



ORIGINAL ARTICLE

First Egyptian experience of Transcatheter Aortic Valve Implantation: Immediate results and one year follow up



Ahmed A. Khashaba ^{a,*}, Walaa Adel ^a, Alaa Roshdi ^a, Ahmed Gafar ^b,
Sherif Essam ^c, Mohammad A.S. Algendy ^d

^a Cardiology Department, Ain Shams University, Cairo, Egypt

^b Cardiothoracic Surgery Department, Cairo University, Egypt

^c Vascular Surgery Department, Ain Shams University, Cairo, Egypt

^d Department of Anesthesia and Critical Care Medicine, Ain Shams University, Cairo, Egypt

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Abstract *Background:* Trans-catheter Aortic Valve Implantation (TAVI) offers a less invasive modality to manage aortic stenosis (AS) especially in high risk patients. It was not available in Egypt until the end of 2011.

Aim: The aim of this study is to report immediate and one year follow up results of first TAVI implantations in Egyptian patients.

Patients and methods: Ten patients with severe symptomatic AS underwent TAVI implantation using Edwards SAPIEN™ and SAPIEN XT™ valves.

Results: The mean age was 78.6 ± 4.6 years and 5 (50%) were males. The mean Logistic EuroSCORE and EuroSCORE II were $21.9 \pm 11.5\%$ and $12.6 \pm 7.2\%$, respectively. Procedural success was achieved in all (100%) patients using SAPIEN™ ($n = 8$) and SAPIEN XT™ ($n = 2$) valves. Almost all ($n = 9$) patients underwent a trans-femoral approach and percutaneous closure devices were used in the last 2 patients. Post procedural NYHA grade (1.3 ± 0.3), aortic valve area ($2.0 \pm 0.1 \text{ cm}^2$) and mean pressure gradient ($14.1 \pm 2.7 \text{ mmHg}$) were nearly maintained all over the one-year-follow-up period.

Conclusion: TAVI provides a safe and effective alternative to the surgical AVR in high risk patients with severe symptomatic AS. Financial issues, however, limits its application in developing countries.

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* Corresponding author. Address: 138 Gesr El-Suez Street, Heliopolis, Cairo 11351, Egypt. Tel.: +20 100 522 1233.

E-mail address: ahmed@khashaba.net (A.A. Khashaba).

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1. Introduction

Trans-catheter Aortic Valve Implantation (TAVI) is a great milestone in the rapidly evolving field of cardiovascular interventions especially as it targets aortic stenosis (AS), the commonest valve disease in adults.¹ Although surgical aortic valve replacement (AVR) had gained solid evidence and widespread use, one third of the patients are declined due to prohibitively high operative risk.² This proportion is expected to further increase with the aging population and improving medical care (Figs. 1 and 2).

These issues raised the need for a less invasive modality and led to the introduction of the first percutaneous aortic valve by Cribier et al. in 2002.³ By 2007, two devices, the Edwards SAPIEN™ (Edwards Lifesciences LLC, Irvine, CA, USA) and CoreValve ReValving® System (Medtronic LLC, Irvine, CA, USA) received the CE mark approval. This was followed by progressive technical support and scientific evidence.

It was not before the end of 2011 when the first device, Edward SAPIEN™, was approved in Egypt. Having the chance to be the first team to perform TAVI in Egypt, we here report our early data which represents the premier Egyptian experience.

2. Methods

2.1. The team

Our team consists of three cardiologists, a cardiothoracic surgeon, a vascular surgeon, an anesthesiologist and an echocardiographer. The cardiologists underwent training in a specialized training center in Neon, Switzerland. The first 5 cases were proctored; thereafter we were declared an approved center for independent Edwards SAPIEN™ prosthesis implantation.

2.2. Patients

Between December 2011 and February 2013, 40 patients with severe (aortic valve area $< 0.8 \text{ cm}^2$ and mean pressure gradient $> 40 \text{ mmHg}$) symptomatic AS were screened as candidates for TAVI. Contraindications included dominant aortic regurgitation, bicuspid aortic valve, unsuitable annular size or landing zone. EuroSCORE system^{4,5} guided the further selection of patients according to surgical risk; main determinants were age, gender, comorbidities and cardiac-related factors.

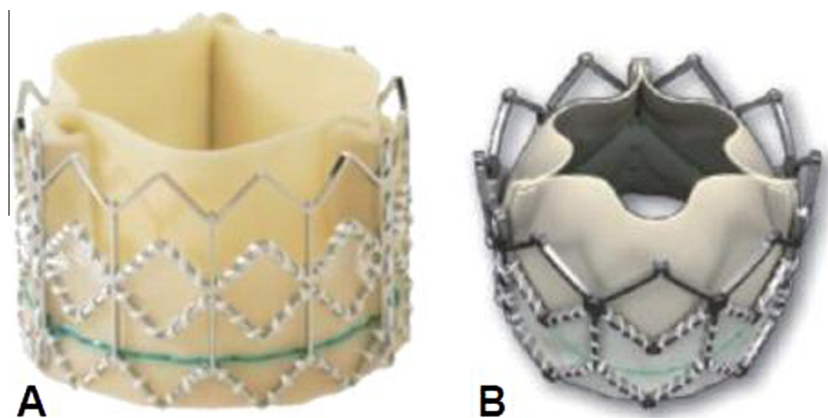


Figure 1 Edwards SAPIEN (A) and SAPIEN XT (B) valves.

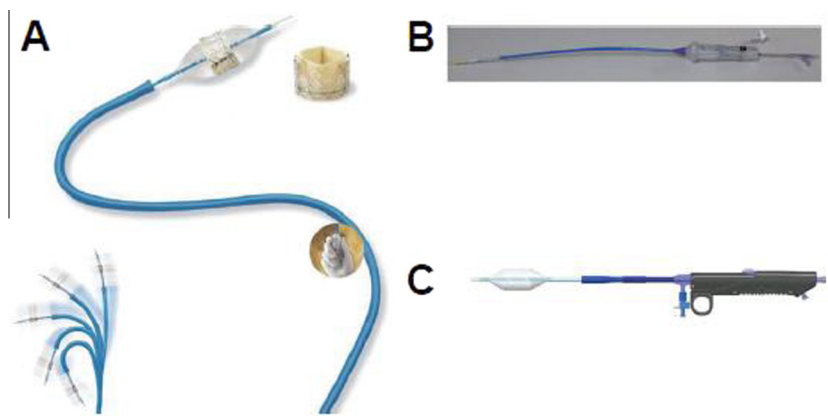


Figure 2 The RetroFlex-3 (A), NovaFlex (B) and Ascendra (C) delivery systems.

Patients underwent transthoracic and transesophageal echocardiography to assess disease severity, annular size and landing zone suitability. Coronary, aortic and ilio-femoral angiography and computed tomography were used to assess the respective arterial tree and choose the preferred route.

2.3. Devices

Patients received Edwards SAPIEN™ and SAPIEN XT™ valves. Both consist of a trileaflet bovine pericardial valve and a balloon-expandable, stainless-steel support frame. Two sizes are currently available: 23 and 26 mm expanded diameter. They were used for 18–22 mm and 21–25 mm annulus diameters, respectively. The prosthetic stent valve is mechanically crimped onto a balloon catheter immediately before implantation.

Edwards SAPIEN™ valve was implanted using the Retro-Flex-II™ delivery system for transfemoral procedures and the Ascendra™ transapical catheter for transapical procedures. Later cases utilized Edwards SAPIEN XT™ valve and the Novaflex™ (Edwards Lifesciences™, Irvine, California) delivery system.

2.4. The procedure

The procedures were performed in a catheterization laboratory under strict sterile conditions. Patients were premedicated with clopidogrel and aspirin, received prophylactic antibiotics immediately prior to and unfractionated heparin (100 IU/kg) during the procedure. All cases were done under general anesthesia to facilitate continuous TEE monitoring. Transfemoral approach was used unless precluded by extensive ilio-femoral calcification.

Surgical femoral arteriotomy (except in later cases) was done to facilitate the passage of the large caliber catheters (24 and 22 French for the 26 and 23 mm SAPIEN valve and 19 and 18 French for the 26 and 23 mm SAPIEN XT valve, respectively). An Amplatz extra-stiff guide wire was passed over the aortic valve. A 20–22 mm balloon was used to pre-dilate the aortic valve under rapid ventricular pacing. The valve was then positioned fluoroscopically and deployed with balloon inflation under rapid ventricular pacing. Immediate success was assessed with supra aortic contrast injection and TEE. The puncture site in the groin was closed surgically in early cases but later percutaneous closure was performed (Proglide, Abbott Vascular, Chicago, IL, USA).

The technique for the SAPIEN XT™ implantation is similar except that the valve is mounted on the delivery catheter, behind the balloon. Once exited from the insertion sheath into the abdominal aorta, the balloon is pulled back into the crimped valve and clicks into place. The mounted valve is then advanced further up the aorta.

For the transapical approach, a left mini-thoracotomy was made exposing the left ventricular apex. After puncture of the left ventricular apex, the rest of the procedure is largely the same as for the transfemoral approach, except that the valve is mounted in the opposite orientation on the balloon catheter.

After the procedure, the patients received clopidogrel for 6 months and aspirin indefinitely.

2.5. Study end-points

After the procedure, patients were assessed for complications, procedural success rate, 30-day mortality and New York Heart

Association functional status. As proposed by Valve Academic Research Consortium⁶, major complications included stroke, major vascular complications requiring acute intervention or blood transfusion, conduction abnormalities requiring permanent pacing and renal failure requiring dialysis.

An echocardiogram was performed prior to discharge, 1 month, 6 months and 1 year post procedure.

2.6. Statistical analysis

All demographic, clinical, and technical data were collected using the “Data Collection Form” and entered into a computerized database. Data obtained from all patients were statistically analyzed on a PC using commercially available statistical analysis software (Statistica® version 7.0).

Continuous variables were compared using analysis of variance (ANOVA) for repeated measures. The Fisher’s exact chi-square test with was used for comparison of categorical variables. A P-value < 0.05 was considered statistically significant. All data were expressed as mean ± standard deviation (mean ± SD) or number (%) as appropriate.

3. Results

3.1. Baseline characteristics

Ten patients who were included in this study completed the one-year follow-up. The mean age was 78.6 ± 4.6 years and 5 (50%) were males. The mean Logistic EuroSCORE and EuroSCORE II were $21.9 \pm 11.5\%$ and $12.6 \pm 7.2\%$, respectively (Table 1).

3.2. Procedural outcomes and complications

Procedural success was achieved in all (100%) patients. Almost all ($n = 9$) patients underwent a trans-femoral approach except the 3rd patient who showed extensive iliac calcification indicating trans-apical approach. The patients received SAPIEN™ ($n = 8$) and SAPIEN XT™ ($n = 2$) valves. Percutaneous closure devices (Proglide) were used in the last 2 patients. Deviations from the smooth classic procedure occurred in some patients (Table 2).

Patient 2 had a baseline conduction abnormality in the form of first degree heart block and left anterior hemiblock. After valve deployment he developed complete heart block necessitating permanent pacing.

Patient 5 showed difficulty in passing the valve into the aortic valve despite several attempts. It was not until we developed a new technique that valve passage was successful; the valve was advanced while simultaneously deflating the balloon “sliding-over-deflating-buddy-balloon technique”.

Patients 6 and 8 underwent concomitant coronary revascularization and patient 10 showed an interrupted inferior vena cava so the wire was passed through the hemiazygous vein.

3.3. Follow-up measurements

Echocardiographic assessment was done immediately, 24 h, 6 months and 12 months after implantation. Neither patients showed any change regarding valve area, mean pressure

Table 1 Baseline clinical characteristics.

Variable	
Age (years)	78.6 ± 4.6
Male gender	5 (50%)
Body mass index (kg/m ²)	29.4 ± 3.7
Past and current smokers	3 (30%)
Diabetes	7 (70%)
Hypertension	6 (60%)
Coronary artery disease	4 (40%)
Stroke/TIA	0 (0%)
Syncope	3 (30%)
Angina at rest	5 (50%)
Previous MI	3 (30%)
Previous PCI	4 (40%)
Previous CABG	3 (30%)
Previous Valvuloplasty	0 (0%)
Peripheral vascular disease	2 (20%)
Porcelain aorta	0 (0%)
Chronic lung disease	3 (30%)
Chronic kidney disease	3 (30%)
Pulmonary hypertension	4 (40%)
NYHA class	3.5 ± 0.5
Logistic EuroSCORE (%)	21.9 ± 11.5
EuroSCORE II (%)	12.6 ± 7.2

Values are presented as mean ± SD and number (percentage). TIA: Transient ischemic attacks, MI: Myocardial infarction, PCI: Percutaneous coronary intervention, CABG: coronary artery bypass graft, EuroSCORE: European System for Cardiac Operative Risk Evaluation, NYHA: New York Heart Association.

gradient nor paravalvular aortic regurgitation. However, at 6 months postprocedure, patient 7 developed severe chest infection followed by infective endocarditis of the prosthetic valve. She was admitted to our hospital and received extensive antibiotic therapy. Unfortunately she did not improve and died 1 month later (Table 3).

4. Discussion

This premier Egyptian experience with TAVI reproduces the results reported by other well-known centers.⁷⁻¹⁰ With good team training, proper patient selection and experienced proctor supervision we reached a 100% success rate with excellent procedural and clinical outcomes despite being in the start of our learning curve.

Results proved the safety of the procedure compared to surgical AVR in a population with logistic EuroSCORE predicted mortality of 21.9 ± 11.5%.¹¹ No procedure-related deaths occurred and the only fatality, patient 7, occurred 5 months later due to an acquired cause (infective endocarditis). Aside from the permanent pacemaker implantation in patient 2, no other major complications were encountered and all procedural difficulties were manageable. Hospital LOS was 8 days as a mean. Even the remarkably high LOS of patient 5, 24 days, was due to ascitic fluid oozing from the femoral incision site and not related to any vascular complications.

All patients experienced a significant early symptomatic improvement (NYHA 1.3 ± 0.3) which was maintained all over the 1 year follow up period together with the good echocardiographic results (AVA 2.0 ± 0.1 cm², MPG 14.1 ± 2.7 mmHg).

Table 2 Procedural parameters and outcomes.

Variable	
Successful valvuloplasty	10 (100%)
Successful valve implantation	10 (100%)
<i>Implanted valve type</i>	
SAPIEN™	8 (80%)
SAPIEN XT™	2 (20%)
<i>Implanted valve size</i>	
23 mm	4 (40%)
26 mm	6 (60%)
<i>Delivery system</i>	
RetroFlex-II™	7 (70%)
Novaflex™	2 (20%)
Ascendra™	1 (10%)
<i>Approach</i>	
Transapical	1 (10%)
Transfemoral	9 (90%)
Right femoral access	5 (50%)
Left femoral access	4 (40%)
Surgical closure	8 (80%)
Percutaneous puncture	2 (20%)
Aortic Regurgitation > grade 1	0 (0%)
Paravalvular leak > mild	0 (0%)
Valve embolization	0 (0%)
Valve-in-valve implantation	0 (0%)
Coronary obstruction	0 (0%)
Myocardial infarction	0 (0%)
Left ventricular perforation	0 (0%)
Permanent pacemaker	1 (10%)
Vascular complications in transfemoral approach	0 (0%)
TIA	1 (10%)
Procedure-related death	0 (0%)
NYHA grade	1.3 ± 0.3
LOS (days)	8 ± 6

Values are presented as mean ± SD and number (percentage). NYHA: New York Heart Association, LOS: Length of stay.

The PARTNER trial is the most important clinical trial of the SAPIEN valve. It was designed as a non-inferiority study where 699 high-risk patients with severe AS were randomly assigned to undergo either TAVI or surgical replacement. The rates of death from any cause were 3.4% in the transcatheter group and 6.5% in the surgical group at 30 days ($P = 0.07$) and 24.2% and 26.8%, respectively, at 1 year ($P = 0.44$). The rates of major stroke were 3.8% in the transcatheter group and 2.1% in the surgical group at 30 days ($P = 0.20$) and 5.1% and 2.4%, respectively, at 1 year ($P = 0.07$). At 30 days, major vascular complications were significantly more frequent with transcatheter replacement (11.0% vs. 3.2%, $P < 0.001$); adverse events that were more frequent after surgical replacement included major bleeding (9.3% vs. 19.5%, $P < 0.001$) and new-onset atrial fibrillation (8.6% vs. 16.0%, $P = 0.006$). More patients undergoing transcatheter replacement had an improvement in symptoms at 30 days, but by 1 year, there was no significant between-group difference. They concluded that, in high-risk patients with severe aortic stenosis, transcatheter and surgical procedures for aortic-valve replacement were associated with similar rates of survival at 1 year, although there were important differences in periprocedural risks.¹²

The PARTNER II Trial which is currently recruiting participants is targeting a new population, those with intermediate

Table 3 Survival, symptomatic and echocardiographic data.

	Baseline	Postprocedure	One-year follow-up
Survival	10	10 (100%)	9 (90%)
Symptoms (NYHA)	3.5 ± 0.5	1.3 ± 0.3	1.3 ± 0.3
<i>Echocardiography</i>			
AVA (cm ²)	0.8 ± 0.1	2.0 ± 0.1	2.0 ± 0.1
MPG (mmHg)	64.8 ± 17.8	14.1 ± 2.7	14.6 ± 2.5
Annulus (mm)	21.4 ± 1.9	NA	NA
EF (%)	40.7 ± 16.5	49.9 ± 11.4	50.9 ± 10.4
AR Grade	0.7 ± 0.6	0.3 ± 0.3	0.3 ± 0.3
MR Grade	1.0 ± 0.9	0.8 ± 0.6	0.8 ± 0.6

Values are presented as mean ± SD and number (percentage). AVA: aortic valve area, EF: left ventricular ejection fraction, MPG: mean aortic valve pressure gradient, MR/AR grade: grade of mitral/aortic valve insufficiency.

risk (Cohort A – operable) versus those who are not suitable for aortic valve surgery (Cohort B – inoperable). This trial is expected to broaden the indications of TAVI but it will not be completed until May 2018.¹³

Side to side with future expected broader indications; technological improvements will further increase the suitability and decrease complication rates of TAVI. New valve sizes will expand the suitable AV annulus sizes and smaller arterial sheaths will decrease vascular complications probably nullifying the need for the transapical approach. However, the limited financial resources available in a developing country like Egypt are still the main obstacle against widespread application.

5. Conclusion

TAVI provides a safe and effective alternative to the surgical AVR in high risk patients with severe symptomatic AS.¹⁴ With technological advances, indications are continuously expanding to cover an ever growing patient population. Financial issues, however, limits its application in developing countries.

Conflict of interest

No conflict of interest.

References

- Iung B, Baron G, Butchart EG, Delahaye F, Gohlke-Barwolf C, Levang OW, et al. A prospective survey of patients with valvular heart disease in europe: the euro heart survey on valvular heart disease. *European Heart Journal* 2003;**24**:1231–43.
- Iung B, Cachier A, Baron G, Messika-Zeitoun D, Delahaye F, Tornos P, et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? *European Heart Journal* 2005;**26**:2714–20.
- Cribier A, Eltchaninoff H, Bash A, Borenstein N, Tron C, Bauer F, et al. Percutaneous transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis: first human case description. *Circulation* 2002;**106**:3006–8.
- Nashef SA, Roques F, Michel P, Gauducheau E, Lemeshow S, Salamon R. European system for cardiac operative risk evaluation (euroscore). *European Journal of Cardio-Thoracic Surgery: Official Journal of the European Association for Cardio-Thoracic Surgery* 1999;**16**:9–13.
- Nashef SA, Roques F, Sharples LD, Nilsson J, Smith C, Goldstone AR, et al. Euroscore ii. *European Journal of Cardio-Thoracic Surgery: Official Journal of the European Association for Cardio-Thoracic Surgery* 2012;**41**:734–44, Discussion 744–735.
- Leon MB, Piazza N, Nikolsky E, Blackstone EH, Cutlip DE, Kappetein AP, et al. Standardized endpoint definitions for transcatheter aortic valve implantation clinical trials: a consensus report from the valve academic research consortium. *European Heart Journal* 2011;**32**:205–17.
- Leon MB, Smith CR, Mack M, Miller DC, Moses JW, Svensson LG, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *The New England Journal of Medicine* 2010;**363**:1597–607.
- Thomas M, Schymik G, Walther T, Himbert D, Lefevre T, Treede H, et al. Thirty-day results of the sapien aortic bioprosthesis european outcome (source) registry: a european registry of transcatheter aortic valve implantation using the edwards sapien valve. *Circulation* 2010;**122**:62–9.
- Kim WJ, Kim YH, Lee JY, Park DW, Kang SJ, Lee SW, et al. Transcatheter aortic valve implantation: early experience in korea. *Korean Circulation Journal* 2012;**42**:684–91.
- Spargias K, Manginas A, Pavlides G, Khoury M, Stavridis G, Rellia P, et al. Transcatheter aortic valve implantation: first greek experience.. *Hellenic Journal of Cardiology: Hjc = Hellenike Kardiologike Epitheorese* 2008;**49**:397–407.
- Cao C, Ang SC, Indraratna P, Manganas C, Bannon P, Black D, et al. Systematic review and meta-analysis of transcatheter aortic valve implantation versus surgical aortic valve replacement for severe aortic stenosis. *Annals of Cardiothoracic Surgery* 2013;**2**:10–23.
- Lefevre T, Kappetein AP, Wolner E, Nataf P, Thomas M, Schachinger V, et al. One year follow-up of the multi-centre european partner transcatheter heart valve study. *European Heart Journal* 2011;**32**:148–57.
- ClinicalTrials.gov identifier: NCT01314313.
- Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients. *The New England Journal of Medicine* 2011;**364**:2187–98.