Midterm follow-up of the status of Gore-Tex graft after extracardiac conduit Fontan procedure

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Abstract

Objective: Extracardiac conduit Fontan procedure has some theoretical advantages over other types of Fontan procedures, such as optimized flow dynamics, a lower frequency of arrhythmias, and technical ease of procedure. However, lack of growth potential and thrombogenicity of the artificial conduit is the main concern and can possibly lead to reoperation for the conduit stenosis. In this study, we investigated the change and the status of the Gore-Tex graft used in extracardiac conduit Fontan procedure.

Methods: Between 1996 and 2005, 154 patients underwent extracardiac conduit Fontan procedure using Gore-Tex graft. Among these, 46 patients underwent cardiac catheterization during follow-up period. We measured the internal diameter of the conduit and inferior vena cava angiographically.

Results: Mean follow-up duration was 36.1 ± 19.7 months. The conduit diameter used was 16 mm in 10 patients, 18 mm in 16, 20 mm in 14, 22 mm in 4, and 24 mm in 2 patients. The mean conduit-to-inferior vena cava cross-sectional area ratio was 1.25 ± 0.33. According to the conduit size used, this ratio was 1.03 ± 0.17 for 16 mm conduits, 1.33 ± 0.37 for 18 mm, 1.33 ± 0.36 for 20 mm, 1.28 ± 0.26 for 22 mm, and 1.05 ± 0.06 for 24 mm conduits (p < 0.05, 16 mm vs 18 mm and 20 mm). The mean percent decrease of the conduit cross-sectional area was 14.3 ± 8.5%, and this did not differ significantly according to the conduit size (p = 0.82). Follow-up duration and the percent decrease of the conduit cross-sectional area did not show significant correlation (r = 0.22, p = 0.14). There was no reoperation due to conduit stenosis.

Conclusions: During midterm follow-up of about 3 years, the conduit cross-sectional area decreased by 14%, and this did not differ according to the conduit size used. The extent of decrease of the conduit cross-sectional area remained stable irrespective of the follow-up duration. Sixteen millimeters conduit showed no evidence of clinically significant stenosis, but careful follow-up is warranted because of the possible conduit stenosis relative to the patients’ somatic growth.

Keywords: Single ventricle; Fontan procedure; Extracardiac conduit

1. Introduction

Fontan procedure is a final-stage palliation for the patients with functional single ventricles, and underwent various technical modifications. Extracardiac conduit Fontan procedure (ECFP), originally introduced for the patients with complex intra-atrial structures [1], has some theoretical advantages over other types of Fontan procedures, such as optimized flow dynamics, a lower frequency of arrhythmias, and technical ease of procedure [2–8]. However, lack of growth potential and thrombogenicity of the artificial conduit is the main concern and can possibly lead to reoperation for the conduit stenosis. There are few reports in the literature about status of the artificial conduits used in ECFP [9,10], and careful interpretation of the results is needed because of relatively small number of patients or various kinds of conduits used. For the growing patients, large conduits comparable with the size of adult inferior vena cava (IVC) may be desirable. However, excessively oversized conduits relative to the patients’ actual IVC size may lead to unfavorable hemodynamics. Selection of optimal size of the conduits is an important issue, but studies dealing with this problem are also limited [11,12].

In this study, we investigated the change and the status of the Gore-Tex graft (W.L. Gore & Associate, Inc., Flagstaff, AZ) used in ECFP by comparing with the patients’ IVC size.
2. Materials and methods

2.1. Patients

Between 1996 and 2005, 154 patients underwent ECFP using Gore-Tex graft in our institution. Among these, 46 patients underwent cardiac catheterization and angiography during follow-up, and these constitute study population. It is our institutional policy to routinely evaluate hemodynamic status of the post-Fontan patients by catheterization during follow-up. Mean age at the time of Fontan procedure was 5.4 ± 6.5 years (1.7–36.0 years). There were 21 male and 25 female patients. Mean body weight and height at the time of Fontan procedure were 16.9 ± 8.8 kg (9.0–51.0 kg) and 101.4 ± 21.6 cm (75–177 cm), respectively. Anatomic diagnoses are summarized in Table 1. Mean number of previous palliations was 1.6 ± 0.9 (0–4).

2.2. Methods

Retrospective study was performed, and all data were collected by reviewing medical records. Institutional Review Board of our institution approved this study. Internal diameters of the conduits and IVCs were measured angiographically in both anteroposterior (AP) and lateral projections. Diameters of the conduits were measured at the mid-portion of the conduits, and diameters of the IVCs were measured at the level of the diaphragm (Fig. 1). All measurements were repeated three times, and the average values were used for analysis. Cross-sectional areas of the conduits and IVCs were calculated as follows, assuming that the shape of cross-section is elliptical.

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\text{Cross-sectional area} = 3.14 \times \left( \frac{\text{AP dimension}}{2} \right) \times \left( \frac{\text{lateral dimension}}{2} \right)
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2.3. Statistical analysis

Continuous data were expressed as mean ± standard deviation (range). Statistical analysis was performed using Mann–Whitney test, Kruskal–Wallis test, Fisher’s exact test, and linear regression. SPSS (SPSS for Windows 11.0, SPSS Inc., Chicago, IL) was used, and the difference was considered statistically significant when the p-value was less than 0.05.

3. Results

3.1. Operative data

All patients underwent cardiac catheterization prior to Fontan procedure. Mean pulmonary artery pressure was 12.1 ± 3.0 mmHg (6–19 mmHg), and mean arterial oxygen saturation was 84.0 ± 4.6% (73–93%).

Fontan procedure was performed under median sternotomy and standard cardiopulmonary bypass. If concomitant intracardiac procedure was not needed, operation was performed with heart beating. Gore-Tex graft was used for extracardiac conduit, and mean diameter of the conduits was 18.8 ± 2.1 mm (16–24 mm) (Fig. 2). Fenestrations were created in 29 (52.2%) patients, when indicated.
3.2. Follow-up

Follow-up was complete, and mean interval between Fontan procedure and follow-up angiography was 36.1 ± 19.7 months (3–96 months). Mean age at the time of angiography was 8.4 ± 6.5 years (4.3–36.3 years). Mean body weight and height were 23.4 ± 9.1 kg (14.9–57.4 kg) and 120.0 ± 18.0 cm (93–178 cm), respectively. Mean pulmonary artery pressure was 13.4 ± 3.3 mmHg (8–22 mmHg), and mean arterial oxygen saturation was 92.4 ± 4.1% (76–98%). Among the 24 patients with fenestrations, spontaneous closure of the fenestrations was observed in 17 (70.8%) patients. Aspirin was used for anticoagulation in most patients, but warfarin was used for the patients who had a history of thrombosis or mechanical valve. There was one late death due to traumatic intracranial hemorrhage. Interventions at the time of follow-up angiography were performed in seven (15.2%) patients, and these were balloon angioplasty of the pulmonary arteries \( (n = 5) \) and fenestration closure \( (n = 2) \). There was no reoperation related to the conduit stenosis.

3.3. Diameters of the Gore-Tex graft and IVC

In all patients, no focal stenosis of the conduits was observed, and laminar flow through the conduits was maintained. Mean AP diameter of the conduits was 19.6 ± 3.0 mm (13.3–26.3 mm) (Fig. 3). Mean lateral diameter of the conduits was 15.5 ± 2.0 mm (10.9–21.3 mm) (Fig. 4). Mean AP-to-lateral diameter ratio was 1.27 ± 0.19 (0.86–1.69), meaning elliptical-shaped cross-section with compression in lateral direction by lung and cardiac mass.

Mean AP and lateral diameter of the IVC were 16.4 ± 3.3 mm (11.4–26.3 mm) and 15.6 ± 3.0 mm (10.4–25.5), respectively. Mean AP-to-lateral diameter ratio of the IVC was 1.07 ± 0.20 (0.68–1.52), meaning near circular-shaped cross-section.

Mean conduit-to-IVC AP diameter ratio was 1.21 ± 0.17 (0.84–1.55), and mean conduit-to-IVC lateral diameter ratio was 1.02 ± 0.17 (0.75–1.47).

3.4. Cross-sectional areas of the Gore-Tex graft and IVC

Mean cross-sectional area of the conduits and IVCs were 240.1 ± 59.6 mm\(^2\) (127.4–418.0 mm\(^2\)) and 205.5 ± 75.0 mm\(^2\) (109.7–414.4 mm\(^2\)), respectively. Mean conduit-to-IVC area ratio was 1.25 ± 0.33 (0.64–2.03) (Fig. 5). The ratio for 16 mm conduits was significantly small compared with those for 18 mm and 20 mm conduits (Mann–Whitney test, \( p = 0.04, 0.01 \)). Six patients had area ratio less than 1.0. Among these, five patients had conduit size less than 20 mm (5/24, 20.8%).
and one patient had conduit size equal to or greater than 20 mm (1/18, 5.6%) (Fisher’s exact test, \( p = 0.06 \)). Mean percent decrease of the conduit cross-sectional area was 14.3 ± 8.5% (0.1—36.6%), and the values according to the conduit size did not differ significantly (Kruskal–Wallis test, \( p = 0.82 \)) (Fig. 6). Follow-up duration and percent decrease of the conduit cross-sectional area did not show significant correlation (linear regression, \( r = 0.22 \), \( p = 0.14 \)) (Fig. 7).

4. Discussion

Extracardiac conduit Fontan procedure has some theoretical advantages over other modifications of Fontan procedure, and excellent short and midterm results were reported [2–5,7–9,13]. One of the most concerning issues of ECFP using artificial grafts is conduit stenosis and possibility of thrombus formation. Recently, pedicled autologous pericardium or tissue-engineered graft is being used at some centers to provide growth potential and to reduce the possibility of thrombus formation, but these kinds of grafts cannot be used universally [13–19]. Gore-Tex graft is the most widely used material in ECFP due to its availability in various size, relatively small amount of pseudo-intimal peel formation, and resistance to calcification. However, little is known about the fate of Gore-Tex graft used in ECFP [9,10].

Mean AP-to-lateral diameter ratio of the conduits was 1.27 ± 0.19 (0.86—1.69), meaning elliptical-shaped cross-section with compression in lateral direction by lung and cardiac mass. This result is comparable with that of other report stating that the ratio was 1.4 [10].

Mean conduit-to-IVC area ratio was 1.25, which means that overall conduit cross-sectional area was 25% larger than IVC cross-sectional area. However, the ratio for 16 mm conduits was 1.03, meaning near same cross-sectional areas of the conduits and IVCs. Theoretically, 16 mm conduits may be stenotic relative to IVC as patients grow. However, it is difficult to expect that small-sized conduit will necessarily lead to reoperation in the future, because venous system readily develops collateral circulation secondary to pathway stenosis. In our study, there were six patients who had conduit-to-IVC area ratio less than 1.0, but they are currently doing well without significant hemodynamic disturbance. Giannico et al. [20] followed-up 165 patients who had undergone ECFP, and Gore-Tex grafts were used in 113 patients. They reported that there was no conduit-related reoperation, although they did not state the exact number of patients who had 16 mm conduits.

Mean percent decrease of the conduit cross-sectional area was 14.3%, and this did not show correlation with follow-up duration. It is possible to speculate that Gore-Tex graft undergoes pseudo-intimal peel formation on its luminal surface early after operation, and then remains stable thereafter. Amodeo et al. evaluated about the status of extracardiac conduits by magnetic resonance imaging, and reported that there was mean 17.8% decrease of the internal diameters for initial 6 months after Fontan procedure. They reevaluated the internal diameters at 5 years after the operation, and reported that no further reduction of diameter was observed [9]. This result is similar to ours in that Gore-Tex graft remained stable after initial peel formation, irrespective of follow-up duration.

Gore-Tex graft has been widely used as a substitute for arterial system, and has been known to form smooth and thin (usually less than 1 mm) pseudo-intimal peel on its luminal surface [21,22]. The ability of Gore-Tex graft to form thin pseudo-intimal peel is due to less fibrous reaction, compared with Dacron graft, and this less fibrous reaction is, in turn, due to optimal pore size of Gore-Tex material (20—30 \( \mu \text{m} \)) for graft healing [23]. However, little is known about the fate of Gore-Tex graft as a substitute for low-pressure venous system. Based on our and previously mentioned others’ results, it is thought that Gore-Tex graft can also be used as a stable conduit for venous system.

Selection of an optimal sized-conduit for ECFP is an important issue. When considering a patient’s somatic growth, conduit size comparable to an adult’s IVC size is desirable, but a large conduit is difficult to use technically in a small patient, and also hemodynamically undesirable. It is known that the mean diameter of adults’ IVCs is about 20 mm [24]. Therefore, it is recommended that ECFP should be delayed until they weigh 15 kg or more to accommodate at least 20 mm sized conduit [25]. However, patients with same weights do not always have identical sized IVCs, because of the diversities of their cardiac anatomy and clinical status.
Indeed, Alexi-Meskishvili et al. [11] measured the diameters of the IVCs intraoperatively at the time of Fontan procedure, and reported that the sizes were variable and that these correlated weakly with the patients’ age, weight, and height. They stated that, considering IVC size, ECFP might be performed at the age of 2–3 years and at a body weight 12–15 kg, when a hemodynamically optimal adult sized conduit could be implanted. However, in some clinical situations, it is difficult to wait until adult sized conduit can be implanted. In these situations, we think that it is prudent to select conduit size based on preoperative and intraoperative evaluation of the actual IVC size.

Excessively oversized conduit relative to the patient’s IVC size can cause hemodynamic disturbance. Lardo et al. [6] reported that the maximum ratio of the conduit-to-IVC diameter, which might not cause significant hemodynamic energy loss, might be 1.5. Alexi-Meskishvili et al. [11] reported two patients who have had thrombus formation in extracardiac conduits due to oversized conduits, and recommended that conduit more than 20% larger than IVC size should not be used.

To overcome the problems of artificial conduits, pedicled autologous pericardium or tissue-engineered graft as an extracardiac conduit are being used at some centers, and the long-term results are worth waiting for [13–19].

5. Limitations of the study

We utilized angiography to evaluate the cross-sectional areas of the conduit and IVC, so this could be a source of error. Imaging tools that can directly evaluate cross-sectional area, such as computed tomography can be more informative about the fate of artificial graft used in ECFP, and longer-term follow-up is mandatory.

6. Conclusions

During midterm follow-up of about 3 years, the conduit cross-sectional area decreased by 14%, and this did not differ according to the conduit size used. The extent of decrease of the conduit cross-sectional area remained stable irrespective of the follow-up duration. Sixteen millimeters conduit showed no evidence of clinically significant stenosis, but careful follow-up is warranted because of the possible conduit stenosis relative to the patients’ somatic growth.

References