Sutureless Aortic Valve: Early and Mid-Term Results at a Single Center

Amjad Shalabi MD[1], Ehud Raanani MD[1], Amihai Shinfeld MD[1], Rafael Kuperstein MD[2], Alexander Kogan MD[1], Alexander Lipey MD[1], Eyal Nachum MD[1] and Dan Spiegelstein MD[1]

Departments of [1]Cardiac Surgery and [2]Cardiology, Sheba Medical Center, Tel Hashomer, affiliated with Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel

ABSTRACT: **Background:** Prolonged life expectancy has increased the number of elderly high risk patients referred for surgical aortic valve replacement (AVR). These referred high risk patients may benefit from sutureless bioprosthesis procedures which reduce mortality and morbidity.

Objectives: To present our initial experience with sutureless aortic bioprotheses, including clinical and echocardiographic results, in elderly high risk patients referred for AVR.

Methods: Forty patients (15 males, mean age 78 ± 7 years) with symptomatic severe aortic stenosis underwent AVR with the 3F Enable™ or Perceval™ sutureless bioprosthesis during the period December 2012 to May 2014. Mean logistic EuroScore was 10 ± 3%. Echocardiography was performed preoperatively, intraoperatively, at discharge and at follow-up.

Results: There was no in-hospital mortality. Nine patients (22%) underwent minimally invasive AVR via a right anterior mini-thoracotomy and one patient via a J-incision. Four patients underwent concomitant coronary aortic bypass graft, two needed intraoperative repositioning of the valve, one underwent valve exchange due to inappropriate sizing, three (7.5%) had a perioperative stroke with complete resolution of neurologic symptoms, and one patient (2.5%) required permanent pacemaker implantation due to complete atrioventricular block. Mean preoperative and postoperative gradients were 44 ± 14 and 13 ± 5 mmHg, respectively. At follow-up, 82% of patients were in New York Heart Association functional class I and II.

Conclusions: Sutureless AVR can be used safely in elderly high risk patients with relatively low morbidity and mortality. The device can be safely implanted via a minimally invasive incision. Mid-term hemodynamic results are satisfactory, demonstrating significant clinical improvement.

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KEY WORDS: aortic valve stenosis, aortic valve replacement (AVR), sutureless aortic valve, transcatheter aortic valve implantation (TAVI), high risk patients

Due to continued prolonged life expectancy, the number of elderly high risk patients being referred for surgical aortic valve replacement (AVR) has increased. Despite the excellent results of surgical AVR, at least one-third of patients with severe symptomatic aortic stenosis do not undergo heart surgery because of perceived high operative risk, especially secondary to age, major co-morbidities, low ejection fraction and neurologic dysfunction [1]. A significant number of patients would therefore benefit from a less invasive procedure on the aortic valve. Transcatheter aortic valve implantation (TAVI) procedures are used extensively in high risk patients considered to be ineligible for standard AVR, which uses cardiopulmonary bypass [2]. Careful preoperative workup is mandatory to ensure anatomic appropriateness for TAVI; it should include accurate aortic annulus and root sizing, positioning of coronary arteries, delineation of iliofemoral anatomy, and other potential vascular accesses. Moreover, reports have shown that even in experienced centers percutaneous valve implantation has the potential for serious complications (such as paravalvular leak), a high incidence of neurologic and vascular complications, and the need for permanent pacemaker implantation [3-5].

For patients who are not inoperable but are at high risk for surgical AVR, sutureless aortic prostheses provide a good solution. By requiring minimal suturing and tying, the cross-clamp and cardiopulmonary bypass times are reduced. Bearing in mind the data showing that prolonged ischemic times have a negative impact on postoperative morbidity and mortality [6], the quick implantation of the prosthesis makes this technique an option for high risk patients with severe symptomatic aortic stenosis. There are currently three sutureless aortic valves available: 3F Enable™ (ATS Medical Inc., Minneapolis, MN, USA), Intuity™ (Edwards Lifesciences LLC, Irvine, CA, USA), and Perceval S™ (Sorin Biomedica Cardio, Saluggia, Italy). According to the current available literature, sutureless valves provide superior hemodynamic outcomes with reduced gradients compared to surgical AVR [7]. The faster and easier implantation facilitates minimal invasive surgery particularly through right anterior mini-thoracotomy [8], as well as in patients undergoing lengthy and complex procedures (for example, a redo or concomitant surgery) [9]. We report our experience with the Perceval S and 3F Enable valves.

PATIENTS AND METHODS

From December 2012 to April 2014, a total of 40 elderly patients (15 males, mean age 78 ± 7 years, range 48–91) with symptom-

atic aortic valve stenosis underwent AVR with either the 3F Enable (Medtronic) or the Perceval (Sorin) bioprosthesis. The mean logistic EuroScore was 10 ± 3%. Four patients underwent concomitant coronary aortic bypass graft (CABG). Follow-up was prospective and consisted of both clinical examinations and postoperative echocardiography.

OPERATIVE PROCEDURES

Surgery was performed through full sternotomty, J-incision or mini-thoracotomy. Mini-thoracotomy was performed through a right anterior thoracotomy. A computed tomography (CT) scan was done before the procedure to determine the distance and location between the aorta and the chest wall. Standard cardiopulmonary bypass was established by cannulation of the ascending aorta and the right atrium. Femoral cannulation was performed in the right thoracotomy approach and also in redo cases. Myocardial protection was achieved by using cold blood cardioplegia. Due to the high profile of the prosthesis, transverse aortotomy was performed approximately 1–2 cm above the sinus-tubular junction. The valve was excised, and the annulus was only moderately decalcified in order to provide a rough "landing zone" for the prosthesis. Patients were monitored intraoperatively with transesophageal echocardiography (TEE) for the management of cardiopulmonary bypass and for prosthesis evaluation. Implantation techniques and details regarding the Perceval S and 3F Enable valves have been previously described [8,12].

STATISTICAL ANALYSIS

All statistical analyses were performed with SPSS software (version 21). Values are expressed as mean ± standard deviation or as a percentage.

RESULTS

PATIENTS AND PROCEDURE CHARACTERISTICS

Patient characteristics and operative data are summarized in Table 1. There were no intra-procedural deaths. AVR was performed via full median sternotomy in 30 patients, a mini-thoracotomy in 9 and a J-incision in 1 patient. Intraoperative TEE showed a severe paravalvular leak (PVL) in three patients. Since the prosthesis appeared to be positioned too high in the supra-annular position, repositioning was performed in two patients. The valve was exchanged for a larger Perceval bioprosthesis in one patient [Table 2]. These three patients had an uneventful postoperative outcome, with no valve endocarditis, residual regurgitation, degeneration or dysfunction at follow-up.

EARLY RESULTS

Early results are shown in Table 3. There were no intraoperative or in-hospital deaths. Two patients (5%) underwent conversion: one from a J-incision to full median sternotomy, and one from a mini-thoracotomy to full median sternotomy – both due to technical difficulties. Three patients (7%) suffered an ischemic stroke with complete resolution of their neurologic impairment before discharge. A median sternotomy incision was performed in two of those patients and a mini-thoracotomy in the third.

Table 1. Patient data and characteristics

Characteristics	Patients (N=40)
Age (years)	78 ± 7
Males	15 (37%)
Body mass index	28 ± 4
Body surface area	1.8 ± 0.2
Hypertension	30 (75%)
Chronic obstructive pulmonary disease	3 (7%)
Diabetes mellitus	3 (7%)
Peripheral vascular disease	2 (5%)
Prior cerebrovascular accident	4 (10%)
Pulmonary hypertension › 60 (mmHg)	1 (2.5%)
Chronic renal failure (GFR ‹ 60) NYHA III/IV EuroScore (logistic)	21 (52.5%) 32 (80%) 10 ± 3%
Preoperative ECHO data	
Ejection fraction %	63 ± 6
Mean gradient (mmHg)	46 ± 11
Peak gradient (mmHg)	75 ± 22
Aortic valve area (cm^2)	0.8 ± 0.2
Indexed effective orifice area Annulus size (mm) Pulmonary pressure (mmHg)	0.44 ± 15 22 ± 3 42 ± 12

NYHA = New York Heart Association

Table 2. Intraoperative data

Intraoperative data	Patients (N=40)
CPB time (min)	80 ± 47
Cross clamp time (min)	50 ± 24
Concomitant CABG	4 (10%)
Repositioning	2 (5%)
Valve exchange	1 (2.5%)
Conversion to sternotomy	2 (5%)
Paravalvular leak mild	2 (5%)
Sternotomy Right minimal thoracotomy J-incision Enable™ Perceval™	30 (75%) 9 (22.5%) 1 (2.5%) 13 (32.5%) 27 (67.5%)

CBP = cardiopulmonary bypass, CABG = coronary artery bypass graft

Table 3. Early results

Results	Patients (N=40)
Mortality	0
Renal failure	1 (2%)
Atrial fibrillation	6 (15%)
Transient ischemic attack	3 (7%)
Wound infection	1 (2%)
Gastrointestinal bleeding	1 (2%)
Phrenic paresis	1 (2%)
Post-pericardioectomy syndrome	2 (5%)
Intensive care unit time (hours)	50 ± 59
Ventilation time (hours)	21 ± 32
Hospitalization time (days)	7 ± 3

All three underwent similar surgical procedures compared to all other patients. Two patients (5%) needed a tracheostomy due to respiratory failure and prolonged ventilation. One patient (2%) developed renal failure and was connected to continuous venous venous hemofiltration leading to recovery of renal function. There were two wound infections: one patient (2.5%) had a deep sternal wound infection after median sternotomy and was treated with sternoplasty, and a second had a superficial infection (2.5%). Upper gastrointestinal bleeding occurred in one patient (2.5%) who required a blood transfusion. Gastroscopy showed antral gastritis with no active bleeding. Thoracocentesis for a pleural effusion after a mini-thoracotomy was performed in two patients (5%). One patient (2%) underwent permanent pacemaker implantation due to complete atrioventricular block. One patient (2%) developed phrenic paresis. Six patients (15%) had postoperative atrial fibrillation, were treated with amiodarone and returned to sinus rhythm. Early echocardiography demonstrated trivial paravalvular aortic insufficiency in two patients (5%), who did not require surgical intervention. No increase in the severity of aortic insufficiency was noted during follow-up. Mean ventilation time was 17 ± 7 hours. Hospital duration was 7 ± 3 days. Preoperative echo data are listed in Table 1. Mean preoperative gradient and effective orifice areas were 44 ± 14 mmHg and 0.8 ± 0.2 cm^2, respectively. The average postoperative mean gradient was 13 ± 5 mmHg. We observed an excellent reduction of transvalvular gradient in patients with small aortic annulus (19–21 mm).

LATE RESULTS

Follow-up was 21 ± 32 months (range 1–months). During follow-up two patients (5%) were hospitalized with heart failure and pulmonary congestion. At follow-up, 82% of the patients were in New York Heart Association (NYHA) functional class I and II. The mean gradient either remained stable or was reduced, relative to the values at discharge: 12 ± 2 mmHg at 6 months and 11 ± 2 mmHg at 12 months [Table 4].

Table 4. Late results

Results	Patients (N=40)
Follow-up time (months)	21 ± 32
NYHA functional class I-II	32 (97%)
Thromboembolism	0
Major bleeding	0
Heart failure admissions	1 (2.5%)
Late mortality	0
Mean gradient (mmHg)	13 ± 5
Peak gradient (mmHg)	22 ± 7
Ejection fraction %	60 ± 7%
Aortic regurgitation (mild)	2 (5%)
Aortic regurgitation (moderate+)	0

NYHA = New York Heart Association

COMPARISON BETWEEN PERCEVAL™ AND ENABLE™ BIOPROTHESES

The two groups revealed similar NYHA functional class at the latest follow-up. The postoperative mean and peak gradients across the aortic valve did not differ significantly between the two types of bioprotheses.

DISCUSSION

Due to the aging population in recent years, the incidence of aortic stenosis has increased, with patients often presenting with multiple co-morbidities. Conventional AVR may carry an unacceptable high perioperative risk for these patients, while TAVI still carries a significant incidence of paravalvular aortic insufficiency and atrioventricular block [10]. Sutureless bioprostheses, like the valves used in TAVI, have no sewing ring, which offers a larger effective orifice area for any given size. Advantages of the sutureless bioprosthesis include the absence of calcified native valve leaflets, ability to perform concomitant procedures and a minimally invasive approach, quicker implantation because the valve does not need to be sewn in, and reduced cardiopulmonary and aortic cross-clamp times. Our early experience demonstrates no mortality, a low prevalence of morbidity despite the increased risk of an elderly population, and excellent hemodynamic results. Our results are in accord with other published studies, which also report minimal morbidity and improved hemodynamic results [11,12].

Similar to conventional AVR, decalcification of the diseased valve is mandatory prior to sutureless bioprosthesis implantation. This precaution minimizes the risk of PVL, unlike the TAVI procedure where the calcified valve remains in situ. The

PARTNER trial showed a significantly higher incidence of PVL following TAVI than after surgical AVR at both 1 and 2 years [13]. PVL has been identified as an independent predictor of late mortality after TAVI [14]. D'Onofrio et al. [15] showed that the incidence of PVL (at least mild) was higher in a transapical TAVI group compared with a sutureless bioprothesis group (44.7% vs. 15.8%, respectively, $P = 0.001$), but there were no differences regarding the mean transprosthetic gradient. Unlike TAVI, it is technically possible to perform repositioning and to exchange the sutureless valve intraoperatively if the result is unsatisfactory. In our study, we had to remove the prosthesis in two cases after the implantation, due to the presence of moderate to severe PVL diagnosed by intraoperative TEE. The low PVL rate after sutureless AVR should be taken into account during the decision-making process for the optimal valve substitute.

Another advantage of the sutureless valve is its easy insertion in minimal access surgery. Minimally invasive AVR is a recognized and efficient surgical approach in experienced centers. Compared to the standard median sternotomy, minimal invasive AVR offers the following advantages: reduced blood loss and transfusion, lower reoperation risk due to bleeding, reduced pain, shorter ventilation time, shorter intensive care unit and hospital stay, more rapid return to functional activity, and improved cosmetic appearance [16,17]. We performed nine cases of AVR through right anterior mini-thoracotomy and one case through a J-incision with good clinical and hemodynamic results. The cross-clamp time in these patients was identical to that in the sternotomy group. Gilmanov et al. [18] observed that sutureless prostheses implanted through right anterior mini-thoracotomy reduced the times for both AVR and mechanically assisted ventilation, which could influence early- and mid-term survival.

Obese patients are more likely to need prolonged mechanically assisted ventilation, longer postoperative hospitalization, and an increased risk of sternal wound infection and atrial dysrhythmia [19]. Santana and collaborators [20] showed that minimally invasive surgery in obese patients reduced morbidity and mortality when compared with standard median sternotomy. Three of the nine patients who underwent minimal invasive surgery with excellent results were obese, with a body mass index > 30 kg/m^2.

Cardiopulmonary bypass and aortic cross-clamping duration influence patient outcomes. Both are independent predictors of 30 day postoperative mortality after adult cardiac surgery [21]. High risk patients, particularly those undergoing prolonged concomitant surgery, could benefit from reduced length of time of the implantation itself and the overall cross-clamp time by avoiding the need to use sutures to secure the bioprosthesis within the aortic annulus. We performed sutureless bioprosthesis implantation in three cases of redo and four cases of concomitant CABG with good clinical and hemodynamic results, with a reduction in cross-clamp cardiopulmonary bypass and operative times. Shrestha et al. [9] also confirmed the safety and efficacy of the sutureless aortic valve in patients requiring concomitant procedures.

Additional larger studies are needed to confirm the reported advantages of the sutureless bioprosthesis for open, concomitant, redo surgery or a minimally invasive approach. A learning curve is necessary for choosing the appropriate prosthesis size in order to reduce PVL, cross-clamp and bypass times.

Sutureless AVR could be an alternative for both conventional AVR and TAVI with a shorter ischemic time. It appears to be a safe and beneficial procedure for high risk patients especially for those undergoing combined or redo surgery in whom reduced bypass time could play a critical role in patient outcome. Sutureless bioprotheses facilitate minimal invasive procedures. The durability of the device is also an issue. Englberger and team [22] presented the longest follow-up study for a sutureless bioprosthesis (5 year follow-up) and suggested that sutureless valves become an option for all patients with indicated biological AVR.

The present study is limited by the fact that it is a single-center experience, comprising only 40 patients, whose selection might have included patient bias. Furthermore, since follow-up is limited to 2 years, a longer follow-up period would be needed to verify our findings.

Correspondence
Dr. D. Spiegelstein
Dept. of Cardiac Surgery, Sheba Medical Center, Tel Hashomer 52621, Israel
Phone: (972-3) 530-2710
Fax: (972-3) 530-2410
email: danny.spiegelstein@gmail.com

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