the A/PH group (mean, 354 [range, 150-731] days in the cFVH group and mean, 1527 [range, 562-2138] days in the A/PH group; $P = .01$). On univariate analysis a lower need for catheter reinterventions was seen in the cFVH group compared with the A/PH group (6 [35%] vs 13 [81%]) requiring a total of 7 and 29 interventional cardiac catheterizations, respectively ($P = .01$). The need for surgical conduit reoperation was similarly lower in the cFVH group than in the A/PH group (2 [12%] vs 9 [56%]; $P = .01$). The time to conduit change after conduit placement was comparable in both groups (602 [range, 497-815] days and 963 [range, 700-1916] days for cFVH and A/PH groups, respectively; $P = .22$) (Table 2). Kaplan-Meier analysis with log-rank test

**TABLE 1. Demographic, operative, and postoperative data of the 2 study groups**

| Variable | cFVH group (n = 20) | A/PH group (n = 16) | P |
|---|---|---|---|
| Demographic and anatomical data | | | |
| Male gender | 13 (65) | 6 (38) | .18 |
| Prematurity (<37 wk) | 3 (17)* | 2 (17)* | 1 |
| Low birth weight (≤2.5 kg) | 3 (15) | 2 (13) | 1 |
| Confirmed DiGeorge syndrome | 1 (5) | 5 (31) | .07 |
| Confirmed prenatal diagnosis | 8 (40) | 5 (31) | .73 |
| Anatomical diagnosis | | | .50 |
| Truncus arteriosus | 6 (30) | 9 (56) | |
| TOF with pulmonary atresia | 7 (35) | 4 (25) | |
| Truncus arteriosus with IAA | 2 (10) | 1 (6.3) | |
| DORV including Taussig-Bing anomaly | 3 (15) | 0 (0) | |
| Aortic atresia with IAA and VSD | 1 (5) | 1 (6.3) | |
| TGA with PS | 1 (5) | 1 (6.3) | |
| Preoperative mechanical ventilation | 7 (35) | 3 (23)† | .70 |
| Preoperative inotropic support | 5 (25) | 0 (0)† | .13 |
| Operative parameters | | | |
| Age at operation, d | 13 (7-48) | 11 (7-40) | .93 |
| Weight at operation, kg | 3.4 ± 1.0 | 3.4 ± 0.7 | .52 |
| Conduit diameter, mm | 10.7 ± 1.1 | 10.6 ± 1.6 | .87 |
| Cardiopulmonary bypass time, min | 121 ± 37 | 148 ± 60 | .11 |
| Crossclamp time, min | 64 ± 29 | 81 ± 18 | .06 |
| Deep hypothermic cardiac arrest | 8/20 (40) | 5/16 (31) | .73 |
| Type of operative procedure | | | .39 |
| Truncus arteriosus repair | 5 (25) | 9 (56) | |
| Truncus arteriosus repair with aortic arch reconstruction | 3 (15) | 1 (6.3) | |
| Modified Yasui procedure | 3 (15) | 1 (6.3) | |
| Rastelli procedure | 9 (45) | 5 (31) | |
| Delayed chest closure | 11 (55) | 4 (27) | .10 |
| RACHS-1 category | 4 (3-5) | 4 (3-5) | .94 |
| Postoperative parameters | | | |
| Mechanical ventilation duration, d | 6 (3-13) | 5 (2-6) | .18 |
| Inotropic support duration, d | 7 (4-17) | 5 (2-9) | .16 |
| Extracorporeal membrane oxygenator support | 1 (5) | 0 (0) | 1 |
| Complications | | | |
| Bleeding | 1 (5) | 1 (7)‡ | 1 |
| Arrhythmia requiring treatment | 5 (25) | 7 (50)‡ | .16 |
| Seizures | 1 (5) | 2 (14)‡ | .56 |
| Cardiac intensive care unit length of stay, d | 15 (8-34) | 11 (5-15) | .17 |
| Hospital length of stay, d | 32 (13-54) | 16 (15-33) | .16 |
| Operative mortality | 2 (10) | 0 (0) | .49 |

Values are presented as n (%), median (interquartile range), or mean ± standard deviation. *cFVH*, Cryopreserved femoral vein homograft; *A/PH*, aortic/pulmonary homograft; *TOF*, tetralogy of Fallot; *IAA*, interrupted aortic arch; *DORV*, double outlet right ventricle; *VSD*, ventricular septal defect; *TGA*, transposition of the great arteries; *PS*, pulmonary stenosis; *RACHS-1*, Risk Adjustment for Congenital Heart Surgery 1. *n = 18 patients for cFVH group, n = 12 patients for A/PH group. †n = 13. ‡n = 14.

**TABLE 2. Follow-up data of the 2 study groups**

| Variable | cFVH group (n = 17) | A/PH group (n = 16) | P |
|---|---|---|---|
| Median follow-up, d | 354 (150-731) | 1527 (562-2138) | .01* |
| Catheter reinterventions | | | |
| Patients | 6 (35) | 13 (81) | .01* |
| Interventional catheterizations, % | 7 | 29 | |
| Original conduit to first catheterization, d | 169 (104-480) | 191 (118-407) | .64 |
| Conduit reoperations (conduit replacement/revisions) | | | |
| Patients | 2 (12) | 9 (56) | .01* |
| Time from original conduit to replacement, d | 602 (497-815) | 963 (700-1916) | .22 |
| Overall reinterventions (catheter-based interventions or reoperation) | 8 (47) | 13 (81) | .07 |
| Patients still with original conduit | 15 (88) | 7 (44) | NS |
| Echocardiographic findings | | | |
| Significant conduit stenosis | 1 (7) | 1 (14) | |
| Significant conduit insufficiency | 3 (20) | 0 (0) | .52 |
| Mixed conduit disease | 1 (7) | 0 (0) | NS |
| Late mortality | 2 (12) | 0 (0) | NS |
| Conduit reoperations | 2 (12) | 9 (56) | .01* |
| Indication for reoperation | | | |
| Severe conduit stenosis ± mild insufficiency | 1 (50) | 2 (22) | .48 |
| Severe conduit insufficiency ± mild stenosis | 0 | 0 (0) | NS |
| Moderate/severe conduit stenosis and moderate/severe conduit insufficiency | 1 (50) | 7 (78) | .49 |

Values are presented as n (%) or median (interquartile range). *cFVH*, Cryopreserved femoral vein homograft; *A/PH*, aortic/pulmonary homograft; *NS*, nonsignificant. *Statistically significant.

revealed a trend toward lower catheter intervention ($P = .12$) and lower overall reintervention ($P = .35$) in the cFVH group compared with the A/PH group, although the differences were not significant (Figures 1-3).

Multivariable Cox regression model adjusting for conduit diameter and differences in length of follow-up revealed comparable need for catheter intervention ($P = .12$), need for surgical reintervention ($P = .83$), and overall freedom from reinterventions ($P = .74$) between the cFVH and A/PH groups (Table 3). Mixed conduit disease was the predominant indication for reoperation in both groups (Table 2).

## DISCUSSION

This is the first study reporting outcomes of the cFVH for early primary repair requiring RV-PA continuity restoration. Our study shows a trend toward lower catheter and overall reintervention rates in this patient population of neonates and infants, a group otherwise known to require early reintervention for conduit disease.

cFVHs have the advantage of being widely available from adult cadaver donors in contrast to small size

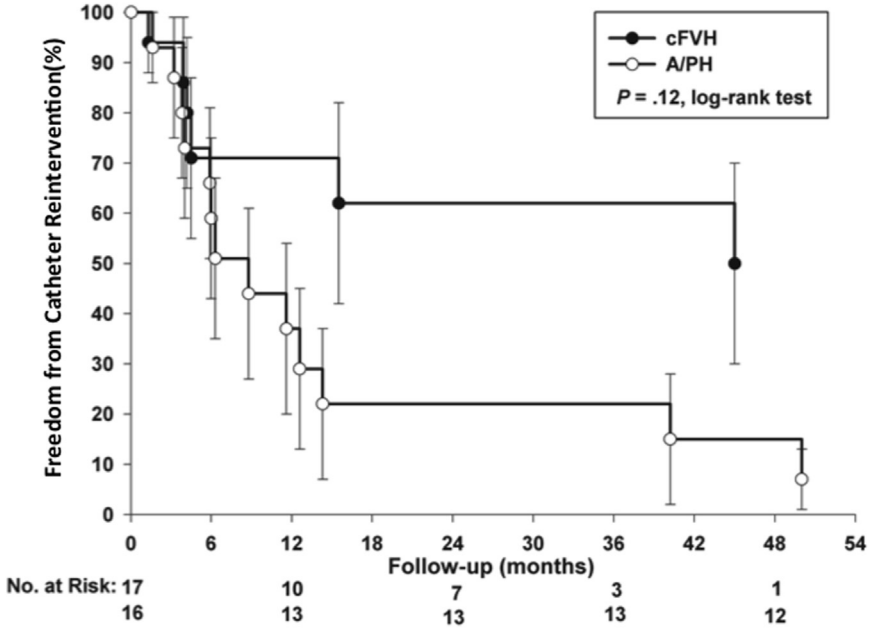


**FIGURE 1.** Kaplan-Meier curves illustrating freedom from catheter reintervention for the cryopreserved femoral vein homograft (*cFVH*) and aortic or pulmonary homograft (*A/PH*) groups. *Top*, Number of patients at risk and available for analysis for cFVH. *Bottom*, Number of patients at risk and available for analysis for A/PH.

A/PHs, which are usually supplied by rare pediatric donors. Adult cFVHs (provided by Cryolife Inc, Kensaw, Ga, or LifeNet Health, Virginia Beach, Va) are available in 25- to 30-cm length segments, with the diameter tapering from approximately 15 mm to 9 mm (ideal size range required for neonates or infants), whereas the shortage in A/PHs is most marked. The femoral vein homograft segments have 2 to 4 competent valves across their length, giving the surgeon a choice in selecting the appropriately sized valved segment. The material is thin walled and

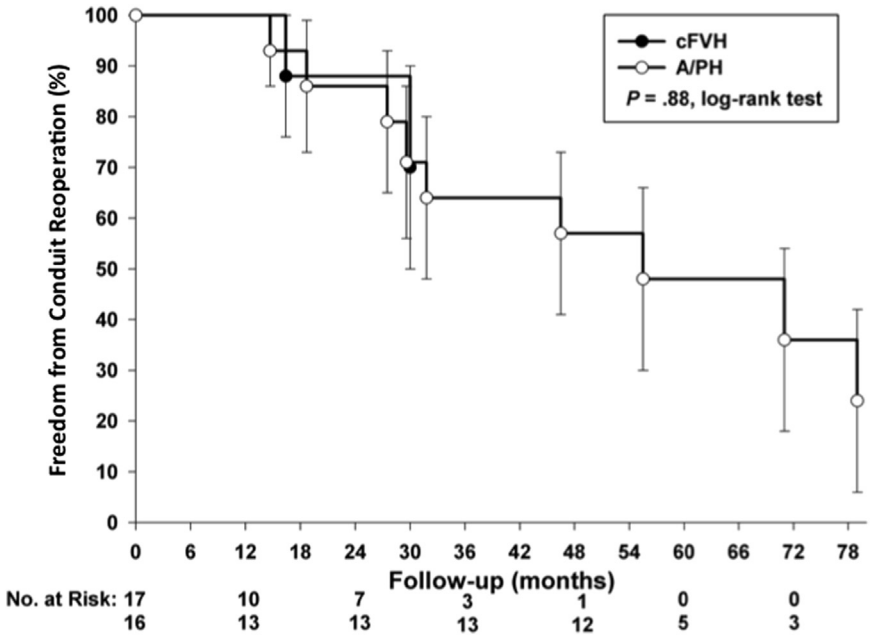


**FIGURE 2.** Kaplan-Meier curves showing freedom from conduit reoperations (surgical reintervention) for the cryopreserved femoral vein homograft (*cFVH*) and aortic or pulmonary homograft (*A/PH*) groups. *Top*, Number of patients at risk and available for analysis for cFVH. *Bottom*, Number of patients at risk and available for analysis for A/PH.

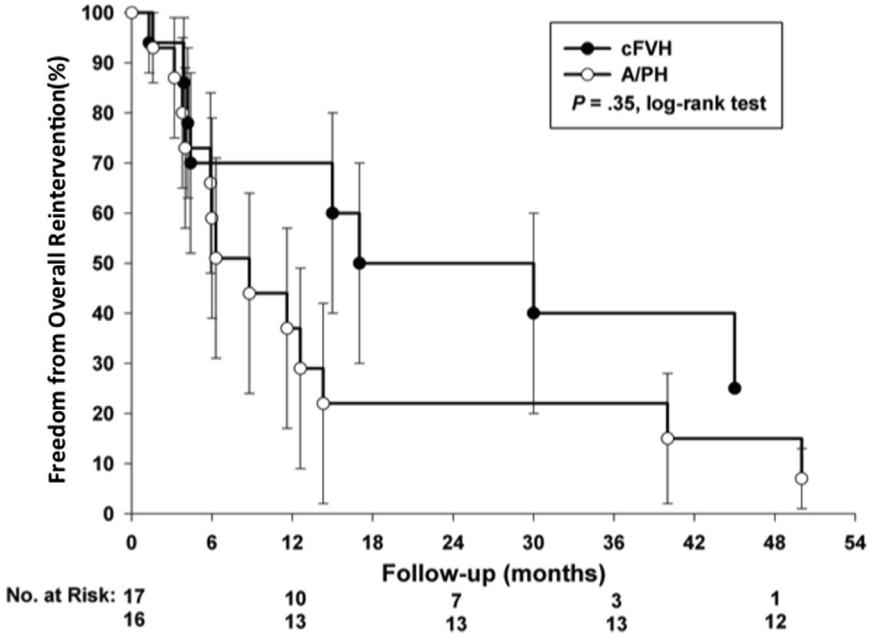


**FIGURE 3.** Kaplan-Meier curves of freedom from overall reintervention (catheter and/or surgical) for the cryopreserved femoral vein homograft (*cFVH*) and aortic or pulmonary homograft (*A/PH*) groups. *Top*, Number of patients at risk and available for analysis for cFVH. *Bottom*, Number of patients at risk and available for analysis for A/PH.

ideally suited for anastomosis to the delicate thin walled distal pulmonary artery bifurcation in infants and neonates. Despite being thin walled it is hemostatic and can be directly anastomosed to the right ventricular incision without a hood, simplifying the technical aspects of the operation. These technical advantages account for the significantly shorter aortic crossclamp time in the cFVH group in this series. The femoral vein homograft is also considerably cheaper compared with the other alternatives, and with appropriate isolation and packaging of the vein segments (eg, isolating individual valved segments by vendors) have the potential for further cost savings.

Although pulmonary homografts may be preferred for RVOT reconstruction due to lower calcification rate and conduit failure rate compared with aortic homografts,[10] in the neonatal and infant age group the choice of conduit is often dictated by the availability of an appropriately sized conduit. Additionally, use of smaller A/PHs has been shown to increase the rate of conduit failure and the reoperation rate.[1,11] Although downsizing (or bicuspidization) of a larger homograft[12,13] is an option to circumvent the shortage of smaller conduits, the resultant conduit is still thick walled, posing a mismatch to the delicate thin-walled pulmonary arteries found in neonates and infants and requires additional personnel and operating time.[14,15]

Bovine jugular vein grafts have shown variable results[16,17] and similar to the A/PHs have a higher intervention rate in the smaller size ranges (ie, 12-16 mm).[18-22]

Despite our study being a retrospective, single-center review of patients with short- to intermediate-term follow-up, and historical controls, femoral vein homografts have been shown to be comparable to A/PHs for early primary repair and RVOT reconstruction in neonates and infants, with a trend toward lower catheter and overall reintervention rates. These comparable results hold after adjustment for differences in follow-up. Larger studies with longer follow-up will be required to further study the potential long-term advantages of this attractive conduit.

**TABLE 3. Results of multivariable time-to-event Cox model for each outcome: Comparison of surgical technique adjusted for conduit diameter and follow-up time**

| Covariate | Catheter reinterventions | Conduit reoperations | Overall reinterventions (catheter and/ or surgical reintervention) |
|---|---|---|---|
| cFVH vs A/PH technique | .33 | .88 | .35 |
| Conduit diameter, mm | .43 | .12 | .19 |
| Follow-up, mo | .13 | .83 | .74 |

Values are *P* values. *cFVH*, Cryopreserved femoral vein homograft; *A/PH*, aortic/pulmonary homograft.

## CONCLUSIONS

Our study shows that cFVH has a comparable perioperative course and short and intermediate outcome compared with A/PH for RV-PA continuity restoration in newborns

and infants, with a trend toward lower reintervention rates. This novel technique offers an attractive alternative to other small conduits for use in neonates and infants.

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