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Original article

A versatile transapical device for aortic valvular disease: One-year outcomes of a multicenter study on the J-Valve system

Mingwui Tung (MD)[a], Xu Wang (MD)[a], Fei Li (MD)[a], Hao Wang (MD)[b], Yingqiang Guo (MD)[c], Chunsheng Wang (MD)[d], Lai Wei (MD)[d], Xinjin Luo (MD)[e], Xin Wang (MD)[e], Wei Wang (MD, PhD)[a,*]

[a] *Structural Heart Disease Center, National Center for Cardiovascular Disease and Fuwai Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing, PR China*
[b] *Department of Echocardiography, National Center for Cardiovascular Disease and Fuwai Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing, PR China*
[c] *Department of Cardiovascular Surgery, West China Hospital, Sichuan University, Chengdu, Sichuan, PR China*
[d] *Department of Cardiovascular Surgery, Shanghai Cardiovascular Institution and Zhongshan Hospital, Fudan University, Shanghai, PR China*
[e] *Department of Cardiovascular Surgery, National Center for Cardiovascular Disease and Fuwai Hospital, Chinese Academy of Medical Sciences, Peking Union Medical College, Beijing, PR China*

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ABSTRACT

Background: The novel J-Valve (JC Medical Inc, Burlingame, CA, USA) was developed to cope with aortic valvular disease by facilitating accurate positioning. We present the first one-year results regarding the safety and efficacy of the J-Valve system implantation in patients with severe aortic stenosis (AS) or aortic regurgitation (AR) undergoing transapical-transcatheter aortic valve implantation.
Methods: This prospective multicenter study enrolled 107 high-risk patients (mean age 74.4 ± 5.2 years; mean EuroSCORE-I 11.2 ± 1.2%) with severe AS (n = 64) or AR (n = 43), at the three largest cardiac centers in China. The study was fully monitored, and adverse events were adjudicated by an independent clinical events committee using Valve Academic Research Consortium criteria.
Results: The success rate of the procedure was 91.6% (98/107). At 1 year, the all-cause mortality was 5.0%, stroke 2%, and rate of new pacemakers 5.0%. Only mild paravalvular leak was reported. Among the patients with AS, the 1-year follow-up demonstrated a sustainable reduction of mean transaortic gradient from 57.7 ± 15.4 mmHg to 15.5 ± 8.3 mmHg. All patients who completed the follow-up reported improvements in New York Heart Association functional class (n = 93) and health-related quality of life as assessed by the EuroQol five dimensions questionnaire index (n = 94). In intergroup comparisons, the 1-year major adverse cardiovascular events-free survival was similar between the groups based on valve disease (AS vs. AR, log-rank p = 0.17) or morphology (tricuspid vs. bicuspid aortic valve, log-rank p = 0.25).
Conclusions: Our study provides further evidence on the safety and efficacy of the J-Valve in high-risk patients with AS or AR for surgery.

Introduction

Transapical-transcatheter aortic valve implantation (TA-TAVI) is a flourishing surgical technique for the treatment of patients with aortic stenosis (AS) who are considered poorly suitable for conventional surgery. Several trials have demonstrated the efficacy and safety of TA-TAVI [1–3]. Recently, TAVI was shown to be non-inferior to surgical aortic valve replacement (SAVR) in intermediate-risk patients with AS [4]. This finding immediately triggered an update of the latest guidelines for valvular diseases [5,6]. However, there are still limitations and concerns surrounding this procedure, particularly in cases of aortic regurgitation (AR) [7].

Therefore, a novel TA-TAVI system, the J-Valve (JC Medical Inc, Burlingame, CA, USA), was developed. The J-Valve bioprosthesis is the first transcatheter heart valve (THV) originally designed in

* Corresponding author at: Ward 53, Northern Block Fuwai Hospital, 167 Beilishi Road, Xicheng District, Beijing 100037, PR China.
E-mail address: drweiwang0728@hotmail.com (W. Wang).

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China that has received China Food and Drug Administration approval (CFDA, certified number: 20173460698) in mainland China based on the initial results from a single center [8–10]. Thirty-day results of the J-Valve have been reported and demonstrated lower rates of complications and mortality [11]. This multicenter analysis, which included patients with AS, AR, or a bicuspid aortic valve (BAV), presents the first one-year results regarding the safety and efficacy of the J-Valve system.

Methods

Study design and patient selection

The J-Valve China Trial was designed as a prospective, fully monitored and independent voluntary study of patients treated for AS (or AR) using the J-Valve. A total of 107 consecutive patients were enrolled between March 2014 and July 2015 in 3 of the largest Chinese cardiac centers. Detailed information about the inclusion and exclusion criteria has been reported previously [8,9]. The centers were required to have an on-site multidisciplinary 'heart team' comprising at least one interventional cardiologist and one TAVI-experienced cardiac surgeon. All enrolled patients were determined poorly suitable for SAVR by the heart team. The study protocol was approved by the local ethics committees and adhered to the Declaration of Helsinki. All patients provided consent before the procedure.

Device description

The J-Valve is a second-generation self-expandable device introduced through TA access, and consists of a porcine aortic valve attached to a nitinol stent with 3 U-shaped graspers encircling the stent by three sutures (Fig. 1). The design of the J-Valve allows it to be implanted in patients with AR or AS and hence was recognized as a versatile device for aortic valvular disease. The procedure is outlined in Supplemental Fig. S1 and has been described in detail elsewhere [11]. The J-Valve sizes of 21, 23, 25, and 27 mm were selected according to the manufacturer's recommendations. Slightly oversized (10%) devices were implanted in patients with AR. The heart team at each center made sizing and procedural decisions. Oral anticoagulation using a vitamin K antagonist was prescribed for the first 3–6 months after transapical implantation of the J-Valve bioprosthesis, followed by lifelong single antiplatelet therapy in patients who do not need oral anticoagulation for other reasons.

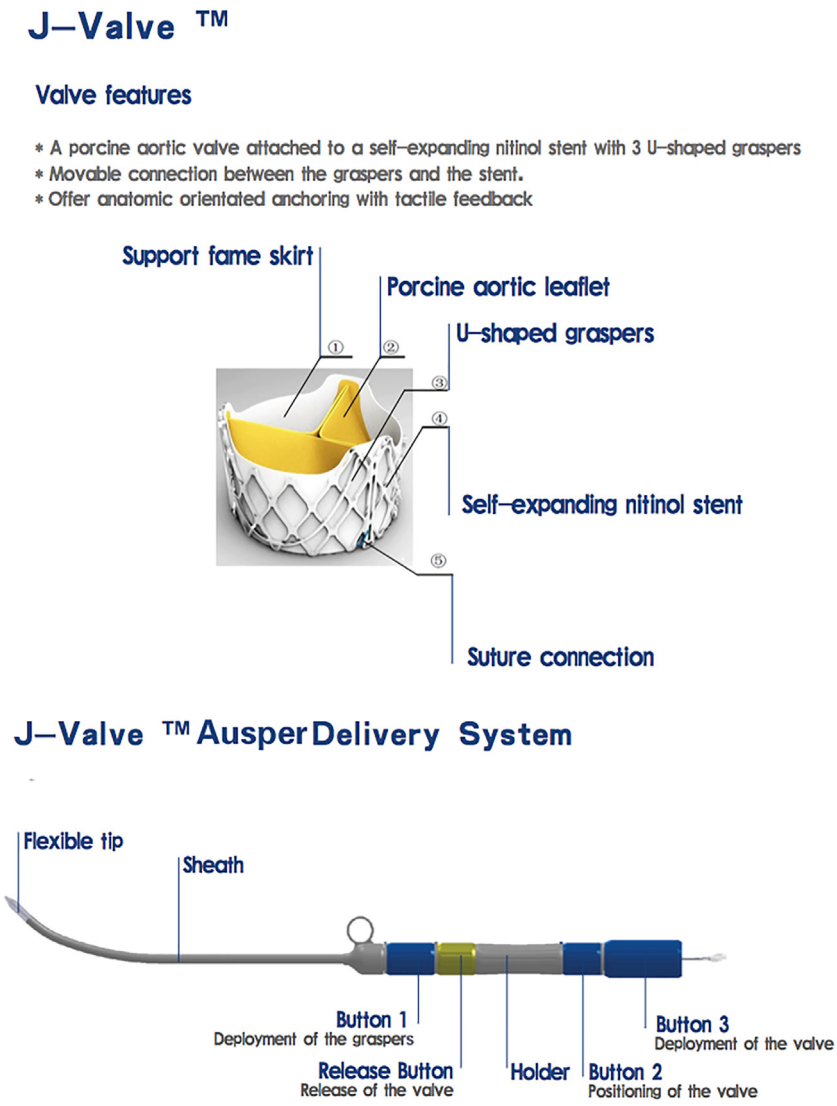

Fig. 1. The J-Valve system.

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