Early hemodynamics and clinical outcomes of isolated aortic valve replacement with stentless or transcatheter valve in intermediate-risk patients

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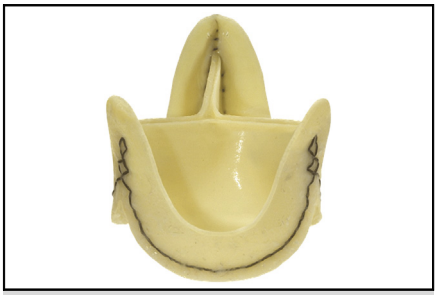
ABSTRACT

Objective: Stentless aortic valves have been developed to overcome obstructive limitations associated with stented bioprostheses. The aim of the current multi-institutional study was to compare hemodynamics of transcatheter (TAVR) and the Freedom SOLO Stentless (FS) valve in an intermediate risk population undergoing surgical aortic valve replacement.

Methods: From 2010 to 2014, 420 consecutive patients underwent isolated surgical aortic valve replacement with FS and 375 patients underwent TAVR. Only patients with intermediate operative risk (Society of Thoracic Surgeons score 4-10) and small aortic annulus (≤23 mm) were included. After a propensity matched analysis 142 patients in each group were selected. Thirty-day postoperative clinical and echocardiographic parameters were evaluated.

Results: Mean prosthesis diameter was 22.2 ± 0.9 mm for FS and 22.4 ± 1.0 mm for TAVR. In-hospital mortality was 2.1% for FS and 6.3% for TAVR ($P = .02$). Postoperative FS peak gradients were 19.1 ± 9.6 mm Hg (mean 10.8 ± 5.9 mm Hg); TAVR peak gradients were 20.2 ± 9.5 mm Hg (mean 10.7 ± 6.9 mm Hg) $P = .57$ ($P = .88$). Postoperative effective orifice area was 1.93 ± 0.52 cm^2 for FS and 1.83 ± 0.3 cm^2 for TAVR ($P = .65$). There was no prostheses-patient mismatch in either group. Postoperative grade 2-3 paravalvular leak was present in 3.5% for TAVR and 0.7% for FS. Postoperative permanent pacemaker implant rate was 12% for TAVR and only 1 case (0.7%) in the FS group ($P < .001$).

Conclusions: In patients with small aortic annulus and intermediate risk, both FS and TAVR demonstrated similar excellent hemodynamic performance. TAVR demonstrated greater mortality and rates of pacemaker insertion. Further studies are warranted to validate TAVR indications in this subset of patients. (J Thorac Cardiovasc Surg 2016;■:1-10)



The Freedom SOLO pericardial stentless valve.

Central Message

In patients with small aortic annuli and intermediate risk, Freedom SOLO stentless valve shows excellent hemodynamics, similar to transcatheter aortic valve replacement, with better outcomes.

Perspective

The use of transcatheter aortic valve replacement negatively affects the perioperative outcome with significantly greater early mortality, greater incidence of periprosthetic regurgitation and postprocedural atrioventricular block requiring pacemaker implant. Further studies are warranted to validate transcatheter aortic valve replacement indications in patients with intermediate-low risk profile and small aortic annulus.

ACQ

The recently published Placement of Aortic Transcatheter Valves (PARTNER) 2 Trial[1] concluded that clinical outcomes for transcatheter aortic valve replacement (TAVR) were similar to surgical aortic valve replacement (sAVR) with respect to the primary end point of death or disabling stroke in patients with an intermediate-risk profile. Despite

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Abbreviations and Acronyms

AVR = aortic valve replacement
CI = confidence interval
FS = Freedom SOLO
OR = odds ratio
PARTNER = Placement of Aortic Transcatheter Valves
PM = pacemaker
PPM = prostheses-patient-mismatch
PVL = paravalvular leak
sAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons
TAVR = transcatheter aortic valve replacement

the findings of this landmark prospective randomized trial, however, this study included a heterogeneous population of patients in the surgical group, particularly in regard to the type of surgical prosthesis used and procedures.

Furthermore, the hemodynamic performance of stented valves could lead to a greater likelihood of patient-prosthesis mismatch (PPM), thus leading to a potential overestimation of the hemodynamic advantages of TAVR in this specific subset of patients. In patients with small aortic annulus, for example, a greater incidence of PPM associated with greater early and late mortality has been reported, mainly when ventricular function is reduced.[2-4] In such cases stentless prostheses provide excellent hemodynamic results compared with stented prostheses,[5-7] possibly with improved long-term durability and reduced long-term mortality rates.[8] The routine use of stentless bioprostheses for sAVR, however, is still limited, despite the well-known superior hemodynamic performances compared with stented bioprostheses,[2,9,10] which continues to be the gold standard treatment in low- and intermediate-risk aortic stenosis patients older than 65 years of age.

During the past decade, the use of TAVR in patients with severe aortic stenosis and high operative risk has been shown to be a reasonable alternative to conventional sAVR in patients with prohibitive surgical risk.[11,12] Nevertheless, an ongoing debate continues regarding the best operative strategy for intermediate-risk patients for whom sAVR demonstrates superior results compared with TAVR in terms of postoperative morbidity and mortality.[13,14] Since their introduction into clinical practice, concerns exist regarding TAVR performance due to a "left-in-place" calcified native valve; however, recent studies have demonstrated low transprosthetic gradients at early and mid-term, even in patients with small aortic annuli.[15] Given the favorable hemodynamic performance of stentless valves and the paucity of data comparing such prostheses with transcatheter valves, we sought to investigate the performance and clinical outcomes of stentless sAVR versus TAVR in a population of patients with isolated, severe aortic valve stenosis and an intermediate-risk profile.

METHODS

Study Population

The present study was an observational, retrospective, multicenter cohort study in 795 consecutive patients with isolated severe aortic valve stenosis and an intermediate-risk profile (Society of Thoracic Surgeons [STS] Predictive of Mortality 4%-10%)[16,17] undergoing sAVR or TAVR after multidisciplinary Heart Team evaluation. Data were collected from 7 European cardiac centers, including data for demographic characteristics, comorbidities, and comprehensive information regarding the type of intervention. All centers were selected according to their high-volume activity either in stentless valve surgery and TAVR procedures. The institutional review board of the University of Brescia approved this retrospective analysis of clinically acquired data, and informed consent for anonymous data treatment for scientific purposes was obtained.

From May 2010 to December 2014, 795 patients with isolated severe aortic valve stenosis and an intermediate-risk profile with aortic annulus ≤23 mm, underwent aortic valve replacement (AVR); 420 patients underwent sAVR with the bovine pericardial stentless bioprosthesis Freedom SOLO (FS) valve (Sorin Group, Milan, Italy; Figure 1), whereas 375 patients were treated by TAVR. Preoperative patient characteristics are listed in Table 1. A propensity score matching analysis was performed to reduce selection bias. Following 1:1 propensity-score matching, 142 patients from each treatment group were selected to obtain 2 homogeneous populations (Table 2). Transthoracic echocardiographic baseline assessment was performed in every patient (Table 3). Transesophageal echocardiography or stress echocardiography was performed only in cases of low-flow stenosis that required further evaluations. Predischarge transthoracic echocardiography was performed in every patient (Table 3).

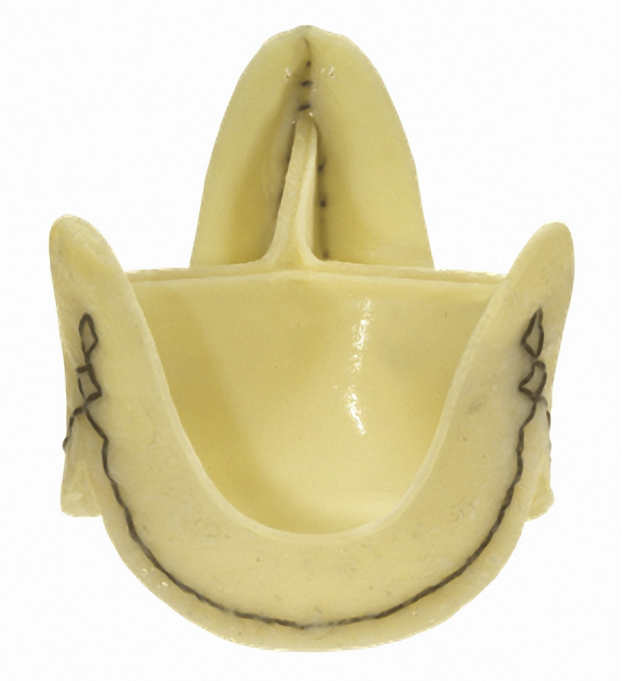

FIGURE 1. Freedom SOLO pericardial stentless valve.