Long-term outcomes of expanded polytetrafluoroethylene conduits with bulging sinuses and a fan-shaped valve in right ventricular outflow tract reconstruction

Takako Miyazaki, MD, PhD,[a] Masaaki Yamagishi, MD, PhD,[a] Yoshinobu Maeda, MD,[a] Satoshi Taniguchi, MD,[a] Shuhei Fujita, MD,[a] Hisayuki Hongu, MD,[a] and Hitoshi Yaku, MD, PhD[b]

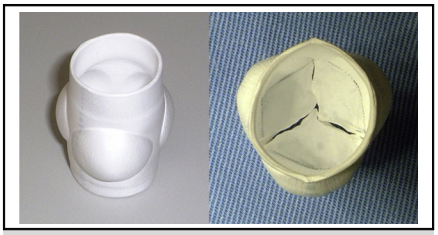
ABSTRACT

Objective: Various types of conduits are available for right ventricular outflow tract (RVOT) reconstruction. We have developed an expanded polytetrafluoroethylene (ePTFE) conduit with bulging sinuses and a fan-shaped ePTFE valve. This study summarized the results of a multicenter study evaluating the valved ePTFE conduit.

Methods: The valve functions of 902 patients (median age, 3.9 years; median weight, 12.6 kg) who underwent RVOT reconstruction using valved ePTFE conduits (9 different sizes, 8-24 mm in diameter) at 65 hospitals between 2001 and 2015 were retrospectively investigated. Median follow-up time was 5.5 years. The valve functions were assessed using echocardiography, cardiac catheterization, and magnetic resonance angiography.

Results: There were no deaths related to the ePTFE conduit. The peak RVOT gradient was 16.5 ± 13.1 mm Hg, and pulmonary insufficiency graded better than mild was 95.9% at the latest follow-up. Conduit replacement was performed in 55 patients, and in only 3 patients because of conduit infection. Freedom from intervention at 5 years and 10 years was 92.3% and 76.1%, respectively, with small conduits (8-16 mm in diameter) and 99.6% and 95.1%, respectively, with large conduits (18-24 mm in diameter).

Conclusions: The long-term outcomes of the ePTFE conduit with a fan-shaped valve and bulging sinuses appear clinically satisfactory. We believe that the longevity of small-sized conduits can yield sufficient time to exchange them to larger-sized conduits without any loss of their valve functions. Regarding longevity and resistance to infections, this ePTFE valved conduit can be one of the best ways to reconstruct the RVOT. (J Thorac Cardiovasc Surg 2018;■:1-10)



Expanded polytetrafluoroethylene conduits with bulging sinuses and a fan-shaped valve.

Central Message

The long-term outcomes of the ePTFE conduit with a fan-shaped valve and bulging sinuses appear clinically satisfactory. This ePTFE valved conduit can be one of the best ways to reconstruct the RVOT.

Perspective

A fan-shaped valve design with bulging sinuses on expanded polytetrafluoroethylene conduits has beneficial effects on long-term valve function. These valves can accomplish excellent long-term outcomes and represent a promising material for right ventricular outflow reconstruction.

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CONG

A large spectrum of congenital heart diseases requires valved conduits to establish anatomic continuity between the right ventricular outflow tract (RVOT) and the pulmonary artery. These valves require good performance to maintain good valve function over the long term, especially for younger children. Thus, we focused on the properties of expanded polytetrafluoroethylene (ePTFE); it has good biocompatibility, and its microporous structure impedes cellular penetration and subsequent calcification, which is a common cause of valvular dysfunction. We have developed handmade ePTFE valves with

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From the [a]Department of Pediatric Cardiovascular Surgery, Children's Medical Center, and [b]Division of Cardiovascular Surgery, Department of Surgery, Kyoto Prefectural University of Medicine, Kyoto, Japan.

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Address for reprints: Masaaki Yamagishi, MD, PhD, Department of Pediatric Cardiovascular Surgery, Children's Medical Center, Kyoto Prefectural University of Medicine, Kyoto, Japan (E-mail: myama@koto.kpu-m.ac.jp).

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Abbreviations and Acronyms

ePTFE = expanded polytetrafluoroethylene
IQR = interquartile range
PS = pulmonary stenosis
RVEDVI = right ventricular end-diastolic volume index
RVOT = right ventricular outflow tract

bulging sinuses and fan-shaped valves, and we previously reported midterm results showing excellent valvular function.[1-4]

In Japan, these valves have been used at 65 institutes given the unavailability of homograft and bovine jugular veins, and they have shown excellent results. All the conduits that were implanted in this study were made at Kyoto Prefectural University of Medicine. Each institute asked us to make the conduits before the operations. We formed bulging sinuses on the conduit automatically using a special machine, and one author personally sutured all the fan-shaped valves on all the conduits in the operating room.[2,3] In addition, all the finished valves were sterilized and delivered to the Japanese institutes as needed. The purpose of this study was to review the clinical outcomes of the ePTFE valved conduit for RVOT reconstruction in a multicenter study (Video 1).

MATERIALS AND METHODS

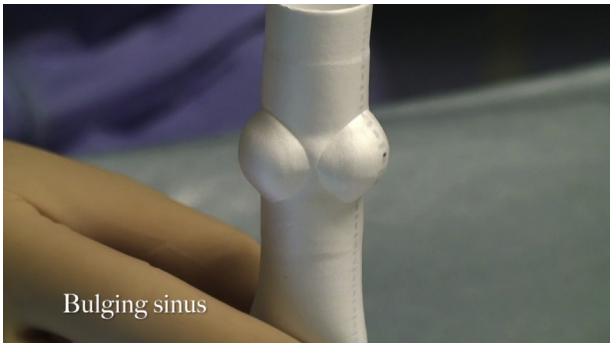
This study was approved by the Institutional Review Board at Kyoto Prefectural University of Medicine (RBMR-C-657-1, January 15, 2010).

Data Collection and Statistical Analysis

This multicenter study included follow-up with each patient at the respective institutes. Preoperative and postoperative data were collected retrospectively from the patients' medical records at each institute. The conduit diameters at the time of insertion were converted into Z-values by regression analysis based on previously published nomograms,[5,6] and a predicted pulmonary valve size was determined using a historically validated nomogram[7] indexed to the body surface area.

To assess the presence of pulmonary regurgitation and to determine the mean blood pressure gradients across the valve, all patients periodically underwent transthoracic, 2-dimensional, color flow, M-mode Doppler echocardiography during follow-up at each institute. The grade of the conduit stenosis was determined using continuous Doppler to measure the maximum velocities across the conduit and the pressure gradient across the RVOT. The grades were as follows: mild, peak velocity < 3 m/s, and peak gradient < 36 mm Hg; moderate, peak velocity 3 to 4 m/s, and peak gradient 36 to 64 mm Hg; and severe, peak velocity > 4 m/s, and peak gradient > 64 mm Hg. The degree of pulmonary regurgitation was classified based on a 5-grade semiquantitative scale (0, none; 1, trivial; 2, mild; 3, moderate; or 4, severe) according to the features of the jet flow as measured with pulsed Doppler echocardiography. All the criteria used for grading were based on the commonly used guidelines for echocardiograms.[8]

All data are expressed as means ± standard deviation, median, and interquartile range (IQR). The Kaplan-Meier product limit method was used to analyze patient survival and freedom from reoperation.



VIDEO 1. How to make the valved conduit. Video available at: http://www.jtcvsonline.org.

RESULTS

Patients

Between February 2001 and January 2015, 902 patients underwent RVOT reconstruction using fan-shaped ePTFE valves and ePTFE valved conduits with bulging sinuses in 65 Japanese institutes. The inclusion criterion was the use of operative treatment as the primary correction for underlying heart disease; patients undergoing palliative procedures were excluded. The anatomic diagnoses are listed in Table 1.

The median age at the time of operation was 3.9 years (range, 0 days to 56.8 years). There were 292 patients (32.4%) younger than 2 years. Their median body weight at the time of surgery was 12.6 kg (2.1-91.3 kg). Three hundred sixty-four patients (40.3%) had previous RVOT reconstruction with prosthetic valves. The diameters of the conduits were 8 mm in 3 patients, 10 mm in 24 patients, 12 mm in 78 patients, 14 mm in 99 patients, 16 mm in 196 patients, 18 mm in 187 patients, 20 mm in 71 patients, 22 mm in 175 patients, and 24 mm in 69 patients. Conduits smaller than 16 mm were implanted in 400 patients (44.3%).

Figure 1, *A*, shows the patients' body weight and the diameters of the conduits used, and Figure 1, *B*, shows the body weights and Z-values. The conduit's Z-value at implantation was 1.3 ± 1.0 (median, 1.3; IQR, 0.46-1.89; range, −2.0 to 5.1), and its size as a percentage of the normal pulmonary annulus was 135.2% ± 15.4% (median, 134.8; IQR, 112.4-150.8; range, 90.9%-237.1%). Conduit characteristics are listed in Table 2. The Z-value at implantation was 1.8 ± 0.8 (median, 1.9; IQR, 1.4-2.3) in patients younger than 2 years and 0.9 ± 1.0 (median, 0.8; IQR, 0-1.7) for patients older than 2 years.

At the initial construction of the bulging sinuses, the ePTFE graft needs to be formally opened, because the bulging sinuses are formed from flat molds. After the bulging sinus has been formed and the fan-shaped valve anastomosed, the graft is rolled up and sutured to form a conduit (Figure 2, *A*).[2] Starting in 2010, it was no longer necessary to cut open the ePTFE because of improved fabrication techniques (Figure 2, *B*).[3]