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CLINICAL STUDY

20-year follow-up and comparison of homografts with bovine jugular vein conduits in children less than 2 years of age

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ABSTRACT

OBJECTIVES: Repair of congenital heart defects involving right ventricular outflow tract (RVOT) may require pulmonary valve replacement at time of primary repair or reoperation. This study compares the outcomes of cryopreserved homografts with bovine jugular vein conduits (BJVC) in children < 2 years of age with RVOT reconstruction.

METHODS: Retrospective, single-center review of 70 conduits implanted in 63 patients undergoing right ventricle-to-pulmonary artery reconstruction with valved conduit from 2002 to 2022.

RESULTS: A total of 70 conduits were implanted in 63 patients, with mean age of 4.5 ± 6.9 months (range 1 day – 23.5 months). The following conduits were used; homografts 38 (54.2 %), BJVC 32 (45.8 %). During mean follow-up of 6.2 ± 5.6 years, there were 12 deaths, 24 conduit reoperations, and 25 catheter reinterventions. Overall survival, reoperation-free, and catheter reintervention-free survival at 15 years was 82.7 %, 31.2 %, and 25.7 %, respectively. Multivariate analysis revealed that low patient weight, age < 30 days at repair, ventilation time, and ICU length of stay were associated with increased risk of death.

CONCLUSION: The performance of homografts and BJVC is comparable in patients < 2 years of age. Reoperation for conduit failure was not significantly different between the two groups *(Tab. 3, Fig. 3, Ref. 16)*.

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KEY WORDS: congenital heart disease, homografts, long-term results, contegra, right ventricular outflow tract reconstruction.

Abbreviations: BJVC – Bovine jugular vein conduit, RVOT – Right ventricle outflow tract, CAT – Common arterial trunk, RV-to-PA – Right ventricular to pulmonary artery

Introduction

Right ventricular-to-pulmonary artery (RV-PA) conduits have made the repair of many complex congenital cardiac lesions involving atresia or hypoplasia of the RV outflow tract (RVOT) possible. These fundamental diagnoses include pulmonary atresia with ventricular septal defect, severe tetralogy of Fallot, common arterial trunk (CAT), transposition with ventricular septal defect and pulmonary atresia, and various forms of double outlet RV. Conduits have also made the pulmonary autograft replacement of the aortic root (Ross procedure) possible (1).

Valved homografts, initially introduced in 1966 by Ross and Somerville, (2) have become the most common valved conduit used for right ventricular outflow tract (RVOT) reconstruction. The advantages of homografts (pulmonary and aortic) are easy implantation and better hemostasis (3). However, some studies have reported limited availability and poor durability of the homografts (4). Moreover, the supply of small-sized homografts is also limited (4). For these reasons, numerous alternative valved conduits have been introduced.

A valid option is to use available xenografts such as bovine jugular vein conduits (BJVC). Advantages of xenografts conduits include abundant supply, wide range of sizes, low cost, and favorable suturing characteristics. BJVC, usually known as Contegra, was introduced in 1999 by Medtronic Inc. (Minneapolis, MN, USA). It contains a trileflet valve within a long conduit lumen and it is available in a variety of sizes (12–22 mm) (5–6).

The comparisons of homografts and BJVC are available in literature, but only a few studies reported their performance in small patients (7, 8, 9, 10). Because every conduit type used in small children will eventually require replacement due to outgrowth or degeneration, we sought to compare homografts and BJVC with respect to patient survival, catheter reintervention, and conduit reoperation in children less than 2 years of age, requiring primary or replacement conduit insertion for RVOT reconstruction at our institution.

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Patients and methods

Patients

The study population was derived from patients who underwent RVOT conduit implantation at Children´s Heart Centre, Bratislava, Slovakia from January 1, 2002, to June 31, 2022. Inpatient and outpatient medical records of the patients were retrospectively reviewed. The study was approved by the Institutional Review Board of the National Institute of Cardiovascular Diseases, Bratislava, Slovakia on 8 February 2023 (Approval Number: 05/2023), and the need for informed consent was waived because of the retrospective nature of the study.

Inclusion criteria were patients below 2 years of age with congenital heart disease that required RVOT reconstruction using RV- to-PA conduits, who received a cryopreserved homograft, or BJVC (Contegra). Exclusion criteria were patients whose operative notes could not be retrieved, and patients receiving other valve and conduit types.

Demographic data, sex, cardiac diagnosis, Aristotle score (11), age at surgery for RVOT reconstruction, conduit characteristics including types and sizes, follow-up clinical data and echocardiographic findings, reintervention, and reoperation data were collected. We also analyzed treatment outcomes, freedom from reoperation, reintervention, and patient survival.

RVOT conduits were classified into 2 groups: homografts (aortic, pulmonic) and bovine jugular vein conduits (BJVC). In Slovakia, cryopreserved homograft valved conduits are supplied by the central tissue bank at the Medical Faculty of Comenius University. Cryopreservation was performed using Dulbecco's Modified Eagle Medium (DMEM) 1 % containing bovine serum and dimethylsulfoxide (DMSO) for preservation and grafts were stored in liquid nitrogen at -150C.

A total of 70 conduits were implanted in 63 patients. Of these, 31 (44.2 %) were pulmonic homografts, 7 (10.1 %) were aortic homografts, and 32 (45.7 %) were BJV conduits. The mean follow-up for the entire cohort was 6.2 (0.008–20.5) years. The mean follow-up was 7.9 (0.008–20.5) years for homografts and 4.1 (0.28–12.5) years for BJV conduits.

The study endpoints included survival, freedom from catheter reintervention, and freedom from reoperation. Freedom from conduit reoperation was defined as the length of time from operative conduit placement to either operative conduit replacement or explantation or patient death. Freedom from reintervention was defined as the length of time from operative conduit placement to transcatheter conduit intervention; balloon valvuloplasty or stent implantation. The orthotopic placement was defined as the placement of the conduit within the native, normally placed RVOT (Ross procedure). In all other patients, the conduit was placed in a heterotopic position. Indications for conduit replacement included endocarditis, severe conduit stenosis with a peak gradient > 50 mmHg and/or severe regurgitation on echocardiography, and RVOT aneurysm. BJVC patients received aspirin for six months postoperatively. Endocarditis incidence was assessed according to the modified Duke classification system (12). Only cases of endocarditis requiring operative conduit replacement were recorded.

Patient survival status was verified with the national population registry. Reoperations performed on patients after initial RV-to-PA conduit placement were ascertained through either our institutional congenital heart disease database or independent registries maintained by the Divisions of Adult Cardiac Surgery in three cardiac centers in Slovakia. Reinterventions in the form of cardiac catheterizations were ascertained through a registry maintained by the Division of Pediatric and Adult Cardiology in Bratislava, Slovakia.

Statistical analysis

JMP Statistical Discovery Software, version 5.0.1. (Cary, NC, USA) was used for statistical analysis. Categorical variables are presented as numbers with percentages. Comparisons for categorical variables were calculated with Fisher's exact test. Continuous data are expressed as mean standard deviation or median and in-

Tab. 1. Demographics and primary diagnosis of patients undergoing right ventricular outflow tract reconstruction.

Variable	Total n=70	Homograft Aortic 7 /Pulmonic 31 n= 38	BJVC n=32	p
Age (months), median (IQR)	1.4 (1 day to 23.5 months)	0.5 (1 day to 20.7 months)	4 (2 days to 23.5 months)	0.001
BSA (m2), median (IQR)	0.23 (0.17–0.57)	0.22 (0.17–0.54)	0.27(0.19–0.57)	0.003
Weight (kg), median (IQR)	3.7 (2.25–13)	3.4 (2.25–12)	4.7(2.7–13)	0.002
Follow-up (years) mean	6.2 ± 5.6	7.9 ± 6.2	4.2 ± 3.9	0.025
Neonates, n (%)	35 (50 %)	25 (65.8 %)	9 (28.1 %)	0.001
Sex, n (%)				0.070
Male	47 (67.1 %)	29 (76.3 %)	18 (56.2 %)	
Female	23 (32.9 %)	9 (23.7 %)	14 (43.8 %)	
Diagnosis, n (%)				0.032
CAT	22 (31.4 %)	8 (21 %)	14 (43.7 % %)	
TOF + TOF/APV	13 (18.5 %)	10 (26.3 %)	3 (9.3 %)	
PA	4 (5.7 %)	1 (2.6 %)	3 (9.3 %)	
Aortic valve disease	21 (30 %)	15 (39.7 %)	6 (18.7 %)	
ccTGA	5 (7.2 %)	1 (2.6 %)	4 (12.5 %)	
Other: IAA, HLHC, DORV	5 (7.2 %)	3 (7.8 %)	2 (6.5 %)	

BSA – Body surface area, DORV – Double-outlet right ventricle, ccTGA – Congenitally corrected Transposition of Grate Arteries, TOF – Tetralogy of Fallot, APV – Absent pulmonary valve, PA – Pulmonary atresia, HLHC – Hypoplastic left heart complex, IAA – Interruption of aortic arch, CAT – Common arterial trunk

Tab. 2. Operative and postoperative data.

Variable	Total n=70	Homograft Aortic 7 /Pulmonic 31 n= 38	BJVC n=32	p
Aristotle score, median (IQR)	11 (7.5–15.5)	12.4(7.5–15.5)	11(7.5–13.8)	0.10
Cardiopulmonary bypass (min.), median (IQR)	143 (71–289)	153(73–263)	138(71–289)	0.76
Aortic cross-clamp (min.), median (IQR)	82 (0–202)	94(0–140)	78(0–202)	0.22
Hospital LOS (days), median (IQR)	28 (8–147)	25(8–89)	13(9–147)	0.32
ICU LOS (days), median (IQR)	13 (1–141)	13.5(1–77)	13(1–141)	0.74
Ventilation (hours), median (IQR)	207 (0–1656)	200(2–1656)	215(0–1128)	0.30
Conduit diameter (mm), median (IQR)	12 (9–18)	11(9–16)	14(12–18)	<0.001
Orthotopic position (Ross), n (%)	22 (31.4 %)	16(42.1 %)	6 (18.7 %)	0.036
Conduit diameter(mm), n (%)				<0.001
9	1(1.43 %)	1(2.63 %)	0(0 %)	
10	10(14.29 %)	10(26.32 %)	0(0 %)	
11	10(14.29 %)	10(26.32 %)	0(0 %)	
12	20(28.57 %)	5(13.16 %)	15(46.88 %)	
13	1(1.43 %)	1(2.63 %)	0(0 %)	
14	17(24.29 %)	8(21.05 %)	9(28.13 %)	
15	2(2.86 %)	2(5.26 %)	0(0 %)	
16	5(7.14 %)	1(2.63 %)	4(12.5 %)	
18	4(5.71 %)	0(0 %)	4(12.5 %)	

ICU – Intensive care unit, LOS – length of stay

terquartile range (IQR). Comparisons for continuous variables were calculated with two-sample t-test unless the data were not normally distributed; in these instances, the Wilcoxon rank sum test was used for comparison.

Survival analysis was performed by Kaplan–Meier analysis to determine freedom from reoperation, freedom from reintervention, and to estimate survival. Endpoints were time to death, surgical reintervention- conduit replacement or explantation, and catheter based-reintervention. Comparisons of survival, reoperation, and reintervention rates between the 2 groups were performed by log-rank test. Risk factors for mortality were analyzed with a linear univariate and multivariate logistic regression model. For all tests, a $p \leq 0.05$ was considered significant.

Results

Baseline characteristics in each group are given in Table 1. The operative and postoperative data are given in Table 2.

Survival

The overall survival rate at 1, 10 and 20 years was 82.7 %, 82.7 % and 82.7 %, respectively Figure 1A. Overall, 12 (17.1 %) patients died during follow-up (including 30-day mortality), 9 (23.6 %) patients in the homograft group, and 3 (9.3 %) patients in the BVJC group, ($p = 0.10$). The early mortality rate within 30 days after conduit implantation was 5.7 % (n = 4). The 30-day mortality was 10.5 % (4/38) in the homograft group and 0 % (0/32) in the BJVC group, but the difference was not significant ($p = 0.058$). Figure 1B. No death was attributed to the structural failure of the conduit.

Causes of early mortality were Multiorgan Dysfunction Syndrome (MODS) in 2, brain death in 1, and mycotic sepsis in 1. One of these patients required extracorporeal membranous oxygenation (ECMO) for postcardiotomy low cardiac output syndrome. The causes of late deaths were pneumonia and respiratory failure in 1, heart failure in 1, brain ischemia in 1, MODS in 2, unknown in 2, and sudden death at home in 1.

Multivariate analysis revealed that low body weight, age less than 30 days at repair, prolonged ventilation time, and length of stay in the intensive care unit were associated with the increased risk of death Table 3. The type and diameter of the conduits and the anatomic position did not impact mortality and were not associated with a higher risk of mortality in our analysis.

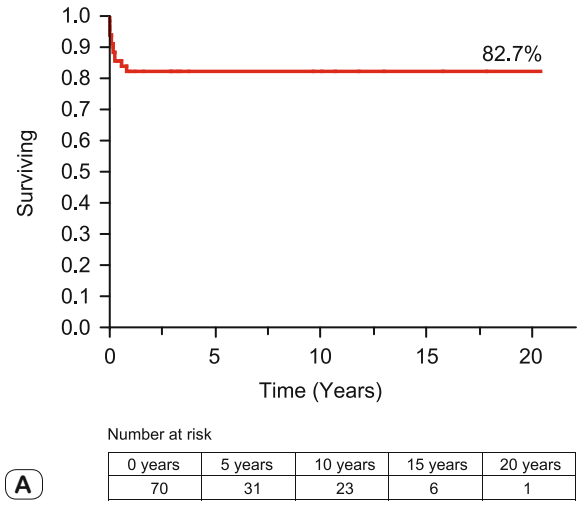
Transcatheter reinterventions

Transcatheter reinterventions were performed in 25 (35.7 %) conduits. The mean time to catheter reintervention in the whole cohort was 3.4 ± 3.9 years. Transcatheter reinterventions were

Tab. 3. Risk factors for mortality by univariate and multivariate analysis, all patients.

Variables	Univariate	Multivariate
	p	p
Sex	0.51	
Weight at surgery (kg)	0.002	0.004
Conduit diameter (mm)	0.065	
Orthotopic position	0.41	
Primary diagnosis		
CAT	0.59	
TOF	0.54	
ccTGA	0.16	
CPB time	0.073	
Conduit type	0.10	
ACC time	0.007	
ICU LOS	<0.001	0.003
Age <30 days	0.040	0.044
Ventilation time	<0.001	<0.001

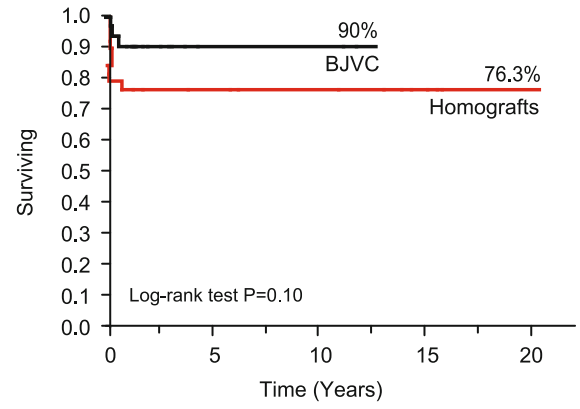
CAT – Common arterial trunk, TOF – Tetralogy of Fallot, ccTGA – Congenitally corrected Transposition of Grate Arteries, CBP – Cardiopulmonray bypass, ACC – Aortic cross clamp, ICU – intensive care unite



Number at risk

0 years	5 years	10 years	15 years	20 years
70	31	23	6	1

A

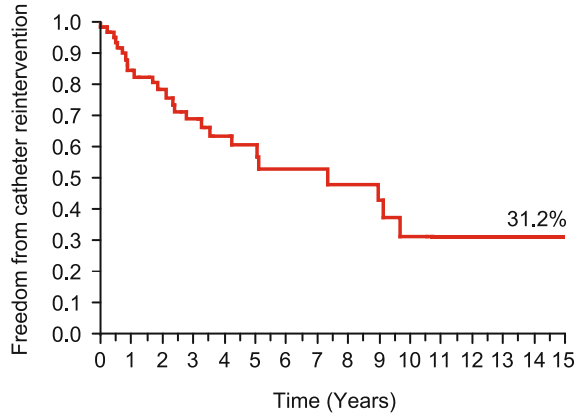


Number at risk

Conduit type	0 years	5 years	10 years	15 years	20 years
Homografts	38	24	17	6	1
BJVC	32	8	5	0	0

B

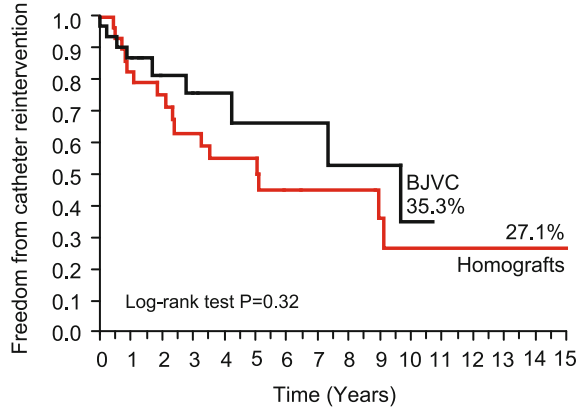
Fig. 1. Kaplan-Meier curve showing survival (A) all patients, (B) by conduit type (log-rank p = 0.10).



Number at risk

0 years	5 years	10 years	15 years
70	17	6	3

A



Number at risk

Conduit type	0 years	5 years	10 years	15 years
Homografts	38	24	17	6
BJVC	32	8	5	0

B

Fig. 2. Freedom from reintervention, (A) all patients, (B) by conduit type (log-rank p = 0.32).

required in 16 conduits in the homograft group (balloon valvuloplasty, n = 12, stent implantation, n = 4), and 9 conduits in BJVC group (balloon valvuloplasty, n = 9).

The indication for transcatheter reintervention in all cases was severe conduit stenosis with a median gradient of 70 (range 47–120) mmHg.

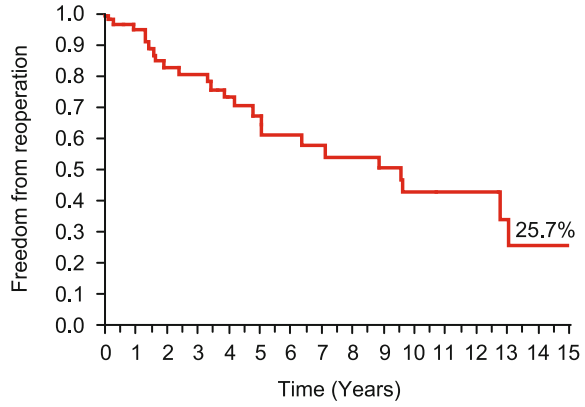
The mean interval between initial implantation and catheter reintervention in the homograft group and BVJC group was 3.6 years (range 2.3–4.9 years) and 3.1 years (range 2–4.2 years), respectively (p = 0.58).

Overall freedom from transcatheter reintervention at 5, 10, and 15 years was 56.9 %, 37.5 %, and 31.2 %, respectively Figure 2A. Freedom from transcatheter reintervention at 5, 10, and 15 years was 55.3 %, 27.1 %, and 27.1 % in the homograft group, respectively. Freedom from catheter reintervention at 5, 10 years was 66.2 % and 35.3 %, in the BJVC group, respectively. Transcatheter reintervention rate was not significantly different between the 2 groups (p = 0.32). Freedom from catheter reintervention according to the type of conduit is shown in Figure 2B.

Reoperations

There were 24 (34.2 %) conduit reoperations performed. Overall freedom from reoperation at 5, 10, and 15 years was 67.5 %, 42.9 %, and 25.7 %, respectively Figure 3A. The mean time to conduit reoperation in the whole cohort was 4.4 ± 4.7 years.

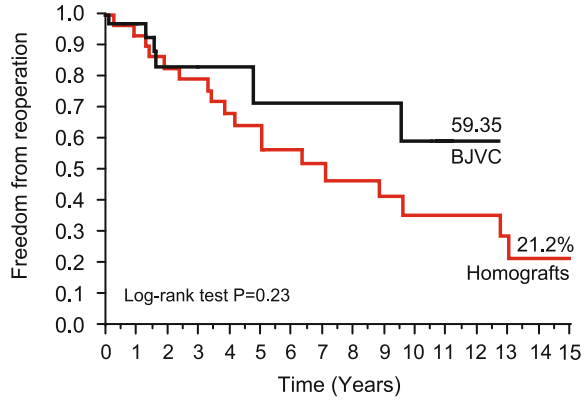
The indications for conduit reoperation were severe stenosis (n = 8; 33.3 %), with a median gradient of 62 (range 55–110) mmHg, severe regurgitation (n = 3; 12.5 %), mixed stenosis and



Number at risk

0 years	5 years	10 years	15 years
70	23	11	3

A



Number at risk

Conduit type	0 years	5 years	10 years	15 years
Homografts	38	17	6	3
BJVC	32	7	5	0

B

Fig. 3. Freedom from reoperation, (A) all patients, (B) by conduit type (log-rank p = 0.23).

regurgitation (n = 10; 41.6 %), RVOT aneurysm (n = 1; 4.1 %), and endocarditis (n = 2; 8.5 %).

Overall, 2 of 70 conduits (2.8 %) were exchanged due to conduit endocarditis: 2 of 32 (6.2 %) in BVJC group, and no conduit replacement due to endocarditis was recorded in the homograft group. However, there was no significant difference between rates of endocarditis in homografts and BJV conduits (p = 0.071).

Freedom from reoperation at 5, 10, and 15 years was 64.4 %, 35.4 %, and 21.2 % in the homograft group, respectively. Freedom from reoperation at 5, 10, and 12.5 years was 71 %, 59.3 %, and 59.3 %, in the BJVC group, respectively. No statistically significant difference regarding the reoperation rate was observed between the 2 groups (p = 0.23). Freedom from reoperation according to the type of conduit is shown in Figure 3B.

The mean interval between initial implantation and reoperation in the homograft group and BVJC group was 5.1 ± 5.3 years and 3.7 ± 3.8 years, respectively (p = 0.21).

Discussion

RVOT reconstruction is required in the management of many congenital heart disease cases and in Ross procedure. Homografts have been regarded as the gold standard for RVOT reconstruction for a long period of time. However, some studies have reported limited availability and poor durability of the homografts (4). The failure of early homografts can be observed, mainly due to early calcifications and shrinking (9). Moreover, the supply of small-sized homografts is also limited (4). For these reasons, numerous alternative valved conduits have been introduced.

Recently there is an increasing number of alternative valved conduits implanted, such as BJVC. In fact, there are centers reporting either the superiority (7) or equivalence (13, 8) of BJVC to homografts.

Small-sized conduits are associated with earlier conduit failure and frequent conduit exchange and exhibit worse durability than larger ones. Moreover, it was reported as a risk factor for reintervention in multiple studies (7, 13, 14). However, there are just a few studies in the literature, with long-term data, which reported the performance of homograts and BJVC in small patients (7, 8, 9, 10).

Hence, the aim of our study was to compare the performance of two types of conduits: (pulmonary, aortic) homografts and BJVC, which were implanted in children less than 2 years of age at our institution as measured by survival, freedom from transcatheter reintervention, and freedom from reoperation. We investigated risk factors for mortality and assessed for incidence of infective endocarditis requiring surgical conduit exchange.

A survival of 82.7 % at 20 years in our cohort is satisfactory and comparable to similar reports (9, 15). The multivariate analysis revealed that body weight, age less than 30 days at repair, ventilation time, and the ICU length of stay were associated with the increased risk of death. Neither the type and diameter of the conduit, nor the anatomic position had a significant influence on mortality in our analysis.

Overall freedom from catheter reintervention for the entire cohort was 56.9 %, 37.5 %, and 31.2 % at 5, 10, and 15 years, respectively. No statistically significant difference between the two groups was found in our study regarding freedom from catheter reintervention, this reflects the same finding in a study by lewis, M.J et al (13), which reported similar freedom from catheter reintervention and similar performance of BJVC to homografts.

Overall freedom from reoperation for the entire cohort was 64 %, 42.9 %, and 25.7 % at 5, 10, and 15 years, respectively. This compares favorably with similar studies (8, 16), which reported 5-year freedom from reoperation between 59.4 % and 70 %, and 10-year freedom from reoperation between 38 and 49 % (8, 16). In our study, the freedom from reoperation at 5 and 10 years after conduit implantation was higher in the BJVC group, but the difference was not significant (p = 0.23). This may be related to the larger size of conduits and shorter follow-up in BJVC group.

In our analysis, the most common cause of conduit failure was mixed stenosis and regurgitation in 41.6 %, followed by severe stenosis in 33.3 % of patients. The incidence of infective endocarditis requiring conduit exchange (i.e., excluding medically treated cases) was 2.6 % for all patients: 6.2 % for BJV conduits, and 0 % for homografts. This compares favorably with similar studies (12, 17), which reported rates of endocarditis in BJV conduits between 4.7 % and 11.3 %.

Currently, in Slovakia, in the setting of low availability of homografts the use of off-the-shelf xenografts such as BJVC is our preferred choice in RVOT reconstruction in small children.

Limitations

The limitations of our study include its single-center, retrospective cross-sectional analysis of patients with diverse cardiac anatomies operated on over a 20-year period and the median follow-up time was shorter for the BJVC group compared to homografts.

Conclusions

Homograft conduits used for RVOT reconstruction showed excellent long-term durability and provided very good long-term survival. Reoperation and catheter reintervention for conduit failure were not significantly different between the 2 groups: homografts and BJVC. BJV conduits are a satisfactory choice and useful option for RVOT reconstruction in children aged less than 2 years, given their easy implantability, off-the-shelf availability, and acceptable midterm durability.

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