Adverse Mid-Term Outcome Following RVOT Reconstruction Using the Contegra Valved Bovine Jugular Vein

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Background. **Current techniques for repair of the right ventricular outflow tract (RVOT) may require interposition of a valved conduit between the right ventricle and the pulmonary artery bifurcation. Recently, the Contegra conduit (Medtronic, Inc.) was introduced as an alternative xenograft tissue for RVOT reconstruction. Promising early hemodynamic and clinical results have been reported so far, but still less is known about mid-term adverse outcome.**

Methods. **A total of 38 Contegra valved conduits (12 to 22 mm) were implanted from October 1999 to June 2004, in 36 children less than 5 years old and in 2 patients 8 and 21 years old. Diagnosis included the following: tetralogy of Fallot (n = 21); pulmonary atresia (n = 4); double outlet right ventricle + pulmonary stenosis (n = 3); d-transposition of the great arteries, ventricular septal defect, and pulmonary stenosis (n = 3); truncus arteriosus (n = 3); and other complex malformations (n = 4).**

Results. **There was no mortality following initial surgery and no valved-conduit–related early morbidity. Early postoperative echocardiographic assessment after 3 months demonstrated favorable hemodynamics in all patients. However, during further follow-up, 5 conduits had to be replaced because of severe stenosis at the level of the distal anastomosis (2 of them had moderate to severe dilatation of the conduit proximally to the valve). Excessive intimal peel formation and severe perigraft scarring reaction were observed in all cases. One child died before surgery.**

Conclusions. **The Contegra valved conduit is an interesting concept for reconstruction of the RVOT. However, because of unpredictable incidence of supravalvar stenosis during mid-term results, we cannot recommend routine use of this material.**

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Current surgical techniques to repair anomalies of the right ventricular outflow tract (RVOT), beside subvalvular resection, include pulmonary valvotomy, transanular patch or replacement of the pulmonary valve. However, transanular enlargement alone is frequently followed by severe pulmonary regurgitation. The latter is generally well tolerated but increase in right ventricular dimensions leads to reduced exercise capacity, arrhythmias, and risk of sudden death [1–3].

The use of homograft and xenograft conduits to reestablish continuity between the pulmonary ventricle (eg, the right ventricle) and the pulmonary artery bifurcation has been an important advance in repair of complex congenital malformations [4–7]. The principal late problem related to extracardiac conduit operations is the inevitable need for one or more conduit replacements because of patient somatic growth or progressive conduit degeneration and calcification leading to stenosis [8–11].

Some years ago, a totally integrated valved conduit (Contegra; Medtronic Inc., Minneapolis, MN) derived from a bovine jugular vein with a trileaflet venous valve has been developed and introduced on the market. Some of the main advantages are the structural continuity between the lumen of the conduit and the valve it incorporates as well as the availability for pediatric and adult patient sizes and the proximal and distal cuffs allowing for extended reconstruction.

Several reports have shown promising early hemodynamic and clinical results with this conduit [12–17]. In this study we focus on a small number of patients who developed severe stenosis at the distal anastomosis leading to explantation of the conduit.

Patients and Methods

Between October 1999 and June 2004, 75 patients between 3 weeks old and 46 years old underwent right ventricular (RV) to pulmonary artery (PA) reconstruction using a valved conduit. A pulmonary homograft was used in 17 patients, a conduit with a stented Hancock bioprosthesis (Medtronic Inc.) in 5 patients, a stentless Shelhigh pulmonic conduit (Shelhigh Inc., Millburn, NJ) in 15 patients, and a Contegra bovine conduit in 38 patients.

Only patients who received a Contegra valved conduit are considered here. There were 36 children less than 5

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years old (mean age 2.1 ± 0.6 years) and 2 patients 8 and 21 years old. All available sizes of the Contegra conduit (12 to 22 mm) were implanted. Initial diagnosis included tetralogy of Fallot (TOF; n = 21), pulmonary atresia (n = 4), double outlet right ventricle (DORV) + pulmonary stenosis (DORV + PS; n = 3), d-transposition of the great arteries (d-TGA), ventricular septal defect (VSD) and PS (n = 3), truncus arteriosus (n = 3), and 4 patients with complex malformations. In 29 patients the conduit was inserted to re-establish the continuity between the pulmonary ventricle and the pulmonary artery bifurcation because absent pulmonary valve, hypoplasia of the pulmonary anulus pulmonary atresia or to connect the right ventricle to the pulmonary artery during the Rastelli procedure or during repair of truncus arteriosus. In 9 patients, the conduit was inserted because of severe pulmonary regurgitation following previous RVOT repair with transanular polytetrafluoroethylene (PTFE) patch (n = 2), monocusp patch (n = 5), homograft (n = 1), or to replace a small Hancock conduit in a patient with truncus arteriosus (n = 1). All patients were operated by two surgeons only (P.B. and T.C.); the choice of the conduit was mainly defined by the surgeon's preference.

Characteristics of the Conduit and Operative Technique

Initially developed by VenPro (Irvine, CA) and currently owned and marketed by Medtronic, Inc. (Minneapolis, MN), the Contegra conduit is a 0.25% glutaraldehyde-fixed segment of bovine jugular vein, containing a venous valve; the whole xenograft is fixed under minimal pressure, less than 3 mm Hg. Therefore, the main characteristic of the conduit that served to generate its name Contegra (conduit with integral valve) is the absence of discontinuity between the inlet and the outlet part of the conduit and the trileaflet venous valve of the jugular vein. The conduit is provided in 10-cm length and the valve is centered in the conduit (except in the 12-mm conduit in which the length is 7 cm). The conduit is available in size range between 12 and 22 mm with a consistent quality. The material has to be rinsed during 15 minutes in physiologic electrolyte solution before implantation but there is no thawing nor preclotting procedure necessary. In vitro data have demonstrated that valve leaflet strength and flexibility are well preserved in the Contegra conduit and experimental and clinical datas have been encouraging.

The conduit is available as native jugular vein or as supported model. The supported model has two polyester-cloth–covered polypropylene rings, one located at the valve inflow and the other at the level of the commissures of the valve. The objectives of the ring support are to provide support at the valve annulus and the commissural level, to prevent compression of the conduit through the sternum that may result in pulmonary valve regurgitation. Caution should be exercised that the ring does not compress the coronary arteries.

Patients are operated using standard cardiopulmonary bypass and moderate hypothermia (32 to 34°C). Myocardial protection using cardioplegic solution is optional since we prefer to operate on the beating heart when isolated RV-PA conduit insertion is required.

During insertion of the Contegra valved conduit, care was taken to locate the valve as cranial as possible immediately below the bifurcation of the pulmonary artery. This avoids geometrical distortion of the valve at the site of proximal implantation in the right ventricle. In 7 patients the conduit was inserted in a strictly orthotopic in situ position through a longitudinal opening of the main pulmonary artery. In all other 32 patients, the xenograft was inserted as an extracardiac conduit with a ventriculotomy. The distal anastomosis was performed with running 6.0 polypropylene suture in 33 patients or with interrupted U-clips (Coalescent, Sunnywale, CA) technique (n = 6). In 11 of 40 patients, a patch enlargement of the pulmonary bifurcation (n = 8) or of a side branch (n = 3) was necessary before RV-PA reconstruction. The proximal anastomosis was always performed with 5.0 or 6.0 polypropylene running suture.

Usually there is no need for proximal augmentation with an additional patch material because length of the conduit allowed for direct closure of the right ventriculotomy. Postoperative anticoagulation treatment included low dose aspirin treatment (eg, 25- to 50-mg daily) during the first 3 months.

Two-dimensional and Doppler echocardiography was performed in all patients before discharge and after 3, 6, and 12 months. All data related to peak and mean transvalvular pressure gradients were recorded, as well as the presence of pulmonary regurgitation and any residual intracardiac lesion.

Results

The following sizes of the conduit were used: 12 mm in 4 neonates (mean body weight 3.4 ± 0.3 kg); 14 mm in 14 children (mean body weight 7.5 ± 3.9 kg); 16 mm in 11 (mean body weight 14.5 ± 2.1 kg); 20 mm in 8 (mean body weight 18 ± 4.1 kg); and 22 mm in 1 adult patient (body weight 65 kg).

There was no hospital mortality following initial surgery and no perioperative morbidity related to the conduit. Early postoperative echocardiographic assessment before discharge and at 3 months follow-up demonstrated satisfactory hemodynamic characteristics (mean peak ΔP across the valve was 14.5 mm Hg, ranging from 8 to 26 mm Hg. Trivial pulmonary regurgitation was seen in 11 patients.

After a mean follow-up of 18 ± 5 months, 6 patients had to be scheduled for conduit replacement because of excessive gradient (peak ΔP ranging from 50 to 120 mm Hg) through the conduit. On echocardiography, the gradient originated mainly at the site of distal anastomosis whereas the function of the valve was normal in all patients. The main findings of these 6 patients are summarized on Table 1. Explantation-free survival was calculated according to the Kaplan-Meier actuarial analysis and is illustrated in Figure 1. In 2 patients, prestenotic dilation of the RVOT was observed with impressive aneurysm formation of the patch used to close the