Original Research

# The ATHENS TAVR Registry of Newer Generation Transfemoral Aortic Valves: 30-Day Outcomes

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Key words:
**Aortic stenosis, transcutaneous aortic valve implantation, transfemoral aortic valve implantation, CoreValve, Edwards SAPIEN.**

**Introduction:** Transcatheter aortic valve replacement (TAVR) is a documented treatment for patients with symptomatic aortic stenosis who are at very high or prohibitive operative risk. We sought to investigate the outcomes of transfemoral procedures with the newer generation valves in four TAVR centres in Athens, Greece.

**Methods:** The ATHENS TAVR Registry included all patients who underwent transfemoral implantation of the newer generation valves in 4 Athens TAVR centres (self-expanding valve 67 patients, balloon-expandable valve 59 patients). We present the procedural and echocardiographic data and the 30-day clinical outcomes according to valve type.

**Results:** A total of 126 patients underwent 126 procedures (67 CoreValve, Medtronic; 59 SAPIEN XT, Edwards Lifesciences). The mean age and logistic EuroSCORE were 80 ± 8 years and 25 ± 13%. The procedural and device success rates were 100% and 98%, respectively. The 30-day mortality was 1% (n=1), the major vascular event rates 9% (similar for both valve types), and a new permanent pacemaker was implanted more often during the same hospitalisation after CoreValve (33% vs. 9%, p=0.001). The mean effective aortic valve area increased and the mean transvalvular pressure gradient declined post implantation (from 0.66 ± 0.15 $cm^2$ to 1.61 ± 0.43 $cm^2$, p<0.001; from 51 ± 14 mm Hg to 10 ± 3 mm Hg, p<0.001). The mean grade of aortic insufficiency increased after CoreValve (from 1.2 ± 0.6 to 1.5 ± 0.7, p=0.03) but remained stable after SAPIEN XT (1.0 ± 0.8 and 1.0 ± 0.6, p=0.88) implantation.

**Conclusions:** TAVR outcomes with both the newer generation transfemoral valves in the ATHENS Registry were excellent. We observed a greater need for a new permanent pacemaker and a greater degree of aortic valve insufficiency after CoreValve implantation.

*Manuscript received:*
October 18, 2011;
*Accepted:*
March 5, 2012.

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Transcatheter aortic valve replacement (TAVR) has emerged as an alternative to surgical aortic valve replacement (SAVR) for patients with symptomatic severe aortic stenosis who are considered to be at very high or prohibitive operative risk.[1-6] The PARTNER randomised trials have demonstrated the superiority of TAVR over standard medical treatment (including balloon valvuloplasty) in patients considered inoperable due to prohibitive risk (Cohort B), and the non-inferiority of TAVR compared to SAVR in high-risk patients accepted for both treatment approaches.[1,2] Since their launch for clinical use in Europe, both available valves (CoreValve, Medtronic, and SAPIEN XT, Edwards Lifesciences) have undergone considerable technical enhancements aimed at improving clinical outcomes and making the devices more operator-friendly. The SA-

PIEN valve, for example, underwent numerous valve and delivery system improvements to reach the currently used SAPIEN XT with the Novaflex+ delivery system and the e-sheath (profile downsized from 22-24 F to 16-18 F). Likewise, the CoreValve, which had already downsized its profile to 18F earlier, has more recently launched its new precision delivery catheter, Accutrak. However, it will take some time to obtain results from prospective clinical trials investigating these latest generation devices. In the meantime, reports from the roll-out in the real-world environment of these newer generation devices are valuable. The objectives of this four-centre study were: 1) to evaluate the procedural, echocardiographic and 30-day clinical outcomes of patients undergoing transfemoral implantation of the newer generation valves in the "real world"; 2) to compare the procedural, echocardiographic and 30 day clinical outcomes of the non-randomised use of the two available valve types.

## Methods

All consecutive patients who underwent transfemoral TAVR performed by the authors using the newer generation valves between October 2009 and September 2011 in 4 centres in Athens, Greece, were included. The valves used were the CoreValve (requiring an 18 F sheath for both the 26 mm and 29 mm sizes, with or without the precision delivery catheter Accutrak) and the SAPIEN XT (requiring an 18 F sheath for the 23 mm and 19 F for the 26 mm size; and more recently the Novaflex+ delivery system requiring the 16 F e-sheath for the 23 mm and 18 F for the 26 mm size in 9 patients). Patients considered eligible for TAVR underwent a systematic workup protocol that included Doppler echocardiography, coronary angiography, aortoiliofemoral angiography, and quite often computed tomography. All potential candidates for TAVR were evaluated by a multidisciplinary team composed of interventional cardiologists and cardiac surgeons, who determined the eligibility of the patient for TAVR. In addition, all the patients' medical files were evaluated and approved by a government committee consisting of senior cardiologists and cardiac surgeons.

Patients' comorbidities were characterised according to the EuroSCORE and the STS risk score definitions.[7,8]

Porcelain aorta was defined as extensive circumferential calcification of the thoracic aorta, as assessed by computed tomography and/or fluoroscopy. Baseline and follow-up clinical and echocardiography data were prospectively gathered in each participating centre. All patients provided written informed consent to the procedures.

### *Procedures*

The procedures were performed in a catheterisation laboratory with operating-room–like sterile precautions. The personnel in the room in most instances consisted of 2-3 interventional cardiologists, 1 cardiac surgeon, 1 cardiac anaesthesiologist, 1 cardiologist echo specialist, 2 nurses and 1 valve technician.

All possible patient body entry sites were subjected to meticulous surgical scrubbing. Premedication with aspirin and clopidogrel was given, and antibiotics were administered intravenously before the procedure according to local hospital practices. Heparin 50 U/kg IV was administered, targeted at an activated coagulation time of approximately 250 s just before valve implantation. Monitored anaesthesia care or general anaesthesia was initiated according to local practices and the medical requirements of each patient. Access to the common femoral artery suitable for valve delivery, and to the contralateral femoral artery and vein was obtained. Preclosure with the Prostar XL system (Abbott Vascular, IL, USA) was performed in all procedures. Cardiac pacing was with a transvenous wire in the right ventricle. Rapid pacing capacity (usually 160-200 bpm) and the consequent haemodynamic effect (aiming at a constant aortic pressure <50 mmHg) were confirmed. Ascending aortography was performed and the view that aligned all three sinuses of Valsalva was used for optimal valve positioning. Following valve implantation the result was checked by angiography and echocardiography. Finally, the peripheral entry site was checked by angiography after the Prostar closure.

### *Endpoints*

For all clinical endpoints, the standardised definitions for transcatheter aortic valve implantation in the consensus report from the Valve Academic Research Consortium (VARC) were used.[9] The clinical endpoints examined were total mortality, major vascular and bleeding complications, any stroke and the need for a new pacemaker at 30 days.

### *Echocardiography*

Transthoracic and/or transoesophageal echocardiog-

raphy were performed prior to the procedure and transthoracic echocardiography was performed prior to hospital discharge and/or approximately 30 days after the procedure. The last complete echocardiographic examination (the 30-day examination in 89% and the examination prior to hospital discharge in 11% of patients) was considered for purposes of analysis. Transaortic flow was recorded with continuous wave Doppler using a multi-window approach, transaortic gradients were calculated using the simplified Bernoulli equation, and the effective aortic valve orifice was calculated by the continuity equation.[10] Semiquantitative analysis based on the characteristics of the regurgitant jet was used for assessment of valvular insufficiency and reported in grades 0 to 4.[10] Retrospective application of the lately introduced VARC criteria for aortic regurgitation was not feasible. All echocardiographic imaging and analyses were performed locally by the same echocardiography teams. The valve cover index was expressed as (prosthesis diameter - TEE annulus diameter) / prosthesis diameter × 100.[11]

### *Statistical analysis*

Data are reported as mean ± SD for continuous variables and percentages for nominal variables. Explorative statistical methods were used to compare the study groups according to the valve type implanted. Continuous variables were analysed using the 2-sample independent or paired *t*-test, as appropriate. All tests were 2-sided, and a significance level of 5% was used. Statistical analyses were performed using SPSS software (version 11.0.1, SPSS Inc, Chicago, Ill).

## Results

A total of 126 patients underwent 126 procedures (67 CoreValve, Medtronic, MN, USA; 59 SAPIEN XT, Edwards Lifesciences, CA, USA). Table 1 shows a breakdown of the procedures performed by participating site and according to the valve type. Two of the centres were using both valve types in a fairly balanced way, while the other two were exclusive users of only one valve type (one CoreValve and one SAPIEN XT). The mean age and logistic EuroSCORE were 80 ± 8 years and 25 ± 13%. The majority of the patients treated were women (59%). Table 2 il-

**Table 1.** The Athens TAVR Registry: patients and valve types per site.

| | All patients | CoreValve | SAPIEN XT |
|---|---|---|---|
| Hygeia Hospital | 50 | 14 | 36 |
| Hippokration Hospital | 38 | 38 | 0 |
| Onassis CTC | 27 | 15 | 12 |
| Attikon Hospital | 11 | 0 | 11 |
| Total | 126 | 67 | 59 |

**Table 2.** Clinical and procedural characteristics.

| | CoreValve n=67 | SAPIEN XT n=59 | p |
|---|---|---|---|
| Age years | 81 ± 7 | 79 ± 9 | 0.14 |
| Gender female, % | 51 | 68 | 0.07 |
| BMI, kg/m$^2$ | 26 ± 4 | 27 ± 4 | 0.06 |
| Logistic EuroSCORE | 26 ± 14 | 23 ± 12 | 0.18 |
| STS | 7.0 ± 5.2 | 9.1 ± 7.1 | 0.21 |
| STS m&m | 28.7 ± 13.4 | 33.7 ± 18.3 | 0.29 |
| NYHA class | 2.9 ± 0.5 | 3.1 ± 0.4 | 0.04 |
| LVEF | 53 ± 8 | 54 ± 11 | 0.75 |
| LOS (median), days | 5.4 ± 1.9 (5) | 7.3 ± 6.0 (5) | 0.02 |
| LOS ICU/CCU (median), days | 2.6 ± 1.5 (2) | 2.1 ± 2.1 (2) | 0.12 |
| AV annulus, mm | 22.5 ± 2.0 | 20.7 ± 1.8 | <0.001 |
| Anaesthesia MAC/GA, % | 40/60 | 88/12 | <0.001 |
| Fluoroscopy time, min | 21.31 ± 5.03 | 18.18 ± 6.43 | 0.10 |
| Valve diameter, mm | 27.4 ± 1.5 | 23.8 ± 1.4 | <0.001 |
| 23/26/29 mm | 0/37/30 | 42/17/0 | |
| Valve cover index | 18 ± 6 | 13 ± 4 | <0.001 |

BMI – body mass index; NYHA – New York Heart Association; LVEF – left ventricular ejection fraction; STS (m&m) – Society of Thoracic Surgeons (mortality and morbidity); LOS – length of stay; ICU/CCU – intensive/coronary care unit; AV – aortic valve; MAC/GA – monitored anaesthesia care/general anaesthesia.

lustrates the clinical and procedural characteristics of the patients according to the valve type received. Patients treated with the SAPIEN XT had a worse functional class at baseline and their hospital stay was on average 2 days longer. The latter was the result of 2 outliers with prolonged hospitalisations in the SAPIEN XT group (the median duration of the hospital stay was 5 days for both valve types).

General anaesthesia was used more often in the CoreValve procedures. The CoreValve patients had on average 2 mm larger annuli than the SAPIEN XT patients and the valve used was on average almost 4 mm larger in diameter. As a result the valve cover index was larger in the CoreValve patients.

Table 3 presents the echocardiographic data from before and after the procedure. The effective aortic valve area increased and the mean transvalvular pressure gradient declined post implantation in all patients (from 0.65 ± 0.15 $cm^2$ to 1.58 ± 0.41 $cm^2$, $p<0.001$; from 50 ± 14 mm Hg to 10 ± 3 mm Hg, $p<0.001$). There were no significant differences between the two valve-type groups at baseline and the only significant difference after implantation was more aortic insufficiency in the CoreValve group as compared to the SAPIEN XT group (42% vs. 17% had grade ≥2, $p=0.004$). The degree of aortic insufficiency increased after CoreValve (from grade 1.2 ± 0.6 to 1.5 ± 0.7, $p=0.03$) but remained stable after SAPIEN XT (from grade 1.0 ± 0.8 to 1.0 ± 0.6, $p=0.88$) implantation.

The procedural success rate was 100% and the device success rate was 98% (due to the need for a second valve in 2 patients). The 30-day mortality was 1% (1 patient who received a SAPIEN XT died at day 5 due to aspiration pneumonia). Table 4 presents the 30-day clinical outcomes. The major vascular event rate was 9% and the major bleeding event rate was 2%, with similar occurrences for both valve types. No stroke of any severity was observed. A new permanent pacemaker was implanted more often after CoreValve implantation (33% vs. 9%, $p=0.001$).

## Discussion

This multi-centre study of 126 patients with severe symptomatic aortic stenosis at very high or prohibitive surgical risk shows that TAVR using the newer generation transfemoral valves was associated with a 30-day mortality of 1%, a stroke rate of 0%, and a major vascular/bleeding event rate of 10%. These results compare favourably to other experiences from trials and registries. The operative risk of these patients was substantial and not inferior to that reported in other series; thus, the excellent outcomes in our registry cannot be attributed to a better patient substrate.[1-6] We suggest that, apart from meticulous pa-

**Table 3.** Pre- and post-TAVR echocardiographic parameters.

| | CoreValve n=67 | SAPIEN XT n=59 | p |
|---|---|---|---|
| Pre-TAVR: | | | |
| EAVO, $cm^2$ | 0.67 ± 0.16 | 0.65 ± 0.15 | 0.37 |
| Mean PG, mmHg | 51 ± 15 | 52 ± 14 | 0.78 |
| Max PG, mmHg | 87 ± 19 | 84 ± 22 | 0.44 |
| AVR grade | 1.2 ± 0.6 | 1.0 ± 0.8 | 0.13 |
| Grade ≥2, % | 22 | 22 | 1 |
| MVR grade | 1.2 ± 0.5 | 1.4 ± 0.9 | 0.21 |
| LVEF | 53 ± 8 | 54 ± 11 | 0.75 |
| PAP systolic, mmHg | 49 ± 17 | 51 ± 15 | 0.64 |
| Post-TAVR: | | | |
| EAVO, $cm^2$ | 1.57 ± 0.46 | 1.67 ± 0.38 | 0.36 |
| Mean PG, mmHg | 9 ± 3 | 11 ± 4 | 0.06 |
| Max PG, mmHg | 18 ± 6 | 20 ± 8 | 0.21 |
| AVR grade | 1.5 ± 0.7 | 1.0 ± 0.6 | <0.001 |
| Grade ≥2, % | 44 | 17 | 0.003 |
| MVR grade | 1.3 ± 0.5 | 1.3 ± 0.8 | 0.63 |
| LVEF | 55 ± 8 | 57 ± 10 | 0.42 |
| PAP systolic, mmHg | 40 ± 11 | 46 ± 13 | 0.23 |

EAVO – effective aortic valve orifice; PG – pressure gradient; A(M)VR – aortic (mitral) valve regurgitation; LVEF – left ventricular ejection fraction; PAP – pulmonary artery pressure.

**Table 4.** Thirty-day clinical outcomes.

| | Total n=126 | CoreValve n=67 | SAPIEN XT n=59 | p |
|---|---|---|---|---|
| Mortality, n(%) | 1 (1) | 1 (1) | 0 (0) | 1 |
| Procedure success, n(%) | 126 (100) | 67 (100) | 59 (100) | 1 |
| Device success, n(%) | 124 (98) | 66 (98) | 58 (98) | 1 |
| Major vascular events, n(%) | 11 (9) | 5 (8) | 6 (10) | 0.75 |
| Major bleeding events, n(%) | 2 (2) | 0 (0) | 2 (3) | 0.22 |
| Stroke (any), n(%) | 0 (0) | 0 (0) | 0 (0) | 1 |
| New pacemaker, n(%) | 27 (21) | 22 (33) | 5 (9) | 0.001 |

tient screening and selection, the newer generation devices used in all our patients offer the best explanation for these excellent outcomes.

The most notable improvement in the newer generation devices is the significant reduction of the system profile from well above 20 F to 16-19 F. This certainly made the accomplishment of vascular access easier and expanded the patient population suitable for transfemoral implantation. Indeed, one recent study demonstrated a threefold reduction in major vascular events when the newer generation SAPIEN XT valve with the Novaflex delivery system (18-19F) was used as compared with the older SAPIEN valve (22-24 F).[12]

The standardised endpoint definitions for transcatheter aortic valve implantation clinical trials were published in January 2011; therefore, attempting comparisons of clinical outcomes among previous reports is not possible without applying non-uniform criteria. In recent reports applying the VARC definitions, the major vascular event rates using older-generation transfemoral valves were double-digit figures and varied from 15.7% to 33.3%.[12-14] The major vascular event rate, according to VARC definitions, in our registry was 9%, while the only other registries that reported on the newer generation transfemoral valves quoted rates of 11.1% and 13%.[12,15] It is reasonable to expect lower vascular event rates with the use of lower profile devices, provided that they are used sensibly and not aggressively by pushing the limits in patients with borderline vascular access. In any case, attention to detail is always required and the value of meticulous vascular screening should be underscored.

The self-expanding and balloon-expandable valves were almost equally used and the baseline clinical characteristics of these patient groups were similar. In addition to comparable surgical risk, they had comparable aortic stenosis severity and similar left ventricular systolic function, degrees of aortic and mitral regurgitation, and pulmonary artery systolic pressures at baseline. Patients implanted with the self-expanding valve had on the average larger annuli and received larger valves, reflecting the coverage of the upper range annulus diameters by this valve. This inherent difference between the two valves also resulted in the use of larger-diameter valvuloplasty balloons and the attainment of a larger valve-cover index with the self-expanding valve. However, these did not translate into a larger effective valve orifice or reduced aortic valve insufficiency with the self-expanding valve post implantation. On the contrary, the average grade of aortic valve insufficiency post implantation was significantly larger with the self-expanding valve as compared to the balloon-expandable valve. In this respect, it is interesting to note that, while the degree of aortic insufficiency remained unchanged after implantation of the balloon-expandable valve, it increased significantly after the implantation of the self-expanding valve.

The degree of post-implantation aortic regurgitation is predictive of in-hospital, 30-day and 1-year mortality,[16,17] and in a recent meta-analysis deaths at 30 days related to severe aortic regurgitation occurred only after implantation of the self-expanding valve.[18] Similarly to our findings, the recently presented German Registry reported a significantly higher occurrence of high grade aortic regurgitation in patients implanted with the self-expanding as compared to the balloon-expandable valve (grade ≥2 in 17% vs. 8%).[17] Our patients appeared to have more aortic regurgitation from the outset (20% had grade ≥2) and, while this proportion remained essentially unchanged after implantation of the balloon-expandable valve, it doubled after implantation of the self-expanding valve.

The use of the two valve types in our registry was not randomised, and moreover two of the four partici-

pating centres were using only one of the two available transcatheter valves (single valve programs). Therefore any comparison of the echocardiographic data and the procedural and clinical outcomes according to the type of valve implanted in our registry can only be descriptive and should not be interpreted otherwise.

Although this study has all the shortcomings of a registry, its value lies in the large number of patients recruited from a country with no previous sizeable registry reports on TAVR outcomes. The adverse clinical events were not centrally adjudicated; however the application of the standardised VARC definitions should result in trustworthy self-reporting. Similarly, the echocardiographic assessments were not done by a core laboratory but locally and the standardised definitions for the prosthetic valve performance were not used. However, the facts that all the examinations were done by the same investigators and that paired examinations of each patient were evaluated adds value to our findings.

Despite favourable surgical outcomes in many elderly patients, the 30-day mortality rate in the top 10% risk range patients undergoing SAVR is 18.8%, which is almost 5% higher than the expected rate based on the Society for Thoracic Surgery (STS) risk-scoring system.[19,20] These high-risk patients often have significant comorbidities that limit their chance for survival, such as obstructive pulmonary disease, renal insufficiency, liver disease, reduced left ventricular function, previous coronary artery bypass surgery or chest wall radiation. Apart from these high-risk patients who do receive SAVR with a high predicted mortality risk, it is estimated that for approximately every 2 patients undergoing SAVR there is an additional patient who is judged to have prohibitive surgical risk by primary care physicians or general cardiologists and is not even offered SAVR.[21]

A number of risk scores have been used to predict the risk of patients considered for SAVR. In assessing the surgical risk of high risk patients, the logistic EuroSCORE tends to overestimate the surgical risk (by up to a factor of 3),[22] and the STS risk score tends to slightly underestimate the procedural risk.[19] In addition, these conventional risk scores do not take into account a number of contraindications to conventional SAVR, including porcelain aortas and extreme frailty, as judged by the consulting surgeon.

To date, the first and only available randomised data on TAVR comes from the PARTNER trials, in which the first-generation SAPIEN valve (profile 22-24 F) was tested. In the PARTNER B trial, 358 inoperable patients with severe, symptomatic aortic stenosis were randomised to transfemoral TAVR or standard medical therapy.[2] The superiority of TAVR was indisputably proved, since the primary endpoint of death at 1 year was reduced by 45% and the number needed to treat was just 5 patients. In the PARTNER A trial, 699 patients with severe, symptomatic stenosis at a high but not prohibitive surgical risk (logistic EuroSCORE>15%) were randomised to TAVR (stratified to transfemoral or transapical according to suitability) or SAVR.[1] The non-inferiority of TAVR as compared to SAVR was proved in this population. In particular, the 1-year mortality in the transfemorally treated patients was 4.2% lower than in their surgically treated counterparts. Since these results were announced, it has been accepted that TAVR should be the standard of care for inoperable patients, and an acceptable (non-inferior) alternative to SAVR in selected high-risk operable patients.

The ability to perform TAVR has transformed the treatment paradigm in symptomatic patients with severe aortic stenosis, particularly in those who are inoperable or at high risk for SAVR. Future technical developments will include further reducing the device profile, enhancing device positioning and retrievability, and promoting valve durability with anti-calcification treatments. When coupled with evidence from sound ongoing and future clinical trials, it is likely that TAVR usage will be consolidated further in inoperable patients and its value as an alternative to SAVR may expand to include more selected high risk patients.

In conclusion, the ATHENS TAVR registry demonstrated excellent 30-day clinical outcomes and an impressively low mortality of 1% with the use of the newer generation transfemoral valves. Our clinical outcomes compare favourably to those reported in other series and clinical trials, all of which used the older generation, larger profile transfemoral systems. The observational comparison of the two available valves in our registry showed similar clinical outcomes and differences that mostly reflect the CoreValve's suitability for larger aortic valve annuli and its greater impact on the conduction system. Our finding of increased aortic valve regurgitation following the self-expanding valve implantation merits further investigation within a randomised trial.

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