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Midterm results of bovine jugular vein conduit for right ventricular outflow tract reconstruction

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Abstract

Objective: To evaluate the midterm results of Contegra conduit.

Methods: The retrospective study comprised patient record at Aga Khan University Hospital, Karachi, of conduits implanted between May 2007 and June 2012. Data collection was made from the clinical notes and from serial echocardiograms by a single cardiologist. The last followup echocardiography was done at the time of data collection in June 2012. SPSS 19 was used for statistical analysis.

Results: A total of 18 conduits had been implanted (16-22mm) during the study period. Median age at the time of surgery was 9 years (range: 2.5-16 years). Early mortality was seen in 3 (16.66%) patients, but none was Contegra related. Of the remaining 15 patients, 2 (13.33%) with a diagnosis of Pulmonary Atresia-Ventricular Septal Defect with hypoplastic peripheral Pulmonary Arteries (PA), developed severe distal pressure gradient (50mmHg) across Contegra over a median period of 18 months (range: 12-24 months), with resultant severe regurgitation and needed percutaneous intervention. There was no thrombosis, calcification, aneurysmal dilation or late deaths.

Conclusion: At midterm followup, Contegra conduit was associated with low re-intervention rates with satisfactory haemodynamic results. However, long-term durability must be determined for this conduit, especially in patients with Pulmonary Atresia-Ventricular Septal Defect with hypoplastic peripheral Pulmonary Arteries.

Keywords: Right ventricular out flow tract, Conduit, Congenital heart disease, Mid term followup, PA-VSD with hypoplastic PAs. (JPMA 63: 1266; 2013)

Introduction

A number of congenital cardiac malformations require Right Ventricular Outflow Tract (RVOT) reconstruction with valved conduits as one of the corrective procedures. These include Tetralogy of Fallot (TOF) with Absent Pulmonary Valve Syndrome (APVS), Truncus Arteriosus (TA), Pulmonary Atresia with Ventricular Septal Defect (PA-VSD), Transposition of Great Arteries, Ventricular Septal Defect with Pulmonary Stenosis, (d-TGA-VSD-PS) and Aortic Stenosis (AS). The incidence of Congenital Heart Diseases (CHDs) is 0.8-1/1000. The above-described malformations make 13-15% of all CHDs, and approximately 5-6% of them would need a valved conduit for primary repair.¹ Despite numerous studies, the ideal valved conduit to repair these complex congenital heart defects is yet to be developed. Porcine xenografts lack durability, and homografts have shown early degeneration, lack of availability in small size, and overall scarcity.² The recently developed Contegra Bovine Jugular Vein Conduit (BJVC)³ has been advocated for its off-the-

shelf availability, small sizes and surgical pliability with favourable early and midterm outcomes in both adult and paediatric populations.³

In Pakistan, due to non-availability of homografts, BJVC Contegra is a good option. The Aga Khan University Hospital (AKUH) was the first in Pakistan to start using Contegra in 2007. We have already published our surgical techniques and immediate outcome;⁴ and now present midterm results of Contegra valve conduit in RVOT position based on echocardiographic evaluation.

Patients and Methods

The retrospective study comprised 15 Contegra valved conduits implanted in RVOT position at AKUH, during May 2007 and June 2012 (Table-1).

The patients were divided into diagnostic categories. The surgical techniques were described in detail in our initial publication.⁴ In brief, the lie of Contegra was kept to the left, pulmonary arteriotomy was extended on to the branch pulmonary arteries, the defect was then closed with a patch of Contegra, making sure that there was intimal contact, but avoiding full thickness bites of Contegra to preempt stenosis.

Data collection was made from the clinical notes and from

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serial echocardiograms by a single cardiologist. Cardiac catheterisation and Cardiac magnetic resonance imaging (MRI) were performed where needed.

The echocardiographic protocol was designed taking in to consideration the recommendations for evaluation of prosthetic valves with 2D and Doppler echocardiography by the American Society of Echocardiography's guidelines.^{5,6} These patients were regularly followed up. Transthoracic Doppler echocardiography was performed post-operatively and reviewed periodically. Last followup echocardiographic study was done at the time of data collection in June 2012. Maximum Instantaneous Pressure Gradient (MIPG) across Contegra exceeding 3m/s (PG=36mmHg) was considered moderate stenosis, and >4 m/s (64mmHg) with serially increasing velocity was taken as severe stenosis. Stenosis was further classified as subvalvar, transvalvar and supra-valvar (at the level of distal anastomosis).

Bio-Prosthetic valve regurgitation was graded as absent, mild, moderate and severe based on the jet size, density, deceleration rate and diastolic flow reversal in the pulmonary artery.^{4,5} Moderate and severe grade were taken as functionally significant.

All the conduits were unsupported. Conduit diameter was measured at the level of the valve, above the valve, and below the valve. A mean of three measurements were taken and conduit aneurysm was defined as conduit dilatation >1.5 fold of initial

diameter. All patients received aspirin post-operatively for six months.

Descriptive data was analysed using SPSS version 19.0. Data was divided into categorical and continuous variables. The categorical variables were expressed in percentages and frequencies. The continuous variables were expressed in median with minimum and maximum values. Non-parametric tests like Wilcoxon Signed Ranks tests were used. A probability value of <0.05 was taken as significant.

Results

The median age at surgery was 9 years (range: 2.5-16 years), and the median weight was 15kgs (range: 9-45kgs). A total of 18 conduits had been implanted initially, but there were 3 (16.66%) early deaths. Of the remaining 15 patients, 1 (6.66%) was lost to followup after immediate post-surgical echocardiographic exam. Clinical outcome with complete echocardiographic followup, as such, was available for 14 (93.3%) patients. Median followup was 24 months (range: 6-60 months). There were no late deaths.

There was none or minimal MIPG across the conduit valves in 10 (66%) patients. However, 5 (33%) had moderate stenosis. Level of stenosis was at the distal region (supra-valvular) in 4 (80%) and at the subvalvular region in 1 (20%). Two of these 5 (40%) patients had increase in MIPG up to 50 mmHg over a median period of 18 months (min=12, max=24) after the implantation, with resultant severe regurgitation and Right Ventricular (RV)

Table-1: Individual case description (n=15).

S.No.	Cardiac diagnosis	Contegra size	Interval from conduit implantation to last follow up(months)	Surgical reintervention	Percutaneous intervention
1.	dTGA, DORV PA S/P homograft replacement	22	45	No	No
2.	PA VSD PDA RMBT	22	55	No	No
3.	PA VSD MBT	20	50	No	No
4.	TOF APVS PDA	20	60	No	No
5.	PA VSD RMBT	18	37	No	No
6.	PA VSD MAPCAS	18	36	No	Yes
7.	DORV,VSD, d TGA PS	20	31	No	No
8.	PA VSD MAPCAS	20	24	No	No
9.	PA VSD MAPCAS	20	23	No	Yes
10.	AS ROSS	22	22	No	No
11.	PA VSD MAPCAS	22	16	No	No
12.	PA VSD MAPCAS	22	14	No	No
13.	PA VSD MAPCAS	22	6	No	No
14.	Aortic Stenosis	22	6	No	No
15.	D TGA DORV PS	22	6	No	No

PA: Pulmonary Atresia, VSD: Ventricular Septal Defect, MAPCAS: Main Aortopulmonary Collaterals, DORV: Double Outlet Right Ventricle, PS: Pulmonary Stenosis, dTGA: Transposition of Great vessels, TOF- APVS: Tetralogy Of Fallot with Absent Pulmonary Valve Syndrome. RMBT: Right Modified Blallock Tausing Shunt, PDA: Patent Ductus Arteriosus, AS: Aortic Stenosis.

Table-2: Literature comparison.

	Bove ²¹	Corno ⁷	Breyman ¹⁶	Boudjemline ¹²	Carrel ¹³	Tiete ¹⁹	Myens ¹⁵	Shebani ¹⁷	Study Group
Number of patients	41	67	108	28	22	29	58	62	15
Mean age (years)	1.9±2.6	13.5	4.3±5.2	3.4	2.7	3.4±3.6	9	3.6	8.9±4.1
Mean follow up (months)	12	26.4	25	15	18	10.2±6.4	22.7±10	14	29±4.6
Need for Reintervention	10%	15%	16%	12%	14%	11%	41%	50%	13%
Time in months ^b	Na	Na	14	Na	Na	Na	Na	Na	18
Embolism	0	0	0	0	1	0	3	1	0
Thrombosis	Na	0	0	2	0	2	Na	6	0
Aspirin therapy	Na	All	All	None ^a	all for 3 moths	Only for 12 mm conduits	None	73% for 6 months	All for 6 months
Conduit regurgitation	4.8%	24%	4.6%	3.5%	36%	3.4%	16%	29%	13%
Conduit stenosis	14.6%	0%	7.4%	11%	4.5%	27.6%	50%	10.5%	13%

^aAspirin now recommended by authors for all Contegra patients.

^bTime interval from implantation to reintervention.

SD: Standard Deviation.

dysfunction. There was no significant increase in MIPG in the remaining 3 (60%) patients ($p < 0.18$).

Both patients had an initial diagnosis of PA-VSD with Main Aortopulmonary Collaterals (MAPCAs) and hypoplastic peripheral PAs. Both underwent cardiac catheterisation, and one required cardiac MRI, which revealed proximal and distal bilateral branch PA stenosis with dilated right-sided cardiac chambers, severe valve regurgitation with severe RV dysfunction. Conduit valve was visualised at the distal end with critical Left PA and severe Right PA (long segment) stenosis distal to the anastomosis. Both patients required percutaneous reintervention.

Aneurysmal dilatation was taken as >1.5 times in size of conduit diameter at the time of implantation. The median diameters of supravalvular, valvular and subvalvular regions were, 22mm (min=17, max=24); 20mm (min=18, max=22); and 19mm (min=18, max=21) respectively. At implantation, median conduit size was 22mm (min=18, max=22). There was no evidence of aneurysmal dilatation. There were no echocardiographic evidence of calcification, thrombosis and endocarditis.

Discussion

BJVC, integrating a natural tri-leaflet valve, was first introduced in 1999 as a clinical alternative with promising haemodynamic results.^{7,8} We have already published our data of patients with immediate and early outcome.⁴ The current study entailed midterm evaluation of BJVC performance primarily based on echocardiographic findings. Our patient population mainly comprised PA-VSD and MAPCAs (68%) with or without complex peripheral pulmonary architecture.

The haemodynamic results produced by Contegra in our patients have been satisfactory; with absent or mild valve regurgitation in 87% of patients. Similar results have been reported in literature^{7,9-13} (Table-2).

None of our patients required surgical replacement of the conduit, and 87% of them did not need percutaneous intervention. Brown et al¹¹ reported similar results with 85% of cases not requiring reintervention at a mean followup of 26 months. Boething et al¹⁴ had similar results and reported no surgical reintervention at 4 years for Contegra, whereas 20% homografts needed replacement over the same period.

However, recent clinical reports on Contegra performance vary, with some excellent midterm competence with minimal gradients, whereas other reports show concerning issues with early stenosis or conduit insufficiency or both. These discrepancies are likely due to heterogeneous patient population and variation in techniques. The most widely reported mechanism of BJVC failure requiring reintervention is stenosis. Anatomic subgroup with complex branch PAs are most vulnerable to this failure. Several etiologies have been proposed for this obstruction, including inadequate glutaraldehyde removal, kinking from excessive outflow length of BJVC, distortion by the ascending aorta from rightward implantation on the PA, and improper suturing technique leading to anastomotic stenosis, turbulent blood flow due to abrupt diameter mismatch from the conduit to diminutive pulmonary vasculature resulting in intimal proliferation. A study¹⁵ noted excessive neo-intimal growth at the distal anastomosis, resulting in need for percutaneous reintervention in 29% and surgical replacement of conduit in 72% of patients. We

determined that the pulmonary artery should be patched and the Contegra should be anastomosed to the patch rather than the artery itself. This helped in avoiding the contact of direct shear forces on the delicate pulmonary artery. We also believed avoiding full thickness of the Contegra in the lumen, as it could lead to the development of a neo-intimal peel at the anastomosed area and maybe a major cause of conduit obstruction as described by Brown et al.¹¹

Breyman et al published their data of 108 conduits extending to mean followup of 4 years, with excellent results.¹⁶ However they did not feature PA-VSD MAPCA's. This subgroup featured in Shebani et al study¹⁷ group (29%) and contributed to 12 (57%) out of 21 reinterventions, making this anatomic group a significant risk factor for reintervention. The authors correlated the poor performance of Contegra in this group to the tendency of these patients to have high RV/LV pressure ratios postoperatively. Myens et al¹⁵ also reported similar findings, but in smaller sized conduits ranging from 12-14mm. They, however reported the discrepancy between the native PA and smaller conduit size to be the risk factor and not the RV/LV ratio post-operatively. Rastan et al showed similar results and suggested that BJVC performed poorly under high pressure conditions (e.g. peripheral pulmonary stenosis) and it should be used cautiously in patients in whom high post-operative RV pressure is anticipated.¹⁸ Our results showed an increase in MIPG from 30-50 mmHg at supravalvular region over a period of 18 months (min=12, max=24) in two patients. Both patients belonged to PA-VSD MAPCAs subgroup with hypoplastic and complex peripheral PAs. In spite of abovementioned surgical techniques, they required early reintervention, which could be related to hypoplastic distal peripheral PAs.

There was no echocardiographic evidence of thrombosis and calcification in our study group, though both have been reported widely in literature. Biological implants cross-linked with glutaraldehyde, though protective against calcification, are potentially thrombogenic. The residual glutaraldehyde released from the implant hinders colonisation of luminal layer exposing the implant to thrombogenic process.¹⁹ Aspirin therapy is well known to reduce the risk of thrombosis in vein grafts. Myens^[15] and Boudjemline¹² recommend aspirin therapy in all patients for 6-12 months post-implant.

Contegra conduits have shown good results in patients who have had previous RVOT reconstruction

with homografts. Immune mediated injury by first homograft is postulated to be the most significant risk factor for second homograft failure.²⁰ Two patients in our group required previous homograft replacement which were implanted at another centre with Contegra, and have shown no complication at 45 month followup.

In terms of limitations, the study had no infant and literature review emphasises the need for including them to evaluate the results of smaller Contegra conduits, specially adequacy of distal anastomosis, on PA bifurcation. Long-term studies are needed to ascertain safety, efficacy and durability of BJVC conduit. Another limitation was the absence of any direct control group. It would be particularly ideal to evaluate these BJVC against small homografts in future as a randomised trial.

Conclusion

Contegra BJVCs have shown satisfactory midterm results with regards to conduit regurgitation, calcification, thrombosis, aneurysmal formation with low rates of percutaneous and surgical interventions. However, PA-VSD- MAPCAs with hypoplastic PAs subgroup results are suboptimal and it carries high risk for reintervention. This subgroup should be cautiously followed. Further analysis as a larger series and longer followup with better focus on infants to elucidate the advantage of BJVC in this age group is also needed.

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