Original Research

The Contegra® Valved Heterograft Conduit for Right Ventricular Outflow Tract Reconstruction: A Reliable Solution

Panagiotis G. Sfyridis[1], Dimosthenis P. Avramidis[2], George V. Kirvassilis[3], Prodromos N. Zavaropoulos[1], John K. Papagiannis[2], George E. Sarris[1]

[1]Department of Pediatric and Congenital Cardiac Surgery, [2]Department of Pediatric Cardiology, [3]Department of Pediatric Cardiac Anesthesia, Mitera Children's Hospital, Athens, Greece

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Introduction: The Contegra® bioprosthetic valved conduit, a glutaraldehyde-preserved valve-containing bovine jugular vein graft (Contegra, Medtronic Inc., Minneapolis MN, USA) introduced for clinical trials in 1998, is used for reconstruction of the right ventricular outflow tract (RVOT), mainly in children. This study evaluates our surgical experience with the Contegra® graft, emphasizing the assessment of conduit durability at mid-term follow up.

Methods: The intermediate results of RVOT reconstruction utilizing the Contegra conduit were retrospectively analyzed in a series of 34 consecutive patients (25 male, 9 female), with a mean age of 10.9 ± 11.2 years (range 0.2-46 years). Included were 14 patients with tetralogy of Fallot (TOF) with pulmonary atresia, 11 with reoperation of previously corrected TOF, 5 with *truncus arteriosus*, 2 with TOF with absent pulmonary valve, 1 reoperation of previously repaired double outlet right ventricle with pulmonary atresia, and 1 undergoing a Ross procedure. Contegra conduit sizes varied in diameter between 12 and 22 mm (mean 18.3 ± 3.2 mm).

Results: There were no hospital deaths. There was one early conduit replacement as a result of recurrent thrombosis. Four patients developed early thrombus formation in a valve cusp with complete resolution following anticoagulation therapy. At mean follow up of 85 months (range 6-136 months) and median follow up of 95 months, one patient required Contegra graft explantation in another institution (indications unknown). Freedom from reoperation for Contegra grafts was 94% at 11.4 years. Mean transpulmonary pressure gradients remained low (9.6 ± 5.3 mmHg postoperative, 19.6 ± 10.6 mmHg at follow up). Although there was a clear trend towards worsening of conduit valve insufficiency, this was neither statistically significant nor considered clinically so.

Conclusions: In our experience of 34 consecutive operations, the Contegra® valved conduit for RVOT reconstruction seems to be a reliable alternative to homograft conduits, with promising mid-term freedom from structural deterioration and reoperation.

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Address:
Panagiotis G. Sfyridis

Mitera Hospital
6, Erythrou Stavrou St.
151 23 Maroussi
Athens,Greece
e-mail: pgsfyridis@yahoo.gr

Implantation of a right ventricular to pulmonary artery (RV-PA) conduit is a common procedure for repair of many congenital cardiac lesions involving atresia or hypoplasia of the right ventricular outflow tract (RVOT) or severe dysfunction of the pulmonary valve. These lesions include pulmonary atresia with ventricular septal defect (VSD), severe tetralogy of Fallot, *truncus arteriosus*, transposition with ventricular septal defect and pulmonary stenosis or atresia, and various forms of double outlet right ventricle. Valved conduits are also used to replace the pulmonary valve in a Ross procedure.[1]

Numerous valved conduits have been introduced since an aortic homograft was first used clinically in the mid 1960s, all in an effort to identify the elusive "ideal" conduit, which would be free of significant complications including early structural valve degeneration.[2-7] In the hope of improving on available conduits, including homografts, the Contegra® conduit was developed (originally called VENPRO®) and was introduced in clinical trials – in which our team also participated – in 1998. This graft is a glutaraldehyde-preserved heterologous bovine jugular vein graft containing a tri-leaflet venous valve. It is available in a wide range of sizes, from 12 to 22 mm.

Early clinical reports (especially in children) have generally described favorable postoperative mid-term results at follow up, although negative experiences were also reported.[8-14]

The focus of this report is to review our overall clinical experience in Greece with the bovine jugular vein conduit (BJVC) and to assess its mid-term performance.

Methods

Patient population

We retrospectively reviewed the medical records of all 34 consecutive patients (25 male, 9 female) who underwent RVOT reconstruction using a BJVC (Medtronic Inc., Minneapolis MN, USA) performed by our surgical team at the Onassis Center (1999-2007) and at Mitera Children's Hospital (2007-2010). Mean age was 10.9 ± 11.2 (range 0.2 to 46) years. At the time of conduit insertion, 3 patients were less than 1 year old (8.8%), 21 were between 1 year and 14 years of age (61.8%), and 10 were older than 14 years (29.4%).

Prior to Contegra insertion, the majority of the patients had undergone previous cardiac operations (palliative or definitive) for the primary diagnosis (Figure 1).

Primary indications for conduit implant are shown in Table 1. The majority of patients underwent operation (14 of 34, i.e. 41%) for tetralogy of Fallot with pulmonary atresia or for residual lesions of previously corrected tetralogy of Fallot.

Conduit description, implantation technique, and postoperative management

The BJVC is a section of bovine jugular vein, 12 to 15 cm in length and 12 to 22 mm in diameter, fixed in buffered glutaraldehyde at low pressure. A key feature of Contegra® is the presence of several centimeters of integral conduit material proximal and distal to the valve, facilitating various implantation requirements. The naturally occurring thin and very pliable tri-leaflet venous valve is in the mid-portion of the conduit. The valve has natural sinuses. The conduit tissue is tough yet pliable and has excellent suturability, allowing very hemostatic suture lines. The conduit is available in both supported and unsupported versions. The supported devices have semi rigid stent rings above and below the valve, which are intended to protect the conduit against compression. Our preferred technique is to use an unsupported Contegra® conduit in all patients.

The conduits used in our series ranged from 12 to 22 mm (mean 18.3 ± 3.2 mm). Indications for conduit insertion included the following: 1) RV to PA

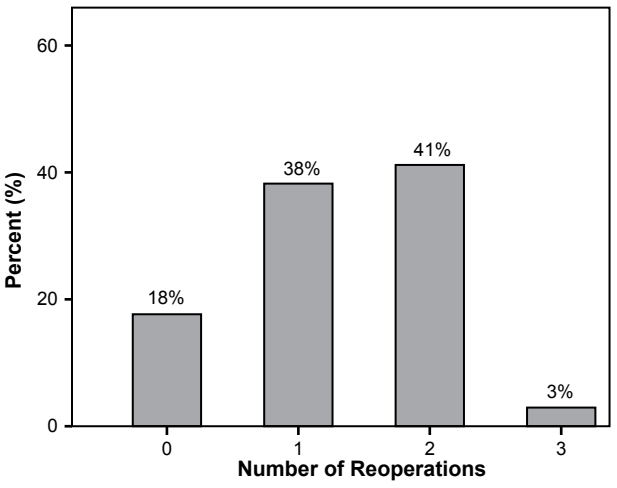

Figure 1. Frequency of previous cardiac operations, prior to Contegra® insertion.

Table 1. Primary diagnoses of 34 patients undergoing Contegra® implantation.

Primary diagnosis	Number of patients	Percent (%)
TOF – PA	14	41.2
Reoperation for corrected TOF	11	32.4
Truncus arteriosus	5	14.7
TOF with absent PV	2	5.9
DORV - PA	1	2.9
Ross procedure	1	2.9
Total	34	100

TOF – tetralogy of Fallot; TOF-PA – tetralogy of Fallot with pulmonary atresia; PV – pulmonary valve; DORV-PA – double outlet right ventricle with pulmonary atresia.

peak gradient greater than or equal to 50 mm Hg; 2) RV pressure greater than or equal to two thirds systemic pressure; 3) pulmonary atresia or stenosis with or without pulmonary insufficiency; and 4) severe pulmonary valve insufficiency after previous RVOT surgery.

All operations were conducted through a median sternotomy, with cardiopulmonary bypass established using bicaval cannulation, and under moderate hypothermia (32˚C). In general, conduit implantation was performed with the heart beating, after completion of intracardiac repair, if any, and release of the aortic cross clamp. Isolated pulmonary valve replacement is usually feasible without aortic cross-clamping. The mean bypass and aortic clamp times were 260 ± 110 and 134 ± 121 minutes, respectively.

Conduit size was determined and compared with normal pulmonary valve size for body surface area (*z* score) at the time of insertion. Oversizing was defined as a *z* score of 2.0 or greater.

The basic principles of conduit insertion include the following (Figure 2):

1. The procedure is designed to position the graft to the left of the midline to avoid sternal compression.
2. The valve must be implanted as distally as possible, near the pulmonary artery bifurcation, in order to avoid valve distortion with sternal closure. Thus, most of the conduit material distal to the valve is typically excised.
3. The distal anastomosis is performed first.
4. To avoid aortic compression, the distal anastomosis should not lie underneath the ascending aorta. Therefore, a distal main pulmonary artery opening lying partially under the typically large ascending aorta must be shifted leftwards onto the left pulmonary artery and after complete mobilization of the central pulmonary arteries.
5. The inflow end of the conduit is spatulated to form a hood over the incision in the right ventricle and sewn in with continuous monofilament suture.
6. Polytetrafluoroethylene pericardial membrane (0.1 mm) is sewn to the pericardial edges prior to closure of the sternotomy to facilitate sternal reentry, if later reoperation becomes necessary.

Postoperatively, according to our protocol recommendation, the majority of patients have been receiving heparin initially (UFH 10 UI/kg/h), switching over to low-dose coumadin for three months, with a target International Normalized Ratio between 1.5 and 2.0.

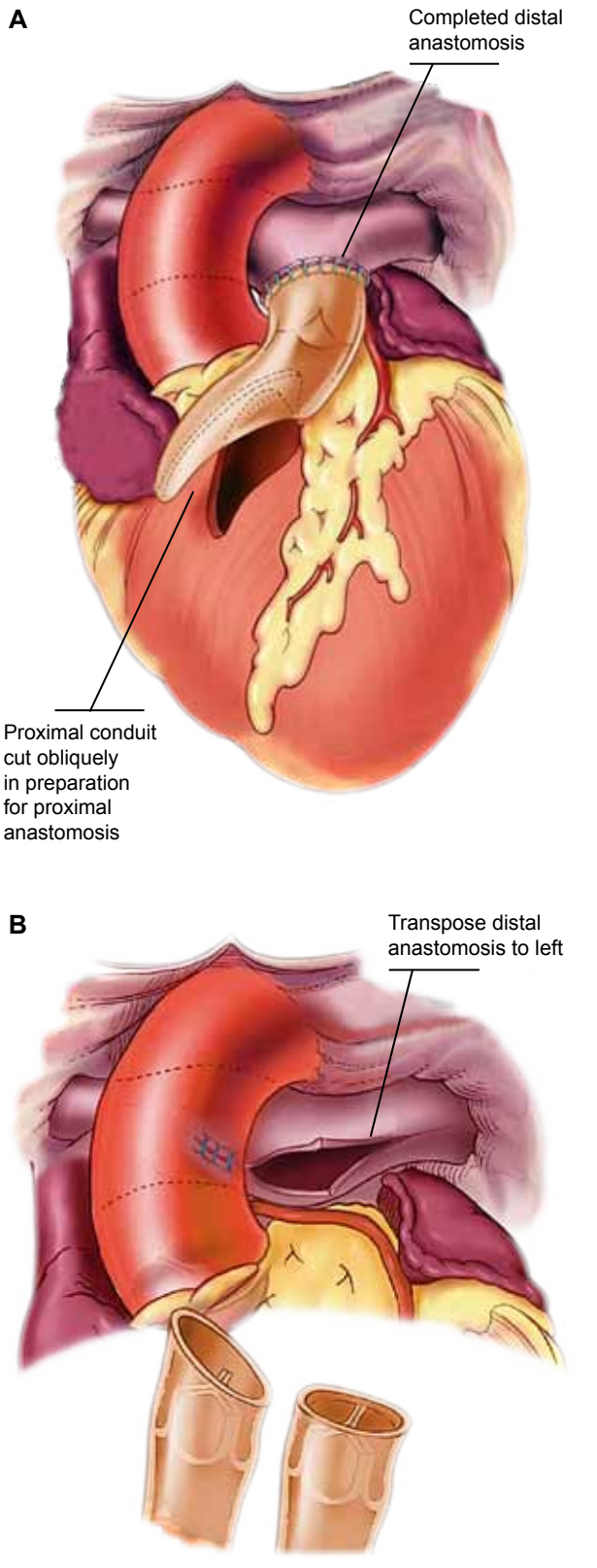

Figure 2. A. Implantation technique for the Contegra® heterograft. B. Shifting the distal anastomosis leftward, to avoid aortic compression.

Follow up

Early postoperative transthoracic echocardiographic assessment was performed in all patients one week after surgery (early follow up), and included measurement of mean transpulmonary pressure gradients, the degree of valve insufficiency, if any, and assessment of right ventricular function before leaving the hospital. The clinical follow-up evaluation, including echocardiography, was performed at a mean of 85 months (range 6-136 months) postoperatively. Echocardiographic examinations were performed by the attending cardiologists. Measurements were compared to the early postoperative results.

Indications for bovine jugular vein conduit re-intervention included: 1) symptoms of RV failure; 2) RV to PA peak gradient greater than 50 mm Hg; 3) RV pressure greater than two-thirds systemic pressure; 4) progressive dilatation of the RV (RV end-diastolic volume index by magnetic resonance imaging >150 mL/m^2), with more than grade II pulmonary regurgitation, with or without significant stenosis; and 5) progressively increasing tricuspid valve regurgitation.[15-17]

Definitions used in follow up

Early death was defined as death in the hospital or within 30 days of discharge. All other events were considered as late.

Conduit dysfunction was defined as a peak conduit gradient greater than 50 mm Hg or greater than 2+ regurgitation. Conduit failure was defined as the need for either conduit replacement or catheter laboratory conduit re-intervention (e.g. balloon dilatation with or without stenting). The severity of regurgitation was graded by visual comparison of the width of the regurgitant jet at its origin to the width of the annulus, using the following criteria:

a. none, no diastolic color flow visualized on the ventricular side of the leaflets;
b. trace (numerically equivalent to +1), pinhole color flow jet on the ventricular side of the leaflets;
c. mild (+2), a jet less than 20%;
d. moderate (+3), a jet 20% to 40%; and
e. severe (+4), a jet greater than 40% of the pulmonary valve conduit width.

Statistical analysis

Statistical software SPSS for Windows version 17 (SPSS Inc., Chicago IL, USA) was used for data analysis. Data are expressed as mean ± SD and ranges where appropriate. Actuarial reoperation-free survival was determined using the Kaplan-Meier method. For all tests, a p-value <0.05 was considered significant.

Results

There was no hospital mortality following surgery. There was only one early RVOT re-intervention, namely conduit explantation in a patient with pulmonary atresia, VSD, and multiple aortopulmonary collateral arteries to hypoplastic main pulmonary arteries. Initial palliation (central shunts and unifocalization of major aortopulmonary collateral arteries) had been performed at age 3 years. At age 5 years he underwent complete repair with Dacron patch closure of the VSD and placement of a 16 mm Contegra conduit between the RV and main PA. The patient underwent reoperation 11 days after initial surgery. Due to conduit valve thrombosis, removal of thrombus which had formed in the valve sinuses was performed. Although the initial postoperative echocardiogram showed a well-functioning valve, one day later recurrent conduit thrombosis developed. Laboratory analysis confirmed heparin-induced thrombocytopenia. At second reoperation, the Contegra graft was explanted and replaced with a 16 mm Hancock porcine-valved Dacron (DuPont, Wilmington DE, USA) conduit (Medtronic, Minneapolis MN, USA). Subsequently the patient recovered uneventfully.

One patient underwent late conduit explantation at another institution 5.5 years after initial placement of a 16 mm Contegra conduit. We were unable to obtain information about the indications for conduit replacement in this patient.

A Kaplan-Meier estimation showed a cumulative reoperation-free survival rate of 0.93 ± 0.47 % at 11.4 years (Figure 3).

Early in our experience, when no prophylactic anticoagulation was employed, early thrombus formation (2 to 4 days postoperatively) on a valve leaflet was observed by echocardiography in 4 other patients (other than the patient mentioned above), but with no impact on conduit valve geometry and competency. Laboratory investigation also confirmed the diagnosis of heparin-induced thrombocytopenia in these patients, who were all successfully treated with intravenous infusions of sodium danaparoid (ORGARAN®, 750 Anti-Xa Factor Units twice a day for

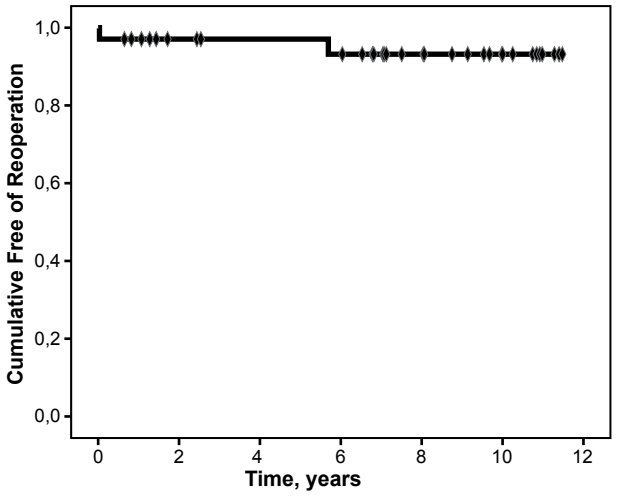

Figure 3. Kaplan-Meier estimation of cumulative reoperation-free survival rate.

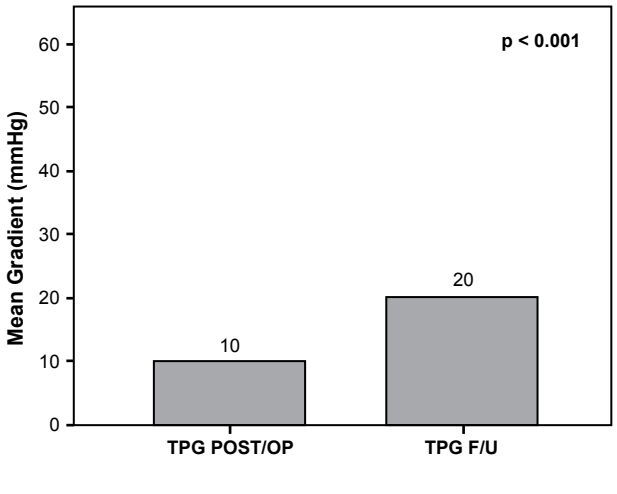

Figure 4. Mean transpulmonary gradient (TPG) in the early postoperative period (POST/OP) and at follow up (F/U).

10 days) transitioning to low dose coumadin for 6 months. Transthoracic echocardiographic evaluation before leaving hospital revealed no residual thrombus in all 4 patients. All subsequent patients received perioperative anticoagulation prophylaxis, as described in the Methods section.

At the time of hospital discharge, mean echo trans-conduit gradient was 9.6 ± 5.3 mmHg (Figure 4). Mean trans-conduit pressure gradients were not significantly different in various diagnostic subgroups, and are listed in Table 2.

At mean follow up of 7.1 ± 3.6 years, the mean echo trans-conduit gradient increased to 19.6 ± 10.6 mmHg (Figure 4). Mean trans-conduit gradients in different diagnostic categories are listed in Table 3 and were not clinically significantly different from each other. The mean increase was statistically significant ($p<0.001$) but with no clinical impact (Table 3).

At the time patients were discharged, 15 (44%) had no pulmonary insufficiency and each of the remaining 17 patients (50%) was judged echocardiographically to have trace to mild conduit valve insufficiency. At last follow up, among the 32 reoperation-free patients, the degree of conduit valve insufficiency had increased, as only 5 patients (15%) had none, but 26 patients (76%) had trace to mild and one patient had moderate regurgitation (Figure 5). Shrinkage or dilatation of the BJVC was not observed by echocardiography in this series. Despite the increasing degree of valve insufficiency, at this time none of these patients has conduit dysfunction approaching the criteria for reoperation.

Discussion

The limited availability and durability of cryopreserved homografts, particularly in small sizes suitable for the pediatric population, together with the increasing call for blood group donor-to-recipient compatibility (in the hope of reducing rates of accelerated homograft degeneration), has provided the impetus for a continuing search for an alternative conduit

Table 2. Early postoperative mean pulmonary pressure gradients in different diagnostic subgroups.

Diagnostic categories	Number of Contegra conduits (total 32)	TPG (mmHg)
TOF – PA	12	7 ± 2
Reoperation for corrected TOF	11	9 ± 4
Truncus arteriosus	5	16 ± 10
TOF with absent PV	2	11 ± 1
DORV - PA	1	8
Ross procedure	1	10

Abbreviations as in Table 1.

Table 3. Mean transpulmonary pressure gradients (TPG) at mid-term follow up (85 months, range 6-136) in different diagnostic subgroups.

Diagnostic categories	Number of Contegra conduits (total 32)	TPG (mmHg)
TOF – PA	12	13 ± 8
Reoperation for corrected TOF	11	24 ± 8
Truncus arteriosus	5	27 ± 15
TOF with absent PV	2	22 ± 1
DORV - PA	1	8
Ross procedure	1	28

Abbreviations as in Table 1.

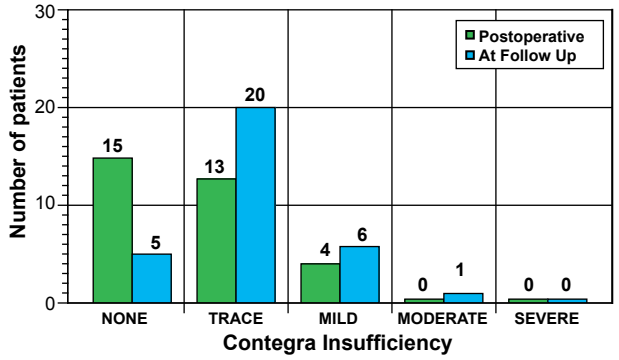

Figure 5. Degree of conduit valve insufficiency in the early postoperative period and at follow up.

to reconstruct the RVOT in congenital heart defects and in patients undergoing the Ross procedure.[18] The Contegra heterograft has been used as a valved conduit between the RV and the pulmonary arteries since the late 1990s.[19] Reconstructing RV to PA continuity using the valved heterologous bovine jugular vein, the Contegra® bioprosthesis, has been widely accepted in the treatment of many patients with congenital heart disease.[13]

Encouraging mid-term results for the Contegra® implantation in children and adults are available and have been reported by most groups, suggesting that this conduit has become a satisfactory alternative to homografts in RVOT reconstruction, with excellent short-term to mid-term results. On the other hand, some few units have reported disappointing results, with a high incidence of distal stenoses and re-interventions.[10,12,13,18-22]

The main advantages of using the Contegra® graft in RVOT reconstruction are: 1) its immediate availability in a broad spectrum of different sizes, making it suitable as an alternative to cryopreserved homografts in neonates and very young children, when blood group-compatible homografts in an appropriate size cannot be easily obtained; 2) the presence of an ample length of tissue proximal and distal to the venous valve, facilitating reconstructive procedures; and 3) its moderate cost.[13,18]

In this report, we describe our overall experience in Greece with 34 consecutive implants of the BJVC in a mixed children and young adult population. Notably, few results are available concerning the use of the Contegra® graft in adults.[13] Indications included tetralogy of Fallot (TOF) with pulmonary atresia, reoperation for residual lesions after previously corrected TOF, *truncus arteriosus*, TOF with absent pulmonary valve, reoperation of previously repaired double-outlet right ventricle with pulmonary atresia, and a Ross procedure. The majority of our patients had TOF as primary diagnosis, as noted in studies reported by others.[3,18,23]

Our overall early postoperative and mid-term follow-up results have been very satisfactory. One patient had early reoperation because of recurrent thrombus formation at the conduit valve, representing an aggressive immunological reaction, as heparin induced thrombocytopenia was confirmed. In our early experience, we also identified xenograft thrombus formation (but without valve dysfunction) in another 4 patients, associated with heparin antibodies. In all of these 4 cases the thrombus resolved completely with appropriate anticoagulation therapy. One explanation could be that the Contegra graft may present xenogeneic proteins that are recognized as antigenic. A possible role for residual glutaraldehyde has been mooted by some. We practice meticulous conduit rinsing and avoid conduit adventitia being incorporated into the lumen at the anastomotic sites. Beyond these measures, we also recommend, unless contraindicated, a 1-2 day postoperative continuous intravenous infusion of heparin, switching over to low-dose warfarin for 3 months to decrease the potential thrombus formation at the Contegra valve leaflets. Using this protocol, we have not encountered formation of thrombus in the valve sinus since our early experience.

Consistent with the findings of others, we have demonstrated a low reoperation rate for Contegra grafts in our 11.4 year experience.[12,18] Only 1 patient had late conduit replacement at another institution, but we were unable to learn the indications which led to reoperation in this case. In our study, the overall reoperation rate was 5.8%, consistent with a recent

report by Christenson and associates in which the reoperation rate was 7.2% in the Contegra group and, significantly, lower compared with the homograft groups (26.4% cumulative for non-ABO and ABO compatible homograft groups).[18]

In our series, in contrast to other investigators, dilatation, severe calcifications of the Contegra conduit or distal anastomotic stenosis due to fibrous tissue growth were not observed.[24,25] We believe that critical details of the implantation techniques employed at the distal anastomosis may be relevant. We believe that it is important to perform the distal conduit anastomosis leftwards, towards the proximal left PA. This prevents anastomotic compression by the lesser curvature of the ascending aorta on the distal conduit anastomosis, which could potentially trigger mechanical narrowing.

Conduit dilatation is reportedly related to high RV and intra-conduit pressure, possibly secondary to distal branch pulmonary artery stenosis in some reports.[19,21,26] Our study, in which no conduit dilatation was observed, as well as others, suggest that the Contegra® conduit can withstand high distal pressures without the formation of aneurysm or conduit valve degeneration.[19]

In our series, the overall mid-term performance of the Contegra® conduit has been excellent, with 32 of 34 patients (94%) free of any intervention at a mean follow up of 85 months. The RV to PA mean gradient increased statistically significantly during this interval (from 9.6 mmHg to 19.6 mmHg), but this increase was clinically insignificant, with no impact on the longevity of the conduit. Similarly, the observed increase in conduit valve regurgitation remained clinically insignificant, although one must anticipate possible continued deterioration of valve function.

Conclusions

Although approximately 5 decades have passed since the introduction of the extracardiac RV to PA conduit, the "perfect" conduit has yet to be developed. The Contegra® valved BJVC, given its ready availability in a wide range of sizes, its excellent handling characteristics and early hemodynamic results, its low rates of conduit dysfunction and low reoperation rates at mid-term follow up in the pediatric and adult population, seems to be a valid alternative to homografts for RVOT reconstruction. True long-term outcome data are not available yet and should definitely be sought.

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