How-to-do-it

A new endovascular size reducer for large pulmonary outflow tract

Brahim Amahzoune a,b,d, Catherine Szymansky d, Jean-Noël Fabiani a,b,c, Rachid Zegdi a,b,c,d,*

a Université Rene Descartes, Paris V, France
b Inserm U849, Faculté de Necker, Paris, France
c AP-HP, Service de Chirurgie Cardio-Vasculaire, Hôpital Européen Georges Pompidou, Paris, France
d AP-HP, Laboratoire du Fer à Moulin, Paris, France

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Abstract

Around 75% of patients with severe pulmonary insufficiency requiring valvular replacement are excluded from percutaneous pulmonary valve implantation (PPVI) due to a large ventricular outflow tract. To extend the indication of PPVI to these patients, a new size reducer has been designed. This 35-mm size reducer was successfully deployed inside the main pulmonary artery through a 21-Fr delivery catheter in six sheep. A 20-mm pericardial valved stent was subsequently deployed inside the size reducer to restore pulmonary valve continence. We successfully verified the efficiency of the delivery catheter by controlling the deployment precisely and reversibly. In all six cases, device positioning was satisfactory. There was no post-procedural residual stenosis in the right ventricular outflow tract in haemodynamic (9.5 ± 3 mmHg), echocardiographic and angiographic studies. After 8—12 weeks of follow-up, no prosthetic migration occurred. The transprosthetic systolic gradient remained low (4 ± 2.5 mmHg) during follow-up. There was one trivial persistent paraprosthetic leak. This study confirmed the feasibility and the effectiveness of this new size reducer to reduce the size of the pulmonary artery.

Keywords: Percutaneous; Heart valve; Endovascular stent; Pulmonary insufficiency

1. Introduction

Current indications of percutaneous pulmonary valve implantation (PPVI) are limited to patients with a right ventricular outflow tract (RVOT) lesser than 22 mm in diameter. To extend the indication of PPVI, some investigators have proposed the use of percutaneously implanted size reducers of the RVOT [1,2]. Despite promising preliminary experimental results, these first-generation devices have shown some limitations, regarding their size, their surface of anchorage and their delivery. Furthermore, clinical evaluation of these reducers has not been published to date.

Herein, we report the initial experimental evaluation of a new size reducer that may address most of the limitations of the previously reported devices.

2. Methods

2.1. Size reducer, valved stent and delivery device

The endovascular size reducer (Cormove; Ivry le Temple, France) consisted of a self-expandable nitinol stent (diameter = 35 mm; length = 35 mm), inside which was attached a specifically designed polyester graft (a 20-mm diameter central tube with two flared extremities) (Fig. 1).

The valved stent (Cormove; Ivry le Temple, France) was made of three glutaraldehyde pre-treated bovine pericardial leaflets sutured onto a 20-mm nitinol stent (Fig. 1).

Both implants were compressed and introduced inside a 21-Fr delivery catheter. The delivery system has been described previously [3]. It has the capability to recompress and reposition a valved or non-valved stent if initially deployed in an inadequate position.

2.2. Experimental protocol

Six sheep (>40 kg) were used for our experiments. All of the animals were treated according to the European regulations for animal experimentation [4]. The procedure was performed under general anaesthesia and after systemic heparinisation (500 IU kg).
The infrarenal inferior vena cava was accessed through a right retroperitoneal approach. A guide wire was inserted into the vein and passed under fluoroscopic guidance into the pulmonary artery. The size reducer was positioned and then delivered proximally within the pulmonary artery trunk. Through the same access, the valved stent was introduced secondarily and positioned within the deployed size reducer (Fig. 2). Specific radio-opaque markers allowed its precise deployment within the central tubular part of the size reducer.

After removal of the delivery catheter, the surgical wound was closed and the sheep allowed to recover. Postoperative follow-up was undertaken over an 8- to 12-week period.

2.3. Evaluation of the valved stent

Transprosthetic gradients were measured and presence of any peri- or intra-prosthetic leak checked after device implantation using standard haemodynamic, fluoroscopic and echo-Doppler techniques. Re-evaluation was performed 8–12 weeks later prior to sacrifice. Macroscopic analysis of the explanted heart was also performed.

3. Results

The experiment was completed in all six sheep. Due to the repositioning capacity of the delivery catheter, the final position of the size reducer and of the valved stent was always judged as adequate.

Systolic transvalvular gradient was low after implantation (9.5 ± 2.3 mmHg) and before sacrifice (4 ± 2.5 mmHg). There was no size reducer or valved stent migration during follow-up. In one animal, a trivial paraprosthetic leak was noted that persisted during follow-up.

Macroscopic study confirmed correct positioning and firm anchorage of the size reducer and of the valved stent (Fig. 2). No stent fracture was detected.

4. Discussion

Percutaneous implantable RVOT size reducers are a potential approach to extend the feasibility of PPVI. The main characteristics of an ‘ideal’ size reducer include the capacity to adapt to most variations of RVOT anatomy, a low risk of migration, structural deterioration, paraprosthetic leak and thrombo-embolic events.

RVOT anatomy is variable in patients with severe pulmonary regurgitation [5]. It is usually believed that the shorter the length of the size reducer the higher the proportion of patients amenable to an endovascular treatment.

The length of the first size reducer described in the literature may be excessive (55 mm) for most clinical situations [1]. The excessive length may also predispose to an increased risk of stent fracture [6]. Furthermore, the anchoring surface is restricted to both ends and may be insufficient to prevent secondary device migration.

The second reducer proposed by Boudjemline and colleagues is a 55-mm-long stent with extremities that curve back during deployment so that the ‘effective’ length of the deployed stent is short (20 mm). This shorter length provides an advantage to this size reducer as it allows potential use in the majority of cases. However, the shorter length is also associated with a reduced anchoring surface and therefore an increased risk of device migration. Furthermore, significant compression stress may exist on the bent extremities predisposing to stent fracture. Finally, the acute connection angles between the reducer and the arterial wall on one side and the reducer and the valved stent on the other side may produce turbulent blood flow predisposing to thrombo-embolic events.

Fig. 1. (Top) Lateral view of the new pulmonary outflow tract size reducer. It consists of a self-expandable nitinol stent inside which was sutured a polyester prosthesis with a specific design (a 20-mm large and long central tube with two flared extremities). (Bottom) Front view of the reducer inside which was placed a bovine pericardial 20-mm valved stent. The valved stent was deployed inside the tubular part of the polyester prosthesis.
The size reducer used in the present experiment has an intermediate length (35 mm) compared with that of the other devices. It should be suitable for the majority of patients, whether the shape of the dilated pulmonary artery trunk is cylindrical or conical. In contrast to the previously mentioned size reducers, its entire external surface participates in anchoring. Furthermore, the present size reducer is made from braided nitinol, which might be more resistant to fracture than cut nitinol stents. Finally, its positioning is reversible until correct placement has been achieved.

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References


Fig. 2. (Top) Fluoroscopic longitudinal view of the size reducer endovascularly implanted in the main pulmonary artery. ‘Revalvulation’ of the pulmonary outflow tract was secondarily done through deployment of a size matched pericardial valved stent (arrow) inside the size reducer. (Bottom) Macroscopic view of the ventricular side of the size reducer 8 weeks after implantation. The reducer covered the native pulmonary valve. The valved stent can easily be seen inside the central part of the reducer (arrow).