A Repositionable Valved Stent for Endovascular Treatment of Deteriorated Bioprostheses

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**OBJECTIVES**

We report our animal experience of endovascular valve replacement (VR) of failed bioprosthesis (BP) using an original delivery catheter allowing repositioning of the valved stent (VS).

**BACKGROUND**

Among the different devices designed for percutaneous VR, none has the potential for repositioning of a fully deployed VS. Five sheep underwent, on beating heart, tricuspid VR with a stented BP. Prolapse of 1 leaflet was induced by tearing. For the endovascular tricuspid VR, we used a VS constructed with a nitinol self-expandable stent and a porcine stentless aortic valve. We also used an original delivery catheter, allowing repositioning of the VS through a compression or relaxation mechanism of the stent.

**METHODS**

Epicardial echocardiography and right ventriculography showed severe tricuspid regurgitation, with a regurgitant jet extending to the inferior vena cava. After surgical exposure to the infrarenal inferior vena cava, the VS was successfully implanted inside the failed BP in all cases. Repositioning of the fully deployed VS was always possible. Echocardiographic and macroscopic studies revealed adequate VS positioning, excellent leaflet opening, and absence of any intraprosthesis or periprosthetic leak.

**RESULTS**

Endovascular VR was easily performed in sheep with failed BP in the tricuspid position. The novel delivery catheter allowed adequate repositioning of our fully deployed VS before its definitive release. One may anticipate that the safety improvement conferred by this new technology will certainly favor the development of percutaneous VR in clinical practice.

**CONCLUSIONS**

Structural valve deterioration (SVD) is the most frequent long-term complication of implanted bioprosthesis (BP). When severe enough, reoperation may be necessary with an increased operative risk in comparison with the first operation (1).

Since the recent publications of percutaneous pulmonary or aortic valve replacement (VR), the enthusiasm of the medical community toward these potential alternatives to surgery has been dramatically increasing (2,3). However, encountered problems are numerous, and there is still a long way before a safe and effective procedure becomes available.

A major problem encountered with percutaneous VR is the impossibility of readjusting the position of a valved stent (VS) once fully deployed. Bad positioning of the VS could lead to a fatal per-procedural issue (3). None of the available VS have the potential to be repositioned after complete deployment (4). Thus, being able to reposition a fully deployed VS could prove of crucial importance and would certainly favor the development of percutaneous VR by improving the safety of the procedure.

The present animal study had 2 main objectives: first, to test the feasibility of the endovascular treatment of a failed BP with a VS, and second, to test a novel delivery device permitting the repositioning of a fully deployed VS.

**METHODS**

Valved stent and delivery device. A 25-mm porcine aortic stentless valve (Toronto SPV, model SPA-101-25, St. Jude Medical, Minneapolis, Minnesota) was mounted onto a 30-mm nitinol self-expandable stent. After compression, the VS was introduced inside a 13-mm delivery catheter.

The originality of the delivery system consisted of the possibility of controlling precisely and reversibly the deployment of the VS after the delivery catheter has been retrieved. This was because of the presence of 2 sutures encircling the stent, whose traction through a proximal handle could reversibly affect the state (deployed or compressed) of the stent (Fig. 1). Therefore, if the location of the deployed VS was judged unsatisfactory, the operator had the possibility of repositioning the VS as often as necessary before final delivery. Once deployed in an adequate position, the VS was definitely liberated from the delivery catheter by pulling on a wire that controlled the attachment of the 2 sutures. The delivery catheter could then be withdrawn, leaving the VS in place.

**Experimental protocol.** Five sheep (>50 kg) were used for our experiments. All of the animals were treated according to the European regulations for animal experimentation (5).

Through a right thoracotomy, tricuspid valve replacement...
was first performed on a beating heart with a Carpentier-
Edwards Perimount number 27 aortic BP (model 2,800,
Edwards Lifesciences, Irvine, California). The anterior
leaflet of the BP was cut along its 2 commissural attach-
ments to create prosthesis failure.

The infrarenal inferior vena cava was then accessed
through a right retroperitoneal approach. A guidewire was
inserted into the vein and passed under fluoroscopic guid-
ance into the pulmonary artery, after crossing the tricuspid
BP. The VS was positioned inside the BP. The external
sheath was then pulled back and the VS deployed by
releasing the traction on the 2 encircling sutures. When
correctly positioned, the VS was definitively released from
the delivery catheter.

Evaluation of the VS. After insertion of the failed BP,
tricuspid regurgitation was assessed semi-quantitatively
with epicardial echocardiography and right ventriculogra-
phy. After implantation of the VS and using standard
echo-Doppler techniques, the transvalvular gradient was
determined and any intraprosthetic or periprosthetic leak
was recorded. Sheep were killed 1 to 2 h after the
procedure, and hearts were then harvested. Positioning,
stent deformation, and leaflet movement of the VS were
carefully analyzed.

RESULTS

The experiment was completed in all 5 sheep. All animals
were weaned from bypass without inotropic support. Dura-
tion (median time) of extracorporeal circulation was 48 mn
(range 38 to 52 mn).

Intraprothetic tricuspid insufficiency was severe in all
sheep. Bidimensional echocardiography showed prolapse of
the anterior leaflet of the BP into the right atrium. The vena
contracta width was 8 mm (range 6 to 10 mm). The color
flow regurgitant jet was large, eccentric, and extending into
the inferior vena cava (Fig. 2). Pulsed Doppler study showed
frank systolic blood flow reversal inside the inferior vena
cava. Right ventriculography confirmed these findings by
showing opacification of the inferior vena cava by the
regurgitation jet (data not shown).

The metallic frame of the BP being radio-opaque, the
target site of the VS implantation was therefore easily
identified. Under fluoroscopic guidance, the VS was properly
positioned inside the BP in all sheep. To evaluate the
effectiveness of the delivery system, the VS was deliberately
malpositioned inside the BP (Fig. 3). It was then very easy
to correct its position using the compression-relaxation tech-
nique mentioned above (Fig. 3). Deployment of the VS in its
correct and final position took no more than 2 min. During
these maneuvers, a transient and mild decrease in systolic
blood pressure (<20 mm Hg in all sheep) was observed.

Abbreviations and Acronyms

BP = bioprosthesis
SVD = structural valve deterioration
VR = valve replacement
VS = valved stent
Unrestricted movement of the VS leaflets was easily observed with epicardial bi-dimensional echocardiography. There was neither residual tricuspid regurgitation nor periprosthetic leak in any case (Fig. 2). Median transvalvular gradient was 7 mm Hg (range 6 to 8 mm Hg).

At final analysis of the explanted hearts, all of the VS were in good position (Fig. 3). Leaflets of the VS were perfectly mobile without any evidence of macroscopic injury. Anchorage of the VS inside the BP appeared to be firm.

**DISCUSSION**

With the extension of the indication of bioprosthetic VR and the ageing of the population, cardiologists and sur-

![Figure 2. Echocardiographic color Doppler study before and after endovascular valve replacement of a failed bioprosthesis. (Left) Tricuspid regurgitant jet extending into the inferior vena cava (IVC). (Right) Absence of any tricuspid regurgitation after valved stent delivery. RA = right atrium.](image)

![Figure 3. Representation of valved stent repositioning. (Top, left) The valved stent has been voluntarily misplaced too proximally inside the failed bioprosthesi. (Top, right) Recompression of the valved stent. (Bottom, left) The valved stent has been ultimately delivered in an adequate position. (Bottom, right) Right lateral view of the heart (the right atrium and the anterior part of the right ventricle have been resected) showing excellent positioning of the valved stented inside the failed bioprosthesis.](image)
geons will certainly face more and more cases of SVD. Besides being far less invasive, endovascular replacement of deteriorated BP should theoretically reduce the operative mortality by preventing complications of repeat heart dissection and the deleterious effects of cardiopulmonary bypass and myocardial ischemia caused by aortic cross-clamping. This should also imply a dramatic reduction of hospital costs.

Regurgitating forms of SVD of BP are easily accessible to an endovascular treatment. The actual self-expandable stents develop a satisfactory radial force permitting a firm anchorage of the VS inside a BP. However, in case of severely calcified BP, a balloon predilation of the BP might be necessary.

Several clinical or experimental observations have reported a number of fatal accidents caused by poor positioning of a VS (3,6). To the best of our knowledge, none of the VS reported in the literature offers the possibility to be readjusted after full deployment. The delivery device we tested permitted the reversibility of the VS positioning as many times as needed before the final release. This relied on a simple maneuver (compression-relaxation of the VS) that could be performed by 1 operator only.

The present delivery system offers other advantages. Mounting of the VS onto its delivery catheter is greatly facilitated by the traction on the encircling sutures, which would compress the valve. Thus, there is no need for any crimping device, as is the case for some other VS models. To achieve adequate positioning of the VS, right ventricular pacing or use of extracorporeal circulation during VS delivery has been recommended by others. With the present device, these potentially deleterious strategies are likely to be unnecessary, as was the case in our experimental study.

In conclusion, endovascular VR was easily performed in sheep with a failed tricuspid BP. The delivery catheter allowed adequate repositioning of our fully deployed VS before its definitive release. One may anticipate that the safety improvement conferred by this new technology will certainly favor the development of percutaneous VR in clinical practice.

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REFERENCES