

Self-expandable valved stent of large size: off-bypass implantation in pulmonary position

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Abstract

Objective: To evaluate the feasibility of the off-bypass implantation of a self-expandable valved stent of large size in pulmonary position. **Materials and methods:** A glutaraldehyde preserved valved bovine jugular xenograft with internal diameter = 22 mm, mounted in two rings of nitinol 'Z' stent, expandable from 7 to 24 mm of internal diameter, was acutely evaluated in 6 adult pigs, mean body weight 55.6 kg (range 47–67 kg). Through a stent-graft delivery system (24 French) the self expandable valved stent was implanted off-bypass in pulmonary valve position by trans-ventricular approach through median sternotomy. **Results:** The mean diameter of the main pulmonary artery measured was 21.7 ± 1.6 mm. The mean length of the self expandable valved stent was 23.1 ± 0.7 mm, the mean internal diameter 21.6 ± 0.7 mm and the mean external diameter 26.3 ± 0.7 mm. The mean peak pressure gradient recorded across the valve was 6.33 ± 2.8 mmHg (range 4.5–9.6 mmHg) at Doppler echocardiography, and 4.5 ± 3.1 mmHg (range 0–7 mmHg) at invasive measurement, with a pulmonary blood flow of 3.03 ± 0.05 l/min. Intra-vascular ultrasound showed complete opening and closure of the valve (mean area reduction from 315.08 ± 54.13 to 0 mm²). **Conclusions:** (a) Off-bypass implantation of self-expandable valved stent is feasible in pulmonary position; (b) off-bypass surgical approach allows for valved stent implantation of adult size with adequate hemodynamic functioning; and (c) intra-vascular ultrasound makes implantation and evaluation easy and reproducible. © 2003 Elsevier Science B.V. All rights reserved.

Keywords: Biological valved conduits; Pulmonary valve implantation; Pulmonary valve regurgitation; Tetralogy of Fallot

1. Introduction

After previous experimental studies with percutaneous valve replacement in pulmonary [1] and aortic [2,3] position, the percutaneous insertion of a biological valve in pulmonary position has been introduced in the clinical practice [4,5].

Insertion of a valve in pulmonary position is indicated mainly in two situations: (a) pulmonary valve regurgitation, generally after surgical repair for tetralogy of Fallot [6–14]; and (b) dysfunction of the biological valved conduit previously implanted to establish the continuity between the right ventricle and the pulmonary artery during repair of complex congenital heart defects [15,16].

So far the conventional treatment for the above situations

consisted in pulmonary valve replacement [6–14] and replacement of the biological valved conduit [15–17], even if with uncertainty about the adequate timing for pulmonary valve insertion in order to prevent or reduce the incidence of sudden death, arrhythmias and right ventricular dysfunction [5–14].

Several alternative strategies, particularly in the presence of a dysfunction of a biological valved conduit, have been considered within the last years, including other types of biological valved conduits [18–20] or endovascular stent implantation to dilate and delay the surgical replacement of the obstructed conduit [21–23].

The main limit in the use of endovascular stents to dilate an obstructed biological conduit implanted between the right ventricle and the pulmonary artery is that, even if the obstruction is relieved or substantially reduced without requiring for a re-operation on cardiopulmonary bypass, the patient remains with a pulmonary valve regurgitation,

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frequently worse than before. The subsequent right ventricular volume overload can cause irreversible myocardial damages, with the known incidence of sudden death, arrhythmias and right ventricular dysfunction [5–14,24].

The advantages of the percutaneous insertion of the pulmonary valve over the conventional surgical techniques are quite evident in terms of avoiding an operation on cardiopulmonary bypass, and in the same time in the ability of implanting a functioning valve, therefore reducing or abolishing both the pressure and the volume overload on the right ventricle [1,4,5]. The major limit of this recently reported technique is the mismatch between size of the venous access and size of the introducer (at least 18 Fr), restricting the use of this strategy to older children and the size of the valve to an 18 mm internal diameter biological valve [5].

Because of the above problems, we devised an experimental study to evaluate an alternative strategy aiming at the off-bypass implantation of a self-expandable valved stent of large size in pulmonary position from right ventricular approach.

2. Materials and methods

A glutaraldehyde preserved valved bovine jugular xenograft with internal diameter = 22 mm was mounted in two rings of non-thermosensitive nitinol 'Z' stents, expandable from 7 to 24 mm of internal diameter. In vitro static performance and dynamic test evaluation of this valved stent have been already reported [25]. The self expanding valved stent was prepared with a Teflon sheath stent-graft delivery system with overall diameter 8.0 mm = 24 F.

Acute in vivo evaluation was performed in six adult pigs, mean body weight 55.6 kg (range 47–67 kg). After general anaesthesia, tracheal intubation and mechanical ventilation, with continuous monitoring of electrocardiogram, arterial and central venous pressure and oxygen saturation, the chest was opened through a conventional median sternotomy. Heparin was administered i.v. (1 mg/kg). After a short incision (4 mm) on the anterior aspect of the right ventricle, controlled by a purse string on 4-0 polypropylene suture, through the sheath stent-graft delivery system the valved stent was implanted off-bypass in pulmonary valve position by trans-ventricular approach (Fig. 1). The correct positioning of the valved stent was evaluated and confirmed before definitive deployment by intravascular ultrasound technique.

Valve function was assessed with colour Doppler echocardiography, flow and pressure drop measurements with Swan-Ganz Oximetry (Baxter-Edwards, CA, USA) catheter, as well as intravascular ultrasound (Boston Scientific Corporation, CA, USA) with a 6F, 12.5 MHz transducer and Acuson Corporation, CA, USA) with 10F, 7.5 MHz transducer in real time.

A high fidelity tip mounted Millar pressure transducer

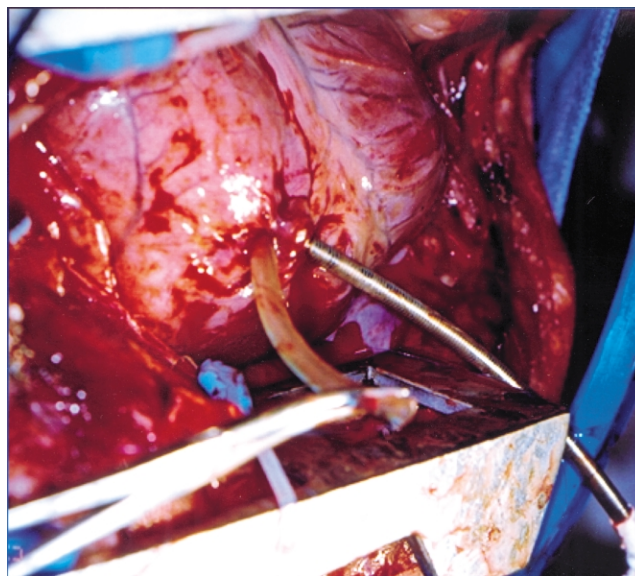


Fig. 1. After a short incision (4 mm) on the anterior aspect of the right ventricle, controlled by a purse string on 4-0 polypropylene suture, through the sheath stent-graft delivery system the valved stent has been implanted off-bypass in pulmonary valve position by trans-ventricular approach.

system was used to invasively measure the pressure proximal and distal to the valve.

At the end of the study the animals were electively sacrificed to check the adequate position of the valved stent, as well as its deployment and anchorage and the presence of any deformation of the valve.

All animals received human care in compliance with the 'Principles of Laboratory Animals' formulated by the National Society of Medical Research and the 'Guide for the Care and Use of Laboratory Animals' prepared by the Institute of Laboratory Animal Resources and published by the National Institutes of Health (NIH publication 85-23, revised 1985). The protocol was approved by the institutional Committee on Animal Research.

Statistical analysis: the Student's *t*-test was utilized, and all data were expressed as mean \pm standard deviation.

3. Results

The mean diameter of the main pulmonary artery measured with intravascular ultrasound was 21.7 ± 1.6 mm. The mean length of the valved stent was 23.1 ± 0.7 mm, the mean internal diameter 21.6 ± 0.7 mm and the mean external diameter 26.3 ± 0.7 mm.

The mean peak pressure gradient recorded across the valve was 6.33 ± 2.8 mmHg (range 4.5–9.6 mmHg) at Doppler echocardiography, and 4.5 ± 3.1 mm Hg (range 0–7 mmHg) at invasive measurement, with a mean pulmonary blood flow of 3.03 ± 0.05 l/min.

Intravascular ultrasound showed complete opening and closure of the valve (mean area reduction from

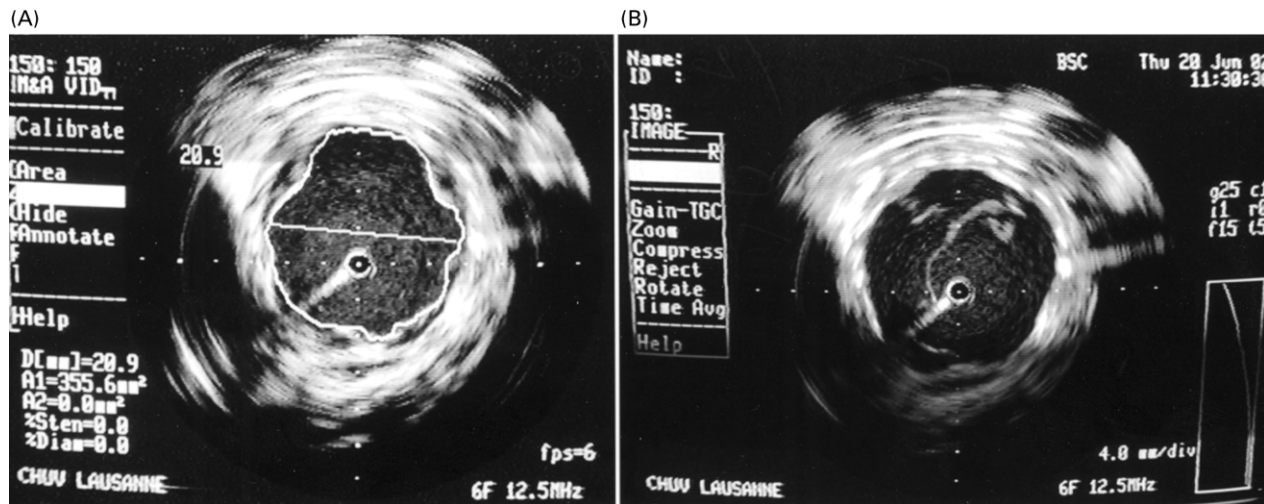


Fig. 2. Intravascular ultrasound showing complete opening (A); and closure (B) of the valve.

315.08 ± 54.13 to 0 mm^2) (Fig. 2). In all animals Doppler echocardiography confirmed the absence of any valve regurgitation as well as of paravalvular leak (Fig. 3).

No significant changes were recorded in electrocardiogram, arterial and central venous pressure and oxygen saturation after self expandable valved stent implantation.

Post-mortem examination confirmed the adequate position of the valved stent in pulmonary position (Fig. 4), as well as ruled out any valve deformation or thrombus (Fig. 5).

4. Discussion

The implant of a valve in pulmonary position has the ideal purpose of abolishing the pulmonary valve regurgitation to prevent or reduce the incidence of sudden death, arrhythmias and right ventricular dysfunction [5–14] with the lowest possible surgical risk.

Because of the difficult balance between costs (risks) and benefits (competent pulmonary valve), timing and type of management so far have not reach general agreement [24].

The percutaneous insertion of a pulmonary valve, recently introduced in the clinical practice [4,5], presents the advantages of avoiding an operation on cardiopulmonary bypass and in the same time the possibility of implanting a functioning valve, therefore reducing or abolishing both the pressure and the volume overload on the right ventricle [1,4,5]. The major current limit of this technique is the mismatch between size of the venous access and size of the introducer (at least 18 Fr), restricting the use to older children ($>25 \text{ kg}$ of body weight) and the size of the valve to an 18 mm internal diameter biological valve [5].

Our experimental study proposes an alternative strategy allowing the off-bypass implantation of a self-expandable valved stent of large size (internal diameter = 22 mm) in pulmonary position from right ventricular approach without cardiopulmonary bypass.

The implant of a functioning pulmonary valve can therefore been accomplished, overcoming the limits of the currently available techniques, with the only additional risks of a limited chest opening. In our initial experimental study

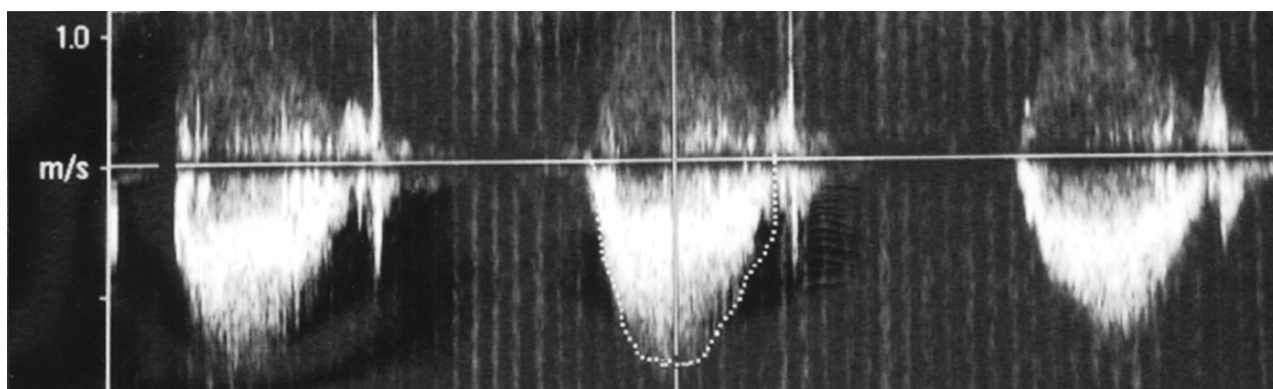


Fig. 3. Doppler echocardiography confirming the absence of any valve regurgitation as well as of paravalvular leak.

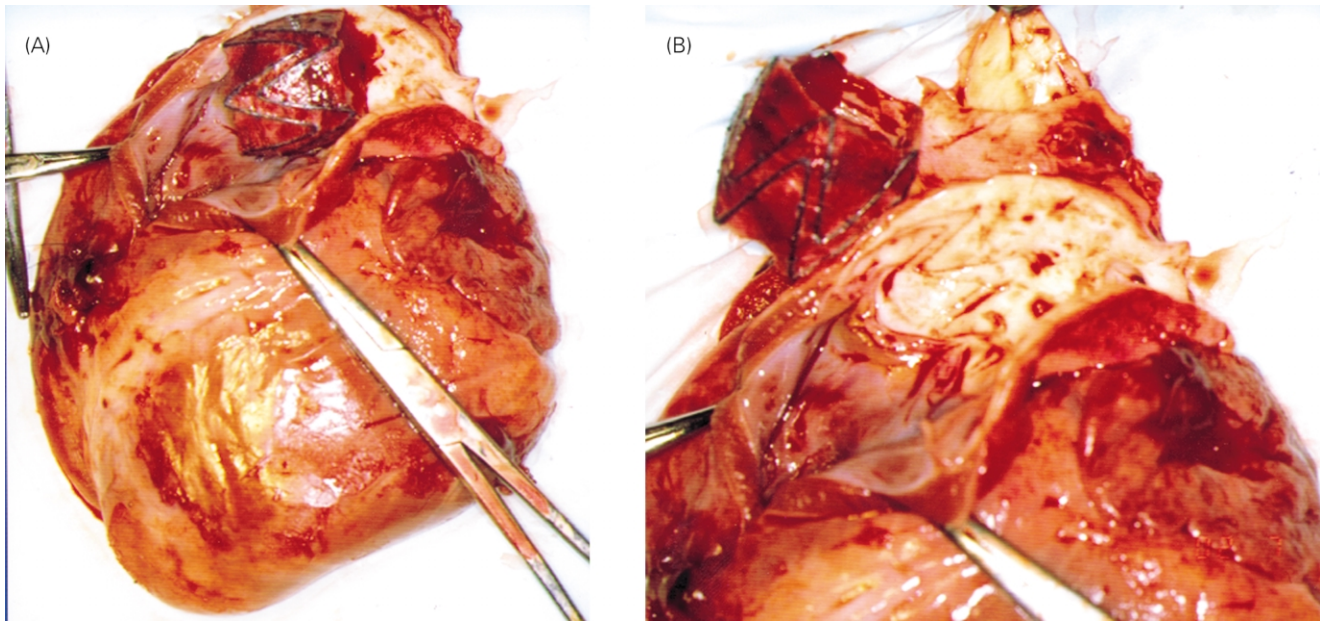


Fig. 4. Post-mortem examination confirming the adequate position of the valved stent in pulmonary position (A); and showing the fingerprint of the Z stent on the pulmonary artery wall (B).

we used a median sternotomy because we wanted to evaluate the feasibility of the new technique. In fact, based on this first experience, the implant of the valved stent in pulmonary position can be accomplished through a limited left anterior thoracotomy, particularly advantageous in clinical practice in the presence of a previous median sternotomy.

With regard to the size of the valved stent, the mean

external diameter of 26.3 ± 0.7 mm should allow adequate implant even in patients with dilated right ventricular outflow tract because of severe pulmonary valve regurgitation, like the situation encountered years after repair of tetralogy of Fallot with transannular patch.

With regard to the larger size of available biological valve, the internal diameter of 22 mm, because of the favourable effective orifice area, allows an adequate

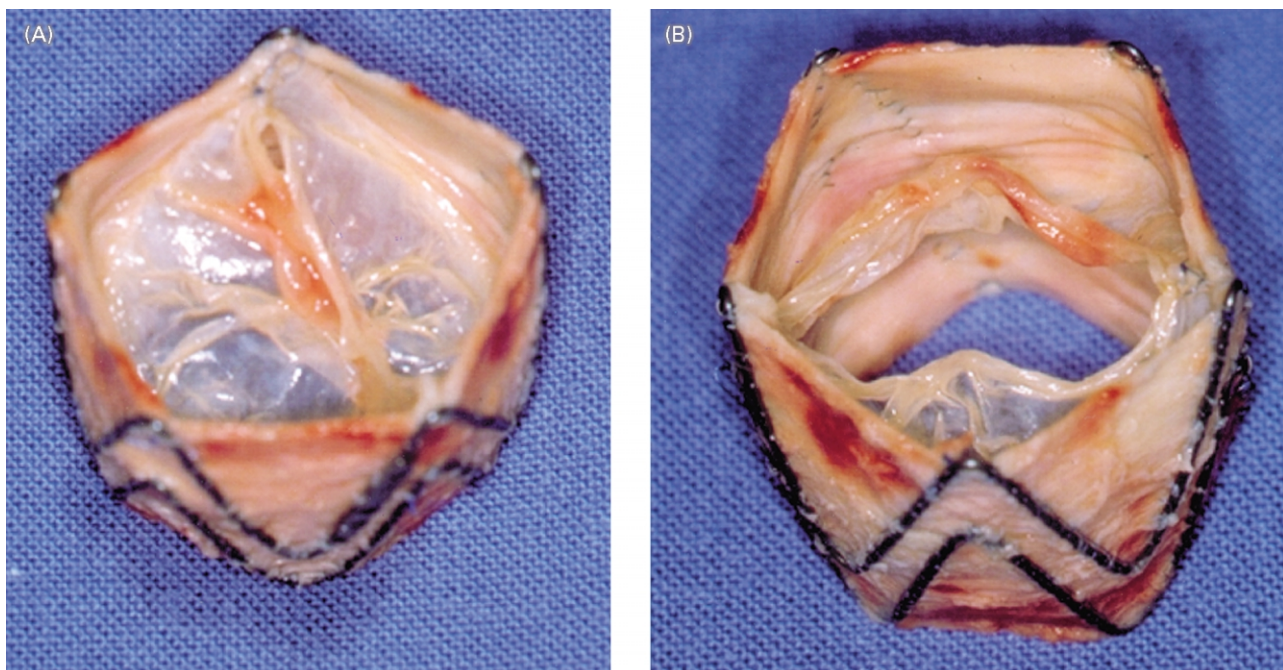


Fig. 5. Post-mortem examination with the explanted valve in open (A); and closed (B) position, excluding any valve deformation or thrombus.

hemodynamics without pressure gradient in patients up to 91 kg of body weight, as we already reported [26].

Of course our positive preliminary experimental data will need to be validated by chronic studies.

4.1. Conclusions

(a) The off-bypass implantation of self-expandable valved stent is feasible in pulmonary position; (b) the off-bypass surgical approach allows for valved stent implantation of adult size with adequate hemodynamic functioning; and (c) intravascular ultrasound makes implantation and evaluation easy and reproducible.

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