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New Xenograft Valved Conduit (Contegra) for Right Ventricular Outflow Tract Reconstruction

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ABSTRACT

Background: The well-known flaws of existing valved conduits for reconstruction of the right ventricular outflow tract (RVOT) continue to stimulate research for the elusive "perfect" conduit. In this study, we describe our experience with a glutaraldehyde-treated bovine jugular vein valved conduit (Contegra).

Methods: From June 1999 to February 2002, 15 consecutive patients aged 2 months to 55 years underwent implantation of a Contegra conduit. Diagnoses/procedures included repair of truncus arteriosus (2 patients), pulmonary atresia (3 patients), severe pulmonary insufficiency after prior repair of tetralogy of Fallot (9 patients), and replacement of degenerated valved conduit (1 patient).

Results: No operative deaths occurred. One patient required an early conduit replacement for unexplained valve thrombosis. The early postoperative mean transconduit pressure gradient was 7.7 ± 4.9 mm Hg. At a mean follow-up time of 18.5 ± 6.9 months, all patients were asymptomatic with no discernible calcification in the valve or conduit or significant valve incompetence, while the mean transvalvular gradient remained low (11.1 ± 4.5 mm Hg).

Conclusion: The Contegra valved conduit is well suited for RVOT reconstruction, avoids the use of additional foreign material, and remains well functioning during early follow-up. Nonetheless, the long-term durability remains to be ascertained.

INTRODUCTION

The reconstruction of the right ventricular outflow tract (RVOT) involves the use of a valved conduit. The proper selection of the components of such conduits, especially the valve, remains debatable. The need for the use of foreign (synthetic or biological) material for outflow tract patching, the limited durability combined with the difficulty in handling and/or availability of homografts, the early degeneration of bioprosthetic valves in general, and the unsuitability of mechanical valves, especially in young patients, have all raised immense concern over the years and continue to stimulate research in the field in the search for the "perfect" conduit. In this report, we describe our early experience with a new xenograft valved conduit derived from glutaraldehyde-treated bovine jugular vein (Contegra; Medtronic, Minneapolis, MN, USA) for reconstruction of the RVOT.

MATERIALS AND METHODS

The Contegra bioprosthesis consists of a heterologous bovine jugular vein of sufficient length on either side of a naturally incorporated trileaflet valve, with sinuses resembling those of the pulmonary valve. The conduit is available in both supported and unsupported models and sizes from 12 to 22 mm in internal diameter. The length of the conduit on either side of the valve facilitates tailoring, allowing implantation without the use of synthetic foreign material.

From June 1999 to February 2002, 15 consecutive patients (10 male and 5 female) who required RVOT reconstruction underwent implantation of a Contegra valved conduit. The age range was 2 months to 55 years (median age, 10 years), and the median weight and body surface area were 27 kg and 1 m^2, respectively. Diagnoses and procedures are shown in the Table and Figure 1. The conduit was implanted in an orthotopic position in 9 patients and in a nonorthotopic position in 6 (Figure 2). In all cases, the valve was positioned as distally as possible near the pulmonary bifurcation to prevent its compression and distortion by the sternum. The proximal anastomosis was completed in oblique fashion with integral conduit material only. Conduit function was assessed by intraoperative transesophageal echocardiography or immediately postoperative transthoracic echocardiography in the intensive care unit and prior to hospital discharge in all cases. At the follow-up assessment, all patients underwent transthoracic echocardiography examination.

RESULTS

There have been no deaths in this series of patients as of this writing. Complications appeared in 3 of 15 patients. One 6-year-old patient with a 16-mm conduit required early

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Diagnoses and Procedures for Patients with Contegra Valved Conduit Implantations*

Diagnosis/Procedure	Patients, n
Repair of truncus arteriosus	2
Repair of TOF with pulmonary atresia	3
Late reoperation after prior repair of TOF (for severe pulmonary insufficiency ± residual RVOT obstruction, VSD, or branch pulmonary artery stenosis)	9
Replacement of degenerated valved conduit	1
Total	15

*TOF indicates tetralogy of Fallot; RVOT, right ventricular outflow tract; VSD, ventricular septal defect.

replacement of the conduit for unexplained valve thrombosis, which was discovered on a routine early postoperative echocardiographic examination showing an immobility of one leaflet that suggested thrombus formation. Appropriate anticoagulation therapy was instituted. However, the size of the thrombus increased, and the patient underwent reexploration and thrombectomy. Again, despite adequate anticoagulation treatment, valve rethrombosis necessitated exploration for a third time and eventual conduit replacement with a porcine bioprosthetic valved conduit (Hancock 16 mm; Medtronic). One patient who developed mediastinitis underwent reoperation for debridement with subsequent complete resolution, and another patient developed pericardial effusion requiring pericardiocentesis. All patients made a full recovery without residual problems.

Immediately postoperatively, the mean transconduit pressure gradient was 7.7 ± 4.9 mm Hg and was 11.6 ± 5.4 mm Hg at patient discharge from the hospital. Mild-to-moderate insufficiency of the valve was found in 3 patients, whereas in the remaining 11 patients the valve had no or trivial insufficiency. At a median follow-up time of 21.5 months (mean, 18.5 ± 6.9 months; range, 1-28 months), all patients were asymptomatic with no discernible conduit or valve calcification. The mean transvalvular gradient was 11.1 ± 4.5 mm Hg with no significant changes in valve competence (Figures 3 and 4).

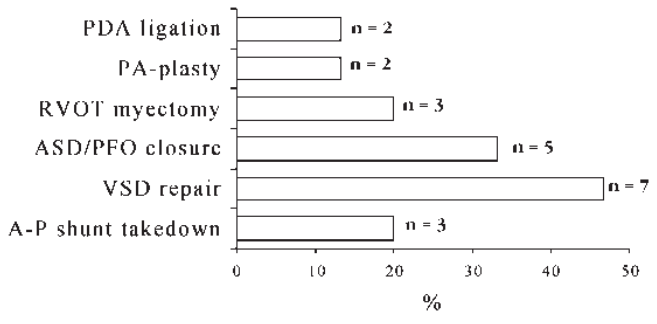

Figure 1. Concomitant procedures. PDA indicates patent ductus arteriosus; PA, pulmonary artery; RVOT, right ventricular outflow tract; ASD, atrial septal defect; PFO, patent foramen ovale; VSD, ventricular septal defect; A-P, aorto-pulmonary.

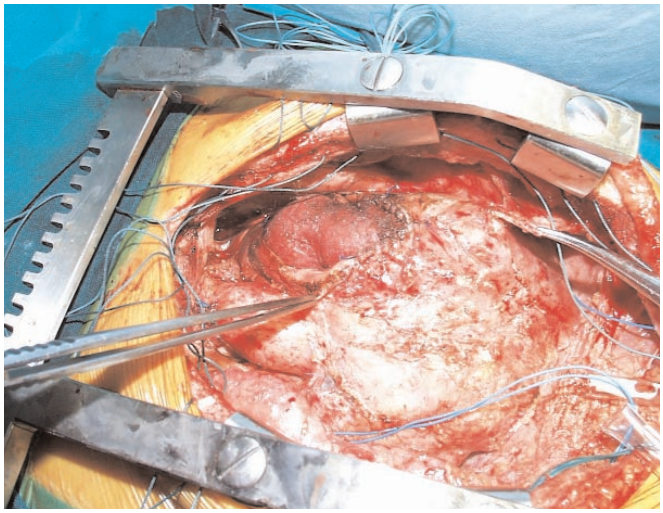

Figure 2. Orthotopic implantation.

DISCUSSION

Since the first homograft implantation for RVOT reconstruction [Ross 1966], several valved conduits have been developed, yet no one has seemed to maintain prolonged satisfactory hemodynamic function in the low-pressure pulmonary circulation. The major problems have been valve thrombogenicity, susceptibility of the synthetic prosthetic valves to infection, and early degeneration of the bioprostheses, especially in young patients. In addition, all prostheses lacked growth potential.

Although mechanical valves, particularly the tilting-disk type, may be used successfully in the pulmonary position in selected young adult patients to avoid repeated future reoperations [Rosti 1998], there is a general consensus in the cardiothoracic community advocating a cautious use of prosthetic valves in children [Ilbawi 1987].

Aortic and pulmonic cryopreserved homografts have been used extensively for RVOT reconstruction in children, with the pulmonic homografts proving more durable, especially in patients younger than 4 years [Bando 1995]. However, early valve failure has been reported in a number of cases, with

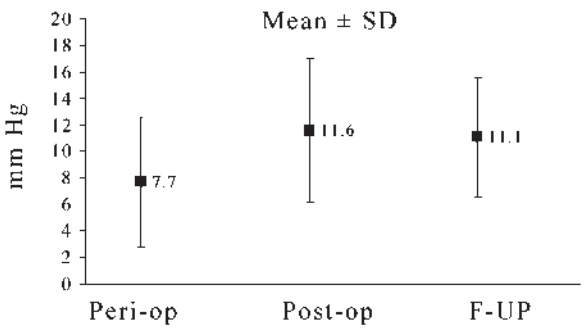

Figure 3. Peak gradient. Mean follow-up (F-UP) time, 18.5 ± 6.9 months. Peri-op indicates perioperative; Post-op, postoperative.

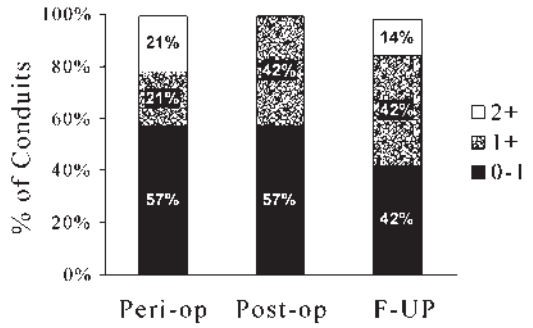

Figure 4. Regurgitation. Mean follow-up (F-UP) time, 18.5 ± 6.9 months. Peri-op indicates perioperative; Post-op, postoperative.

young age and small size being the main predicting factors [Chan 1994], and immunogenicity has been suspected to play a role [Baskett 1996]. Limitations in the size and availability of homografts pose additional problems to their use in infants and neonates.

Other bioprosthetic valves seem to be durable in adult patients yet undergo earlier leaflet degeneration in younger patients [Fucada 1997]. Autologous pericardial valved conduits do not show any advantages over other conduits. Nevertheless, their creation requires special skills, and their structure is not laboratory tested and validated prior to implantation [Schlichter 1996].

The bovine jugular vein graft (the Contegra conduit, originally known as Venpro) showed good performance in an animal model as an arterial conduit from the right ventricle to the pulmonary artery. Animals with the conduit showed no regurgitation of the valve, exhibited a minimal gradient (0-14 mm Hg) at the end of one year, and required no anticoagulation therapy [Ichikawa 1997].

A European multi-institutional trial of the Contegra conduit produced reports of satisfactory early results following its implantation in humans [Breymann 2000, Quijano 2000]. The Contegra valved conduit is well suited for RVOT reconstruction without requiring the use of additional foreign material and remains well functioning without calcification during the early follow-up period in our experience and according to other reports [Bové 2002, Breymann 2002, Corno 2002]. Derived from the systemic venous system and containing natural sinuses, the Contegra valve may have a stronger potential for long-term durability, because valves that have been naturally functioning in low-pressure circulations have been found to last longer [Bando 1995]. However, the durability of the Contegra valved conduit relative to existing alternatives will require longer investigations and larger series to define.

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