

Novel self-expandable, stent-based transcatheter pulmonic valve: A preclinical animal study



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ABSTRACT

Background: Because transcatheter implantation of pulmonary valve is indicated for limited-size dysfunctional right ventricular outflow tract only as a balloon-expandable stent, we investigated the feasibility of a large-diameter self-expandable valved stent and the durability of the valve after >6 months.

Methods: We made a nitinol-wire-based, self-expandable valved stent with leaflets made from porcine pericardium. The porcine pericardium was treated with α -galactosidase, glutaraldehyde, and glycine after decellularization. After cutting the inguinal or cervical area, we implanted a valved stent in 12 sheep through the femoral or jugular vein by using an 18-Fr delivery catheter, controlling the catheter handles and hook block under fluoroscopic and echocardiographic guidance.

Results: The mean body weight of sheep was 43.9 kg. We successfully implanted valved stents (diameter: 24 mm in 7 sheep, 26 mm in 5 sheep) in good position in 8 sheep, in the main pulmonary artery (PA) in 2 sheep, and in the right ventricular outlet tract (RVOT) in 2 sheep. We sacrificed 8 sheep (6 sheep in good position, 1 sheep in the main PA, and 1 sheep in the RVOT) after >6 months. Five of the 6 sheep implanted in good position showed well-preserved valve morphology at the time of sacrifice. Histologic findings after routine sacrifice showed well-maintained collagen wave structure and no visible calcification in all explanted valve leaflets.

Conclusions: Transcatheter implantation of a nitinol-wire-based, self-expandable valved stent in the pulmonic valve was feasible, and stents implanted in good position showed well-preserved valve leaflets with functional competence in the mid-term results.

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1. Introduction

Diverse congenital heart diseases involving the pulmonary artery (PA), such as tetralogy of Fallot with or without pulmonary atresia, or transposition of the great arteries with pulmonary stenosis, require implantation of an artificial conduit between the right ventricle (RV) and the PA. Because these conduits finally degenerate and result in pulmonary regurgitation (PR) and/or stenosis and progressive RV dilation and eventual failure, patients need repetitive surgery for conduit revision. Since the first successful percutaneous pulmonary valve implantation (PPVI) in 2000 by Bonhoeffer et al. for a 12-year-old boy [1], the Melody valve has received European and Canadian approval in 2006 and approval from the US Food and Drug Administration in

2010. However, the US Food and Drug Administration still limits the indication for PPVI using Melody valve to patients with a limited-size RV-to-PA conduit with more than moderate PR, and/or stenosis of the right ventricular outflow tract (RVOT) (mean gradient, ≥ 35 mm Hg) [2,3].

The use of PPVI for diverse dysfunctional RVOT lesions including conduit malfunction with a large diameter greater than 22 mm is still under investigation. Besides the clinically available balloon-expandable percutaneous pulmonary valves such as the Melody valve [4,5] and the Edwards SAPIEN valve [6], several types of self-expandable pulmonic valves have been investigated in preclinical studies for future human use [7–9]. However, any self-expandable stent has not been applied for clinical use until now.

We developed a large-diameter (up to 26 mm) self-expandable stent with a relatively low profile from a nitinol wire backbone with valve leaflets made from porcine pericardial tissue. Then, we performed a preclinical study to investigate the feasibility of self-expandable valved stents through the transcatheter approach and the durability of the tissue valve after >6 months.

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Table 1
Inventory of the valved stents in the pulmonic position.

Type	D type	M type
Wire thickness	Can be folded in longitudinal axis 0.008 in. (0.2 mm)	No folding in longitudinal axis 0.010 in. (0.25 mm)
Delivery system	18 Fr	18 Fr
Valve wall	Full covered	Partially covered
Diameter × total length	20 mm × 24 mm 22 mm × 25 mm 24 mm × 28 mm 26 mm × 33 mm	20 mm × 30 mm 22 mm × 33 mm 24 mm × 36 mm 26 mm × 38 mm
Radial force	0.17–0.20 kgf	0.40–0.5 kgf

2. Methods

2.1. Preparation of the valved stent

An initial outer stent was knitted using a single-strand nitinol wire with 0.008-in. thickness (Taewoong Medical Co., Gyeonggi-do, Republic of Korea). The initial valve diameter (D type in Table 1 and Fig. 1A,B, sheep 1–9) ranged from 20 mm to 26 mm, with the overall ratio of stent height to the valve diameter of approximately 1.1–1.2. Both ends of the stent were flared to 4 mm wider than the valve diameter for stable positioning (Fig. 1A,C). During the preclinical study, the stent was modified as an M type (Table 1 and Fig. 1C,D, sheep 10–12) with a 0.010-in.-thick double-strand wire, which increased the radial force to >2 times that of the initial stent. Furthermore, the wall of the M-type valved stent was covered partially to decrease the overall stent diameter and for ease in stent crimping.

Porcine pericardium was used for making the valve in the stent and was treated for maximal tissue preservation, following the previously published methods from our xenotransplantation research center [10–13]. Decellularization with 0.25% sodium dodecyl

sulfate and 0.5% Triton X-100, treatment with 0.1 units/mL α -galactosidase (α -gal) (to reduce immunogenicity), space filler treatment with 25% polyethylene glycol, 0.5% glutaraldehyde (GA) fixation with solvent (75% ethanol + 5% octanol), and finally detoxification with 0.1 M glycine were performed. The 3 leaflets from the treated porcine pericardium were tightly hand sewn to the stent wall with 5–0 braided polyester to allow their good coaptation (Taewoong Medical Co.) (Fig. 1B,D).

2.2. Preparation of the delivery system

We developed an initial transcatheter delivery system with a self-expandable nature (Taewoong Medical Co.), as in Fig. 2. The proximal part of the delivery catheter has a valved stent loading area with a 17.5-mm conical tapered tip for smooth vessel introduction (Fig. 2A,B). The diameter of the outer sheath in the stent loading zone was 18 Fr, and the diameter of the catheter shaft was 14 Fr. By turning the roll counterclockwise, the outer sheath could be pulled back to the proximal part of the stent area and the self-expandable valved stent could be completely deployed by pulling the lever (Fig. 2C,D).

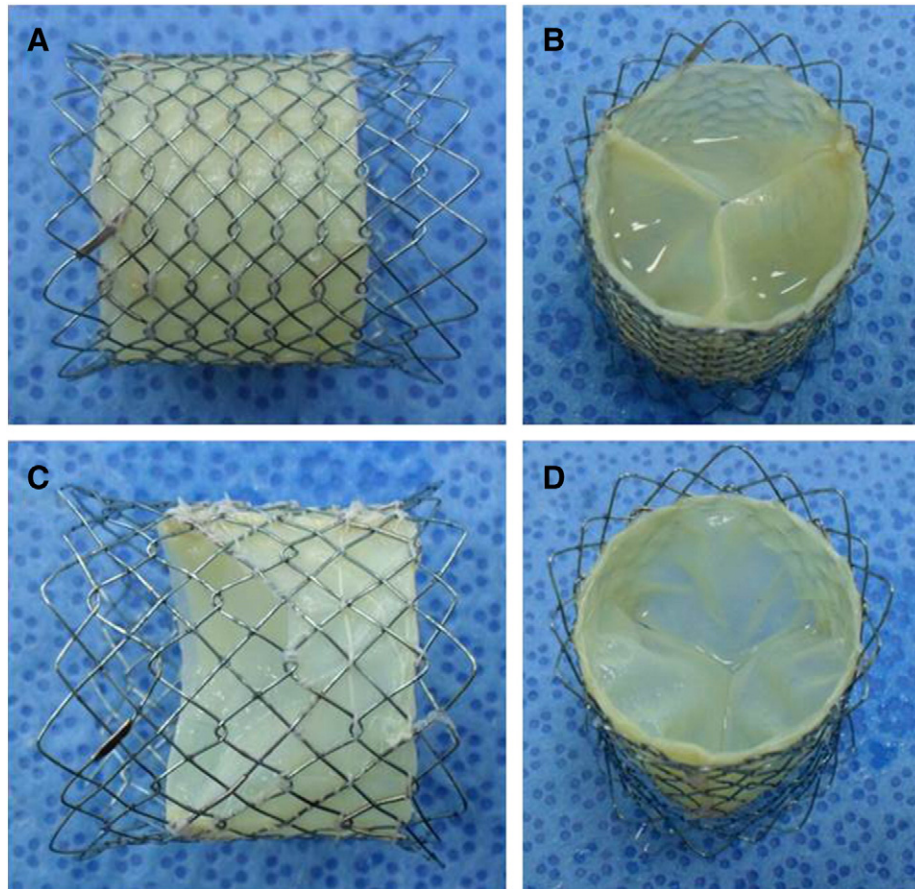


Fig. 1. Morphology of the initial valved stent (D type; A, B) and the modified valved stent (M type; C, D). The valve diameter ranged from 20 mm to 26 mm, and both ends of the stent were flared to 4 mm wider than the valve diameter. The wall of the M-type stent was covered partially to decrease the overall valved stent diameter. The valves in the stent showed good coaptation grossly (B, D).

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