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Short communication

First-in-human, off-label use of BeGraft® stenting of non-conduit, large right ventricular outflow tract for transcatheter valve landing zone preparation

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ABSTRACT

Transcatheter implantation of pulmonary valve has emerged as a reliable approach in congenital heart patients presenting with chronic right ventricular volume or pressure overload after primary repair. Initial experience was limited by relatively narrow range of working diameter of transcatheter valves. Nowadays, improved technology allows extending this option to patient with large right ventricular outflow tract or conduit. A stable landing zone is of paramount importance before considering valve implantation. We present two cases of right ventricular outflow tract pre-stenting using the BeGraft® stent, which may become an interesting add to our tool kit in the preparation of valve landing zone.

1. Introduction

Transcatheter pulmonary valve implantation (TPVI) has emerged as an alternative therapeutic option for patients surviving after repair of congenital heart disease and presenting with right ventricular outflow tract (RVOT) severe abnormalities [1]. In this patient population, after primary surgical repair long-term detrimental effect of chronic pressure and/or volume overload is usually observed as a consequence of native pulmonary valvular disruption, patch enlargement and conduit dysfunction. In contrast with early experience (Melody© valve, Medtronic, Minneapolis, Minnesota, US, larger working diameter 22 mm) recent technology improvement lead to the clinical availability of different valve types with great flexibility regarding working valve diameter (up to 29 mm) [2,3]. This allowed the extension of the indication for TPVI to patients with large conduits or patch-plasty (nonconduit) RVOT. However, in these patients a small but clinically relevant risk for paravalvular leak is reported, due to the irregular shape of the landing zone and the large working valve diameter [4]. To avoid the risk of paravalvular leak and reducing potential mechanical stress fracture of valve framework, RVOT pre-stenting using covered stent has been proposed to create a sealed valvular landing zone. The historically, and United States Food and Drug Administration approved covered stent (CP 8zig polytetrafluorethylene covered stent®, NuMED, Hopkinton, New York, US) presents significant size limitation (dilation up to 24 mm). [5] Accordingly there is a clinical need for larger covered stent before TPVI using larger transcatheter valves [6].

We present the first in-human experience with RVOT pre-stenting using the BeGraft® stent (Bentely Innomed GmbH, Hechingen, Germany) in two patients.

2. Cases

2.1. Case 1

TS was a 27-year old female referred to our adult congenital outpatient clinic due to progressive shortness of breath on exertion (NYHA class II). Her initial diagnosis included tetralogy of Fallot (TOF) with pulmonary stenosis. After shunt palliation, she underwent complete intracardiac repair at 15 months of age with Dacron transanular RVOT patch. Her cardiovascular magnetic resonance (CMR) showed severe right ventricular dilation (volume of 164 ml/m^2) with good function and severe "pulmonary" regurgitation (regurgitant fraction of 50%). Heart-team based decision was to consider transcatheter valve implantation in the patch enlarged right ventricular outflow tract. Staged stenting was considered with the goal of implanting a highly stable stent as the landing zone for the covered stent reducing the risk for the Begraft stent embolization or malposition. After routine balloon testing of RVOT to exclude potential coronary compression or aortic

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root deformation (Fig. 1/Video 1 of the Online Supplementary Material) pre-stenting was accomplished implanting a 43 mm AndraStent® XXL (Andramed GmbH, Reutlingen, Germany) manually crimped onto a 26 (13) × 50 mm Balloon-in-Balloon (BiB®, NuMED, Hopkinton, New York, US). After three months she was brought to the catheterization laboratory for her following procedure. Rotational angiography confirmed the anatomy, showing an internal diameter of the implanted stent at 26 mm (Fig. 2/Video 2 of the Online Supplementary Material). In addition, there was evidence of retrograde contrast filling of a "pouch"-looking space between the stent struts and the native pulmonary artery (Fig. 1A/B). Accordingly, a second 43 mm AndraStent® XXL was implanted using the "flower blossom" technique [7]. A 48 mm BeGraft® stent (Bentely Innomed GmbH, Hechingen, Germany) was then manually detached from the delivery balloon (Video 3 Online Supplementary Material). The stent was then manually crimped onto a 28(14) × 50 mm BiB® balloon and it was in-stent implanted during rapid ventricular pacing to increase stent stability during deployment. The stent was post-dilated with a 28 × 40 mm high-pressure balloon. Following angiography showed good stent expansion with almost exclusion of the previously described extra-stent contrast filling (Fig. 1C/D and Video 4 Online Supplementary Material). Finally, a 29 mm Sapien XT® was crimped onto the NovaFlex® system (Edwards LifeSciences, Irvine, CA, US) and delivered into the BeGraft® stent. Exit angiography showed no significant pulmonary valve regurgitation, no evidence of paravalvular leak with good hemodynamic result (Fig. 2 and Video 5 Online supplementary material).

2.2. Case 2

LG was a 48-year old female with severely progressive shortness of breath on exertion (NYHA class III) and history of repaired TOF using patch plasty of the RVOT. She presented significant cardiogenic limitation (peak VO2 44% of predicted by age and gender), a dilated right ventricle (131 ml/m^2 by CMR) with normal function and severe pulmonary regurgitation. A staged transcatheter approach was considered. Due to bilateral occlusion of the femoral veins, interventional procedures were accomplished using the jugular veins. Initially, a 48 mm AndraStent® XXL was manually crimped onto a 28(14) × 50 mm BiB® and implanted in the RVOT**.** After four months, venous accesses were obtained in the left jugular vein. Initial angiography confirmed the anatomy, showing an internal diameter of the implanted stent at 28 mm (Fig. 3 Online Supplementary Material). A 48 mm BeGraft® stent was then manually detached from the delivery balloon and then crimped onto a 28 × 50 mm BiB® balloon and it was in-stent implanted. Finally, a 29 mm Sapien XT® was crimped onto the NovaFlex® system and delivered into the BeGraft® stent). Exit angiography showed no significant pulmonary valve regurgitation, no evidence of paravalvular leak with good hemodynamic result (Fig. 4/Video 6 of the Online Supplementary material).

Echocardiographic follow-up was available for both patients after 6 months from the last procedure. In both patients there was an instantaneous peak systolic gradient across the transcatether valves below 30 mmHg with mild pulmonary regurgitation.

3. Discussion

Ability to create a safe and reliable valvular landing zone is of paramount importance before considering TPVI. To reduce the risk for paravalvular leak, sealing-off the valve landing zone with a covered stent could be a reasonable step in selected cases before implanting the valve. Size limit precludes using the CP stent® in some cases. We found the off-label use of BeGraft® stent effective in this preliminary experience as shown in these first-in-man cases. The Bentley InnoMed "BeGraft Aortic Stent Graft" is an hybrid open cell stent design

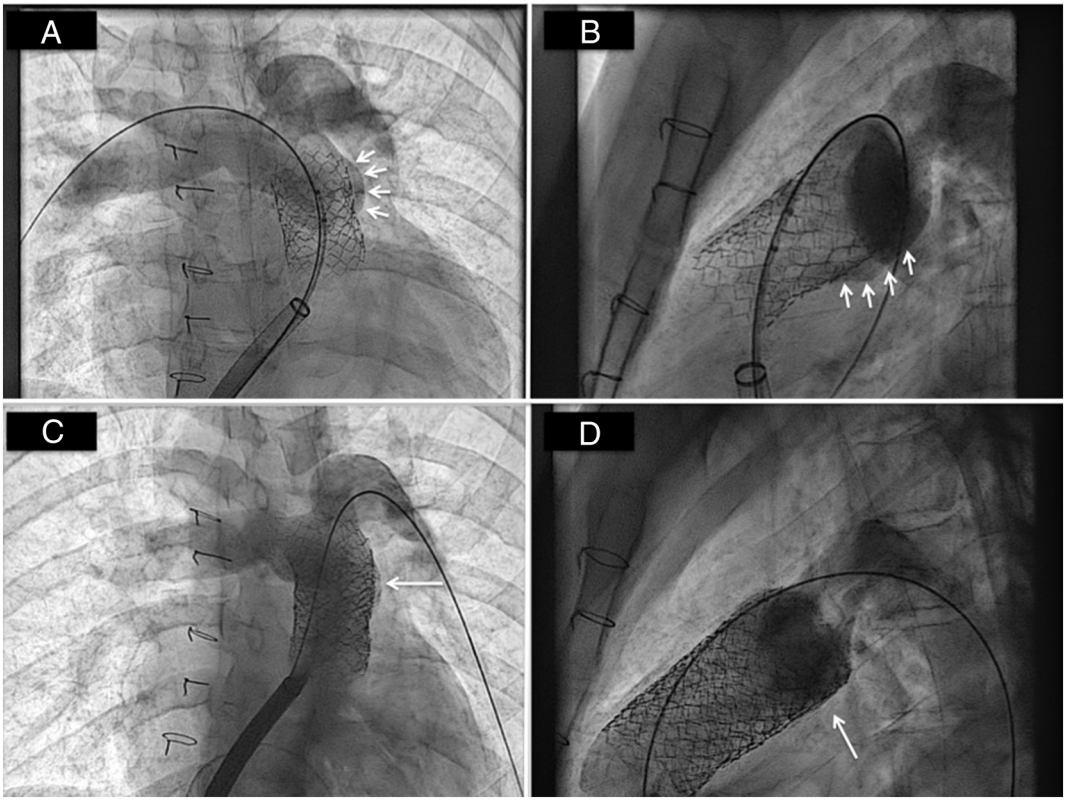

Fig. 1. Anterior (A) and lateral (B) angiographic view of the RVOT of the first patient after the first initial procedure. White arrows delineate the "extra-stent" filling between stent and vessel wall. Anterior (C) and lateral (D) angiographic view of the same patient after implantation of the BeGraft® stent, showing the almost exclusion of extra-stent contrast filling (single white arrows).

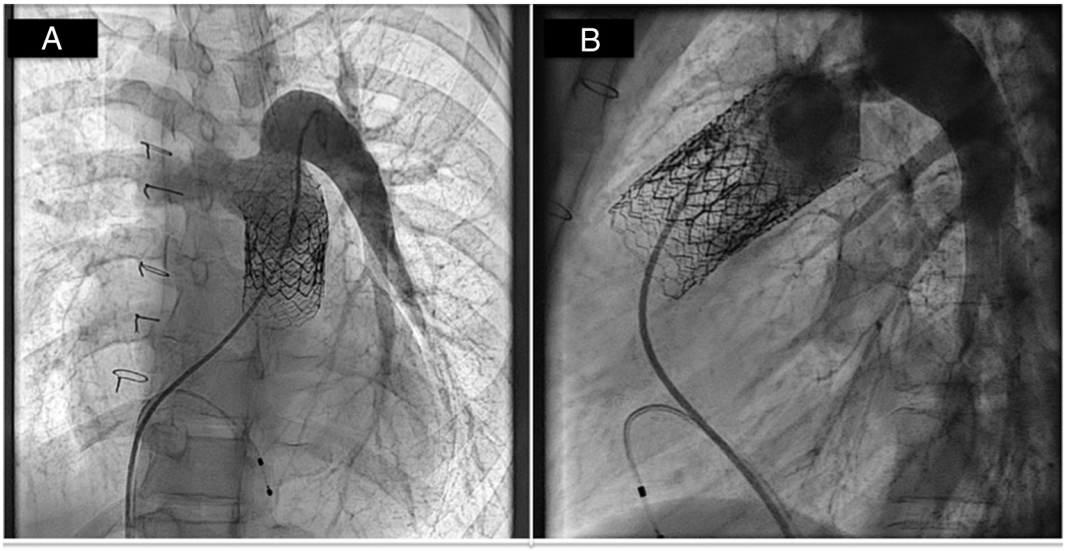

Fig. 2. Anterior (A) and lateral (B) angiographic view of the RVOT of the first patient after valve implantation. No intra or paravalvular regurgitation is shown.

composed of L605 cobalt-chromium (CoCr) alloy and is available in 3 different stent designs (working diameter of 12 to 14 mm, 16 to 18 and 20 to 24 mm). The three designs are based on a series of zigzagging rings with multiple articulations per ring with small modifications at the end rings to accommodate the PTFE tubing. The labeled stent graft length ranges from 19 to 58 mm, and the labeled expanded graft outer diameter range from 12 to 24 mm. Of importance, at this stage, based on in vitro testing, this is the only stent that, in the largest outer diameter version, can be safely dilated up to 30 mm without jeopardizing the sleeve coverage [8]. It can be either implanted using the manufacturer delivering balloon or it can be easily detached from the delivering balloon (if larger working diameter is required) and manually crimped onto an appropriately sized over-the-wire balloon as usually performed with non-premounted stents using gentle manipulation to avoid damage to PTFE sleeve. Stent trackability was similar to other non-premounted stent even in an unusual and tortuous course as in our second patient.

4. Limitation

We are reporting our preliminary results with the Begraft stent in two consecutive patients referred to our Center for transcatheter valve implantation in large RVOT. Clinical delivery of this technology in the routine clinical practice will require larger studies with longer follow-up and multicenter (and multioperator) experience.

5. Conclusion

We think that, if confirmed in larger clinical experience, the BeGraft® may become a valuable add to our tool kit for pre-stenting preparation of transcatether pulmonary valve landing zone in large RVOT/conduit.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2019.01.036.

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