Non-surgical aortic valve replacement

MILES DALBY, HELENE ELTCHANINOFF, ALAIN CRIBIER

Abstract

This article discusses percutaneous aortic valve replacement, a new technique developed to overcome the problem of restenosis of the native valve in patients treated with balloon aortic valvuloplasty. It describes the first four cases which have been undertaken using this new technique that show the potential for its development for more widespread use in the future.

Key words: percutaneous aortic valve replacement, aortic stenosis, stent technology.

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Introduction

Aortic stenosis is a common condition in an ageing population. Surgical aortic valve replacement (AVR) in otherwise fit octogenarians can be performed with a relatively low mortality and morbidity as discussed by Chikwe *et al.* in this edition of the journal (see pages 453–61). There remains, however, an increasing cohort of elderly patients with multiple co-morbidities who are highly symptomatic but not surgical candidates. Balloon aortic valvuloplasty (BAV), first performed in 1985,[1] appeared to offer a good solution for such patients. After initial enthusiasm for the technique, however, it became clear that there was a high rate of restenosis. In the National Heart Lung and Blood Institute Balloon Valvuloplasty registry, many patients reported an improvement in symptoms at two years, but long-term survival was poor at 55% at one year and 23% at three years.[2] Investigators have, therefore, worked towards the development of percutaneous AVR to overcome the problem of restenosis of the native valve.

Development of percutaneous valve replacement techniques

Investigators have focused on combining bio-prosthetic valve leaflets with balloon expandable stent technology to develop a fully implantable aortic valve. Andersen reported successful aortic valve replacement using a stent-mounted, porcine, aortic valve in a porcine model and, although there were problems with coronary flow, it was clear that the technique had potential.[3] Subsequently, a further series of animal experiments evaluated percutaneous aortic valve replacement in sheep using a stent-mounted bovine jugular valve. Although implantation in the descending aorta was successful, placement in the native position failed due to coronary obstruction, interference with the mitral valve, or migration. These problems were resolved with an orientation device.[4] Sheep anatomy is such that the distance between the mitral valve and the coronary ostia is only a few millimetres, which makes for significant limitations to this model.

Department de Cardiologie, Charles Nicole University Hospital,
1 Rue de Germont, 76000 Rouen, France.
Miles Dalby, Fellow in Interventional Cardiology
Helene Eltchaninoff, Professor of Cardiology
Alain Cribier, Director of Cardiology
Correspondence to: Professor A Cribier
(email: alain.cribier@chu-rouen.fr)

Figure 1. The stent-mounted, pericardial, tricuspid, percutaneously-implantable, aortic valve

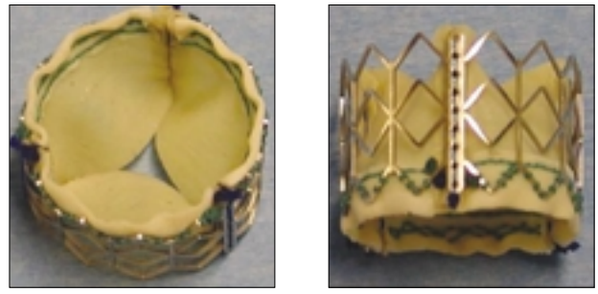


Figure 2. The partially **a**) and fully **b**) crimped valve – seen in **b**) mounted on a valvuloplasty balloon

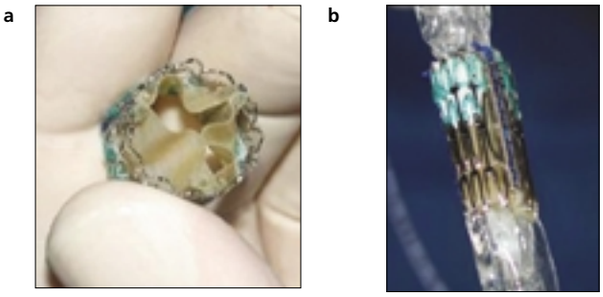
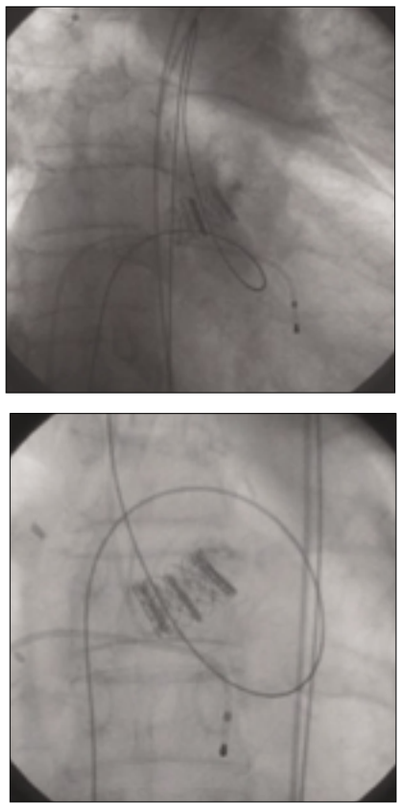


Figure 3. Percutaneous aortic valve during **a**) and after **b**) balloon deployment



Human percutaneous aortic valve replacement

Our centre has developed, in association with Percutaneous Vascular Technologies (Fort Lee, NJ, USA) a balloon-expandable, stent-mounted, equine, pericardial valve (figure 1). Preliminary studies using the sheep model, both in the descending aorta and in the native position, indicated that the technique was feasible.[5] This model, as discussed above, has significant limitations and valve migration was frequently seen. In man there is approximately 1.0–1.5 cm between the coronary ostia and mitral valve; observations on human autopsy specimens indicated that it was possible to place a stent within the native aortic valve which remained strongly anchored, without impinging on the coronary ostia or mitral valve.

The first human percutaneous aortic valve replacement was performed in April 2002 at the Charles Nicole University Hospital in Rouen, France, in a 57-year-old man with severe aortic stenosis, cardiogenic shock and multiple other co-morbidities, who was considered unfit for surgical valve replacement. A stent-mounted, tricuspid, pericardial valve was crimped onto a balloon (figure 2), passed over a guidewire antegradely via the transseptal approach and deployed in the position of the native valve (figure 3). Positioning was satisfactory and aortography and echocardiography indicated excellent valve function with only a small para-valvular leak. The patient died four months later of unrelated causes, but valve function assessed by transoesophageal echocardiogram remained excellent through the follow-up period.[6] Subsequently, a further three patients have undergone percutaneous AVR. In the second case, the patient was moribund and part of the native aortic valve was dehissed following BAV. As a result, the percutaneous valve could not be properly implanted and embolised distally. In the third and fourth cases, valve implantation was successful. Although there was a degree of para-valvular regurgitation, valve function was excellent with a good immediate clinical outcome, and further follow-up is awaited.

Key messages

- Aortic stenosis often presents in elderly patients with multiple co-morbidities preventing surgical aortic valve replacement
- Balloon aortic valvuloplasty is associated with a high rate of restenosis
- Early results with percutaneous aortic valve replacement show potential for its more widespread development

Conclusion

There have been exciting developments in the percutaneous management of aortic stenosis and these first cases demonstrate that it is feasible to replace the human aortic valve through a catheter using a stent-mounted device. The technique is reserved at present for compassionate cases, but if this is successful, a multicentre trial is planned.

Although percutaneous aortic valve replacement is very early in its development, and potential implications for clinical practice must be guarded, it seems likely that the technique, either in its current form or following modification will become available for more widespread use in the future.

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