International Journal of Cardiology 186 (2015) 129–135

Contents lists available at ScienceDirect

International Journal of Cardiology

journal homepage: www.elsevier.com/locate/ijcard

Percutaneous pulmonary valve implantation for free pulmonary regurgitation following conduit-free surgery of the right ventricular outflow tract

Bjorn Cools [a], Stephen C. Brown [a,b], Ruth Heying [a], Katrijn Jansen [a], Derize E. Boshoff [a], Werner Budts [a], Marc Gewillig [a,*]

[a] Paediatric Cardiology, University Hospitals Leuven, Belgium
[b] University of the Free State, South Africa

ARTICLE INFO

Article history:
Received 11 August 2014
Received in revised form 14 January 2015
Accepted 7 March 2015
Available online 10 March 2015

Keywords:
Intervention
Percutaneous pulmonary valve
Stent
Balloon

ABSTRACT

Introduction: Pulmonary regurgitation (PR) following surgery of the right ventricular outflow tract (RVOT) is not innocent and leads to significant right heart dysfunction over time. Recent studies have demonstrated that percutaneous valves can be implanted in conduit free outflow tracts with good outcomes.
Objectives: To evaluate in patients with severe PR – anticipated to require future pulmonary valve replacement – the feasibility and safety of pre-stenting dilated non-stenotic patched conduit-free right ventricular outflow tracts before excessive dilation occurs, followed by percutaneous pulmonary valve implantation (PPVI).
Patients and methods: Twenty seven patients were evaluated, but only 23 were deemed suitable based on the presence of an adequate retention zone ≤24 mm defined by semi-compliant balloon interrogation of the RVOT. A 2 step procedure was performed: first the landing zone was prepared by deploying a bare stent, followed 2 months later by valve implantation.
Results: RVOT pre-stenting with an open cell bare metal stent (Andrastent XXL range) was performed at a median age of 13.0 years (range: 6.0–44.9) with a median weight of 44.3 kg (range: 20.0–88.0). Ninety six percent (22/23) of patients proceeded to PPVI a median of 2.4 months (range: 1.4–3.4) after initial pre-stent placement. Twenty one Melody valves and one 26 mm Edwards SAPIEN™ valve were implanted. Complications consisted of embolization of prestent (n = 1), scrunching (n = 4) and mild stent dislocation (n = 2). During follow-up, no stent fractures were observed and right ventricular dimensions decreased significantly.
Conclusions: Post-surgical conduit-free non-stenotic RVOT with free pulmonary regurgitation can be treated percutaneously with a valved stent if anatomical (predominantly size) criteria are met. In experienced hands, the technique is feasible with low morbidity.

1. Introduction

Pulmonary regurgitation (PR) after transannular patching or even limited infundibulotomy is associated with late adverse events such as aneurysmal dilation of the right ventricular outflow tract (RVOT), right ventricular dysfunction, progressive tricuspid valve regurgitation, dysrhythmias and premature sudden death [1–3]. Surgical pulmonary valve replacement (PVR) is an efficient technique to avoid these late problems [4,5]. However, this strategy is not free of either early or late complications, requiring repeated re-interventions of increasing complexity and risk. Proper timing is therefore essential not only to reduce the number of sternotomies, but also to limit cumulative risk and keep long term morbidity as low as possible. The ideal timing of re-intervention in order to allow a patient to experience a cardiac event-free existence as well as a normal life expectancy has yet to be determined and remains a hotly debated issue [6]. Current survival studies with long term follow-up of patient groups where current guidelines have been applied report on an ongoing excess mortality in every decade: this suggests that there is a margin for improvement and that current guidelines may require refinement [3,7].

Percutaneous pulmonary valve implantation (PPVI) may be of benefit in these patients [8,9]. PPVI is recognized as an acceptable method for right ventricular outflow tract valve implantation in selected patients, typically with a surgical conduit. However, the majority of patients that will eventually require a pulmonary valve do not have a surgical conduit as landing zone.

In recent publications, it was shown that PPVI is effective and safe in patients with conduit-free RVOTs [10–12]. The aim of this study was to determine the safety and feasibility of RVOT stenting and subsequent PPVI in patients with non-stenotic dilating RVOTs. This included

* Corresponding author at: University Hospital Gasthuisberg, Herestraat 49, B 3000 Leuven, Belgium.
E-mail address: marc.gewillig@uzleuven.be (M. Gewillig).

http://dx.doi.org/10.1016/j.ijcard.2015.03.108
0167-5273/

assessment of right ventricular (RV) changes and determination of the limitations and complications of this strategy and also, to start accumulating data to compare the different strategies.

2. Methods

Patients were recruited from the outpatient clinics where they routinely present for annual evaluation. The main inclusion criterion for this ongoing, prospective study was severe pulmonary regurgitation (grade 3 or 4) in a conduit-free RVOT with progressive dilation of the right ventricle, where one would anticipate the need for a pulmonary valve in the near future. Such patients typically have no significant gradient across the RVOT. During the study period only the Melody valve (Medtronic, Minneapolis, MN, US) was considered because of reimbursement issues; due to the maximum indicated outer diameter of 24 mm, RVOT diameter at the level of the pulmonary valve had to measure between 18 and 21 mm on echocardiography to qualify for inclusion. The severity of PR was classified on color flow Doppler similar to our previous publication [10]. Patient records were used to obtain catheterization and follow-up data. Digital measurements of catheterization data were performed using an IMPAX® viewer (Agfa Heartlab®, Mortsel, Belgium). Cardiovascular magnetic resonance imaging (MRI) was performed in some cases, but information was not used for selection.

The study was conducted in accordance with local Ethics Committee guidelines; fully informed consent after extensive discussion of all different strategies was obtained from the patient and parents.

2.1. Cardiac catheterization and PPVI: technical aspects

All procedures were performed under general anesthesia. The catheterization procedure and valve implantation were similar to that previously described [9,10,13].

2.2. Interrogation of the RVOT

2.2.1. Angiography

Biplane angiography was performed in the RVOT by means of a Multi-Track™ angiographic catheter (NuMED, NY, USA) using the lateral projection for the pulmonary valve region, and a frontal view with extreme cranial angulation to demonstrate predominantly the pulmonary artery bifurcation.

2.2.2. Guide wires

A stiff exchange length guide wire was securely positioned in a distal pulmonary artery branch (e.g. E®-wire, JOTEC, Germany; Amplatz UltraStiff, COOK, Bloomington, USA; Lunderquist™, COOK, Bloomington, USA). It is helpful to put a curve on the wire matching the shape of the RVOT and pulmonary artery since this will facilitate balloon retrieval after stent placement by improving the inner curve.

2.2.3. Delineation of the RVOT anatomy (Fig. 1)

Balloon-interrogation during low-pressure sub-maximal inflation and deflation was performed using a semi-compliant, mildly oversized balloon, e.g. a 23–25 mm Tyshak® balloon (NuMED, NY, USA) (Table 1). At nominal pressure the balloon typically stretched open the outflow tract almost completely without a significant indentation (Fig. 1B); the balloon at this point has a predetermined size which facilitates interpretation of diameters. Also, the absence of movement and mild indentation of the inflated interrogation balloon are important and comforting signs. If there was no or minimal indentation, simultaneous injection through the side-arm of a long Mullins sheath was carried out. This assists in further outlining the RVOT, provides evidence that the inflated balloon is securely seated (confirms probable stent fixation) and assesses the (un)likelihood of a paravalvular leak post valve implantation. Simultaneous aortogram was performed during full inflation of the balloon to exclude coronary compression.

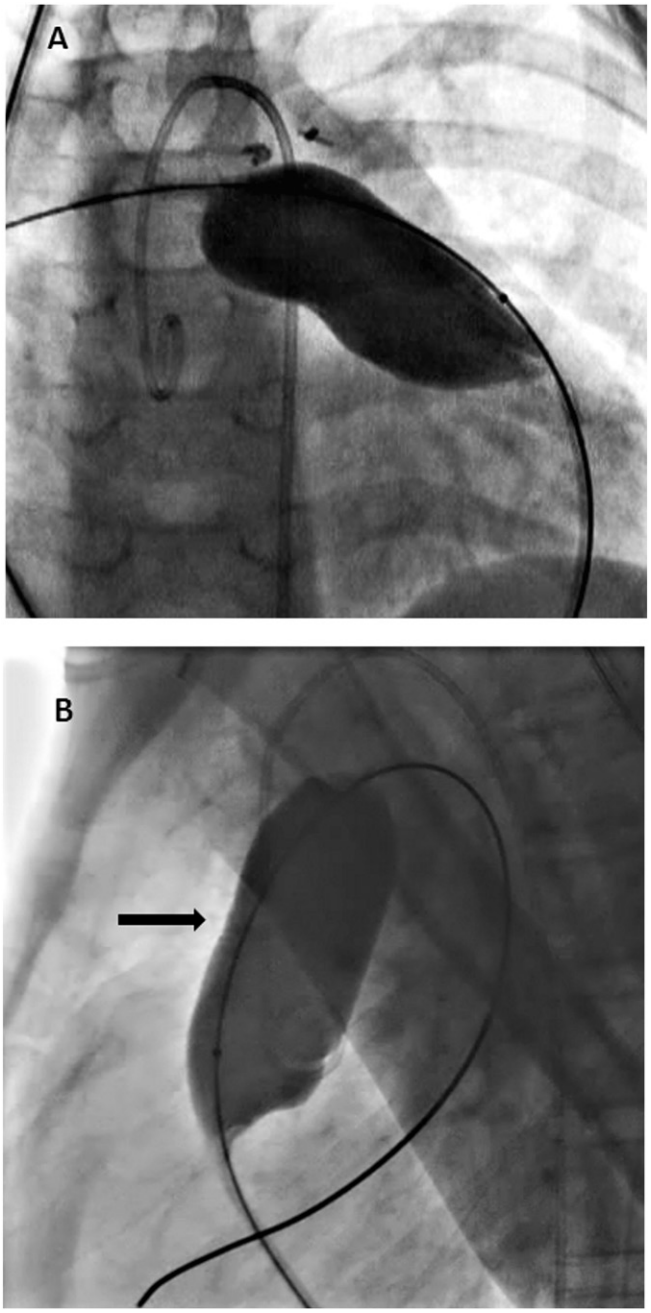

Fig. 1. Balloon interrogation of RVOT. A. Cranially tilted antero-posterior view of 23 mm Tyshak balloon inflated in RVOT patient 12, with mild indentation. B. Lateral view of 25 mm Tyshak balloon fully inflated in RVOT of patient 24. Note minimal indentation of future landing zone (arrow).

2.2.4. Pre-stenting the RVOT

2.2.4.1. Stent placement (Figs. 2 & 3). Open cell design, bare metal stents (Andrastent XXL series, Andramed, GmbH, Reutlingen Germany) were hand-crimped on balloon-in-balloon (BIB) balloons (NuMED, Hopkinton, NY, USA). More detail can be viewed in Table 1. BIB balloons were selected to be 2–4 mm larger than the retention zone or – most frequently – a BIB 24 mm was used if only mild indentation of a 25 mm Tyshak was observed. Ideally the length of the balloon should be matched to the stent; if too long, these large balloons will push themselves back due to the distal shoulders locked in the bifurcation. The Andrastent XXL