Rev Port Cardiol. 2012;31(2):143–149

Revista Portuguesa de Cardiologia
Portuguese Journal of Cardiology
www.revportcardiol.org

ORIGINAL ARTICLE

Transcatheter aortic valve implantation: Results of a new therapeutic option for high surgical risk aortic stenosis☆

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Received 31 March 2011; accepted 8 September 2011

KEYWORDS
Aortic valve stenosis;
Heart valve prosthesis;
Transcatheter aortic valve implantation;
Non-coronary intervention;
Aortic valve replacement

Abstract
Introduction: Transcatheter aortic valve implantation (TAVI) is an alternative to surgical aortic valve replacement in patients with severe aortic stenosis (AS) and unacceptably high surgical risk.
Methods: We present our first two years' experience with TAVI. A total of 76 AS patients were evaluated for TAVI and 23 of them underwent a TAVI procedure. These patients had a mean EuroSCORE of 22.4% and a mean age of 81.5 years, and were prospectively followed for a mean of 12.9±11 months.
Results: The percutaneous aortic valve was successfully implanted in 100% of the patients. Mortality at 30 days was 4%. The most common complications were access site-related bleeding and transfusion (22%), followed by new permanent pacemaker implantation (9%). After a mean follow-up of 12.9 months, survival was 87%. In a maximum follow-up of 30 months there were no cases of prosthesis dysfunction or cardiovascular death.

☆ Please cite this article as: Salinas P. Implantação percutânea de próteses valvulares aórticas: resultados de uma nova opção terapêutica na estenose aórtica com alto risco cirúrgico. Rev Port Cardiol. 2011. doi:10.1016/j.repc.2011.12.008.
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Conclusions: Two years after the introduction of a TAVI program in our center, the procedure has established itself as a safe and effective alternative for patients with severe AS and unacceptably high surgical risk.

PALAVRAS-CHAVE
Estenose aórtica grave;
Prótese valvular cardíaca;
Prótese aórtica transcateter;
Intervenção cardíaca não coronária;
Substituição valvular aórtica

Implantação percutânea de próteses valvulares aórticas: resultados de uma nova opção terapêutica na estenose aórtica com alto risco cirúrgico

Resumo
Introdução: A implantação da válvula aórtica transcateter (TAVI) é uma alternativa à substituição valvular aórtica cirúrgica convencional para doentes com estenose aórtica (EA) grave e risco cirúrgico inaceitável.
Métodos: Apresentamos a experiência com TAVI no nosso centro durante os primeiros anos, desde o seu início. De 76 doentes com EA avaliados para eventual TAVI, realizou-se o procedimento em 23 dos mesmos, que apresentavam um Euroscore médio de 22,4% e uma idade média de 81,5 anos. Estes 23 doentes foram seguidos de modo prospectivo durante 12,9±11 meses.
Resultados: A prótese foi implantada com êxito em todos os doentes. A mortalidade aos 30 dias foi de 4%. As complicações mais frequentes foram as vasculares e a necessidade de transfusão (22%) seguida de colocação de *pace-maker* definitivo (9%). Após um *follow-up* médio de 30 meses não se registou nenhum caso de disfunção protésica nem de morte cardiovascular.
Conclusões: Dois anos após o início de um programa de TAVI no nosso centro, a TAVI evidencia-se como uma alternativa eficaz para doentes com EA grave inoperáveis por risco cirúrgico elevado.

Introduction

The course of aortic stenosis (AS) is slow and asymptomatic for most of its natural history, but progresses rapidly in its more advanced stages. Mortality two years after symptom onset is 50%, and when there are symptoms of heart failure, it is 50% at one year.[1] AS is the most common isolated valve disease, accounting for around 40% of all diagnoses, and is the most frequent indication for valve surgery. Over the age of 75 years, the prevalence of severe AS can reach 4.6% in the general population, a figure that is expected to rise with aging populations.[2]

The standard treatment for severe symptomatic AS is valve replacement surgery, which has been shown to improve survival.[3,4] However, in daily clinical practice, around a third of AS patients who in principle are indicated for surgical replacement are rejected because of high surgical risk, mainly due to the frequent association of advanced age and comorbidities.[5,6] An alternative treatment for patients with severe symptomatic AS who are refused for surgery has recently been developed, which consists of percutaneous implantation of a prosthetic valve mounted on a metal stent, known as transcatheter aortic valve implantation (TAVI). This procedure avoids the morbidity and mortality associated with sternotomy and extracorporeal circulation, and can be performed by apical ventriculotomy or a transarterial approach (usually transfemoral).[7]

We present our center's experience with TAVI during the first two years since its introduction.

Methods

In 2008 a TAVI program was introduced using a transfemoral approach.[8] A total of 23 Edwards SAPIEN prosthetic valves (Edwards Lifesciences, USA) have been implanted to date and these patients have been followed prospectively through outpatient appointments and serial echocardiograms. The aim of this study is to describe patient selection, immediate results and clinical course in these patients.

Clinical data for this observational, prospective cohort study were collected during appointments before the procedure or during hospital stay. After discharge, follow-up echocardiograms were performed at one month, six months and one year. Clinical follow-up was by outpatient consultations and all patients were contacted.

Patient selection

All patients with severe symptomatic degenerative AS rejected for surgical replacement were assessed for TAVI by a femoral approach over a period of two years. Our center's assessment protocol has been described previously.[9] Severe AS was defined as an aortic valve area calculated by planimetry or the continuity equation of $<1\,cm^2$ or $<0.6\,cm^2/m^2$ indexed to body surface area by echocardiography, as recommended in the ESC guidelines.[4] Patients were assessed by a team of clinical and interventional cardiologists, cardiac surgeons and anesthesiologists who evaluated surgical risk, with the help of standard risk scores: