

## **Incidence of conduction defects in Trans-catheter Aortic Valve Implantation versus Surgical Aortic Valve Replacement in elderly patients**

**Ayman Ahmed Kamal Abou-Elmagd<sup>1</sup>, Mohamed Saad El-gammal<sup>1</sup>, Mohamed Osama Taha<sup>2</sup>, Wael Mohamed Ibrahim Qenawi<sup>2</sup>**

<sup>1</sup>Division of Cardiology, Al Hussien University Hospital, Cairo, Egypt

<sup>2</sup>Division of Cardiology, National Heart Institute, Cairo, Egypt

All authors contributed equally, **corresponding** to: Wael Mohamed Ibrahim Qenawi,

Email: [Waelqenawi@yahoo.com](mailto:Waelqenawi@yahoo.com); Telephone: 0020111332653

### **Abstract**

**Background:** Conduction abnormalities may complicate transcatheter aortic valve implantation (TAVI) and surgical aortic valve replacement (SAVR).

**Objectives:** Aims to determine the incidence of conduction disorders in SAVR versus TAVI with Edwards-Sapien and Core Valve devices.

**Methods and Results:** Among 60 patients undergoing TAVI and 60 patients undergoing SAVR an electrocardiogram (ECG) was recorded after the procedure, during TAVI, 7 days Holter monitoring and ECGs and 24 hr Holter monitoring one month after after TAVI and SAVR were analyzed.

At baseline, TAVI patients had higher EUROSCORE2 and higher diabetes rates compared to SAVR patients. Atrial fibrillation was high in the SAVR (20%) compared to (6.7%) in the TAVI group ( $p= 0.031$ ) and the post-procedure incidence of LBBB was higher in TAVI group (11.7%) vs (1.6%) in the SAVR group ( $p=0.028$ ) also the CHB was higher in TAVI group (16.7%) vs (3.3%) in the SAVR group ( $p=0.015$ ). One month after the procedure the incidence of both LBBB and CHB decreased in TAVI group so, difference compared to SAVR was insignificant.

**Conclusions:** TAVI is frequently followed by the development of new conduction defects mainly the third-degree atrioventricular block demanding for permanent pacemaker implantation and left bundle branch block in comparison to SAVR.

**Keywords:** transcatheter aortic valve implantation, complications, conduction disturbances, permanent pacemaker implantation

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## Introduction

In patients with severe, symptomatic aortic valve stenosis who are not candidates for surgical aortic valve replacement (SAVR), transcatheter aortic valve implantation (TAVI) reduces mortality and morbidity compared to conservative treatment. (1) In appropriately selected high-risk patients procedural success of TAVI is high and mortality low.(2,3) Due to the proximity of the infra-nodal conduction system to the aortic valvular apparatus, patients with aortic stenosis frequently present with atrioventricular (AV) conduction abnormalities (AVCA). In addition, the procedure itself may lead to temporary or permanent injury resulting in AVCA with the need of prolonged monitoring and/or a high rate of permanent pace- maker (PPM) implantation after TAVI. (4) Rates of AVCA reported after SAVR are lower, and a PPM is implanted in only 3–4% of patients undergoing SAVR. (5)

## Methods

### Study Population

Sixty consecutive patients undergoing TAVI and 60 patients undergoing SAVR from December 2014 to February 2017 at our institution were included in the study. Patients with old conduction defects and those with prior PPM implantation were excluded. The study was approved by the institutional committee on human research. All subjects gave

written, informed consent.

The technical and anatomical feasibility of TAVI was assessed by right and left heart catheterization, computed tomography and transthoracic or transesophageal echocardiography. For clinical risk assessment the linear and logistic EuroSCORE II. (6) An interdisciplinary team of cardiac surgeons and interventional cardiologists reviewed all cases and formed a consensus on treatment selection (TAVI vs SAVR).

### **Transcatheter Aortic Valve Implantation (TAVI)**

To be considered for TAVI patients should be fulfilled to be severely, symptomatic aortic valve stenosis with an echocardiographic and the mean gradient  $>40$  mmHg or a calculated aortic valve area  $<1$  cm<sup>2</sup>. Both The CoreValve (Medtronic Inc; Minneapolis, MN), CoreValve Evolut R, (Medtronic, Minneapolis, MN) and Edwards SAPIEN, SAPIEN XT (Edwards Lifesciences, Irvine, CA) were used for patients undergoing TAVI.

According to anatomical characteristics, the transfemoral or transapical approach was chosen after interdisciplinary discussion. Transfemoral TAVI was performed. Following peripheral vascular access, the stenotic valve was crossed using a straight wire advanced through an Amplatz left catheter. A stiff 0.035 inch wire was then placed into the left ventricular cavity and a large introducer sheath (18 French for Medtronic or 22/24 French for the Edwards-Sapien) was carefully placed into the femoral artery. The optimal projection for valve implantation was chosen by identifying an angiographic plane with perpendicular orientation of the base of all 3 aortic valve sinuses. Balloon dilatation of the native aortic valve was performed under rapid right ventricular pacing (180–200/min) using a temporary pacemaker. After successful dilatation of the native valve, a Medtronic or Edwards-Sapien was introduced and deployed under fluoroscopy. The result was controlled by aortography and hemodynamic measurements using simultaneous recordings of the left ventricular and aortic pressure curves. The temporary pacemaker was left in place for at least 48 hours in every patient.

### **Surgical Aortic Valve Replacement (SAVR)**

The aortic valve was replaced in a standard fashion via a median sternotomy. After

administration of intravenous heparin, cardiopulmonary bypass was established with arterial cannulation of the ascending aorta and venous cannulation of the right atrium. A left ventricular vent was placed via the superior right pulmonary vein. All patients were operated at mild hypothermia (32 °C). After cross clamping of the aorta, cardiac arrest was achieved by instillation of cardioplegic solution into the aortic root. An aortotomy was performed and the diseased valve excised with debridement of the annulus. The left ventricle and the aortic root were thoroughly rinsed and cleaned from debris. According to the measurement, a valve prosthesis was implanted supra-annularly with 2-0 Ticron pledged supported stitches (Ticron, Covidien, Mansfield, MA, USA). Under continuous deairing via the aortic root vent and the left ventricular vent, the cross clamp was removed and the heart reperfused. After weaning from bypass, protamin was given. Temporary pacing wires were attached to the right atrium and ventricle and pericardial chest tubes placed. The sternum was closed with wires and the tissue sutured in a layer-wise fashion.

❖ *ECG and seven-day continuous ECG recording analysis after the procedure*

Twelve-lead ECGs were systematically analyzed before, the first and 7 days after the intervention, or before discharge (whichever came first) in all patients. In case of TAVI, 3-lead ECGs immediately before TAVI, after the last predilatation, after valve implantation, and after the last dilatation were also analyzed. All ECGs were evaluated with assessment of heart rhythm, PR interval, QRS width, and AV conduction. Left or right bundle branch block (LBBB and RBBB) were defined using standard criteria. (7)

Second degree AV block included type I and II second degree AV block, second degree AV block with 2:1 AV conduction, and advanced second degree AV block. Complete AV block was defined as absence of AV conduction.

❖ *One month ECG and 24hr continuous ECG recording analysis*

The following analyses were performed:

(1) At intervals of 6 hours, PR interval and QRS width were measured (mean of 3 measurements at each time point). Measurements were censored in case of unsuitable

signals, paced rhythm, or atrial fibrillation (AF; for PR interval).

(2) Screening for second degree or complete AV block.

(3) Screening for episodes of AF, atrial tachycardia and atrial flutter with a minimum duration of 30 seconds.

### Statistical Analysis

Categorical variables are expressed as numbers and percentages, continuous variables as mean and 1 standard deviation or median and interquartile range (IQR). Categorical variables were compared with the chi-square test or Fisher exact test, continuous variables with the unpaired *t*-test or Mann–Whitney test, as appropriate. A P value of <0.05 was considered statistically significant. Analyses were performed using SPSS 17.0 (SPSS Inc., Chicago, IL, USA).

### Results

The clinical, echocardiographic, and preprocedural data of 120 elderly patients with severe aortic stenosis without previous conduction defects on baseline are listed in Table 1.

There were no relevant differences between the SAVR and the TAVI cohorts, except for a higher percentage of diabetics (63.3% vs 33.3%  $p$  0.00086) and a higher EuroSCORE 2 ( $9.68 \pm 1.66$  vs  $4.41 \pm 0.77$   $p$  <0.00001) in the TAVI group.

A total of 60 patients (50%) underwent the SAVR with different mechanical prosthesis sizes ranged from 19-29 mm. On the other hand 60 patients (50%) underwent TAVI with COREVALVE, EVOLUT R, SAPIEN, and SAPIEN XT bioprosthesis sized from 23-31 mm.

Table 1. Comparison of the demographic data between SAVR and TAVI

Characteristic	SAVR (n 60)	TAVI (n 60)	p Value
Age (years)	75.1± 3.8	75.5± 4.0	0.68
Male	(38) 63.3%	(33) 55.0%	0.436
BMI	25.59± 1.2	25.39 ±1.38	0.513
Smoker	(18) 30.0%	(9) 15.0%	0.085
DM	(20) 33.3%	(38) 63.3%	0.00086
HTN	36 (60%)	(34) 56.7%	0.71
NYHA class I	(20) 33.3%	(13) 21.7%	0.158
NYHA class II	(20) 33.3%	(20) 33.3%	1
NYHA class III	(8 )13.3%	(10) 16.7%	0.612
NYHA class IV	(12) 20%	(17) 28.3%	0.29
Previous stroke	(4) 6.7%	(2) 3.3%	0.468
porcelain aorta	0 (0%)	0 (0%)	§
COPD	(6) 10.0%	(7) 11.7%	0.77
PVD	(6) 10.0%	(6) 10.0%	1
Previous MI	(8) 13.3%	(6) 10.0%	0.57
Previous PCI	(4) 6.7%	(6) 10.0%	0.512
CKD	(28) 46.7%	(25) 41.6%	0.585
Creatinine (umol/L)	95.3±34.9	93.8± 27.7	0.827
EuroSCORE 2	4.41±0.77	9.68±1.66	<0.00001
mild AR	(34) 56.7%	(31) 51.7%	0.467
mild MR	(32) 53.3%	(28) 46.7%	0.47
AV mean PG (mmHg)	52.8±14.8	51.96±16.2	0.807
AV max PG (mmHg)	88.87±18.7	84.4±26.9	0.422
Aortic Anulus (mm)	22±1.5	21.35±1.2	0.022
AV area (mm)	0.63±0.13	0.7±0.18	0.089
PASP (mmHg)	47.9±18.7	43.4±20.2	0.306
LVEF %	61.7± 5.2	64.0± 7.5	0.124
BMI; body mass index.HTN;hypertension.DM;diabetes mellitus. CKD;chronic kidney disease. PVD; peripheral vascular disease. §;means not calculated, AR;aortic regurge.MR ;mitral regurge.AV;aortic valve.PASP;pulmonary artery systolic pressure.LVEF;left ventricularly ejection fraction Plus-minus values are means ±SD. p < 0.05 statistical significant			

Table 2. Procedural Characteristics

Characteristic	Total (120)	SAVR (60)	TAVI(60)
<b>Approach</b>			
surgical	(60) 50%	(60) 100%	(0) 0%
Percutaneous transfemoral	(60) 50%	(0) 0%	(60) 100%
prosthesis size (mm)		19 mm (0) 0%	23 mm (20) 33.3%
		21 mm (12) 20%	26 mm (20) 33.3%
		23 mm (17) 28.3%	29 mm(20) 33.3%
		25 mm(17) 28.3%	31 mm (0) 0%
		27 mm (14) 23.3%	
		29 mm (0) 0%	
<b>Prosthesis type</b>			
Mechanical	(60) 50%	(60) 100%	–
COREVALVE	(21) 17.5%	–	(21) 35%
EDWARD-SAPIEN	(9) 7.5%	–	(9) 15%
EVOLUT R	(9) 7.5%	–	(9) 15%
SAPIEN XT	(21)17.5%	–	(21) 35%

The echocardiographic data obtained from postinterventional period revealed no relevant differences between the SAVR and the TAVI cohorts, except for a larger AVA and lower PASP in mmHg ( $2.0 \pm 0.15$  vs  $1.9 \pm 0.4$   $p=0.017$ ) and ( $25.4 \pm 13.7$  vs  $33.4 \pm 15.3$   $p=0.017$ ) respectively (table 2).

Table 3. Procedural echocardiographic data

Characteristic	SAVR (n 60)	TAVI (n 60)	p Value
mild AR	(10)16.6%	(14) 23.3%	0.365
mild MR	(7) 11.7%	(10) 16.7%	0.44
AV mean PG (mmHg)	$14.3 \pm 8.7$	$16.3 \pm 6.4$	0.237
AV max PG (mmHg)	$25.9 \pm 13.4$	$29.5 \pm 10.6$	0.167
Aortic Anulus (mm)	$22.0 \pm 2.1$	$22.0 \pm 1.85$	0.994
AV area (mm)	$2.0 \pm 0.15$	$1.9 \pm 0.4$	0.017
PASP (mmHg)	$25.4 \pm 13.7$	$33.4 \pm 15.3$	0.017
LVEF %	$63.0 \pm 4.5$	$65.4 \pm 7.0$	0.095

AR;aortic regurge.MR ;mitral regurge.AV;aortic valve.PASP;pulmonary artery systolic pressure.LVEF;left ventricularly ejection fraction Plus–minus values are means  $\pm$ SD.  $p < 0.05$  statistical significant

The incidence of atrial fibrillation was high in the SAVR (20. %) compared to (6.7%) in the TAVI group ( $p= 0.031$ ). Other in hospital outcomes as renal dysfunction, Life threatening bleeding, Stroke, Cardiogenic shock, major vascular complications and mortality are comparable between the two groups. Table 4 lists the in hospital clinical outcomes of the SAVR and TAVI cohorts.

**Table 4. In hospital complications**

Characteristic	SAVR (n 60)	TAVI (n 60)	p Value
Renal complication	(15) 25%	(10) 16.7%	0.26
MI	(1) 1.7%	(1) 1.7%	1
Life threatening bleeding	(10) 16.7%	(5) 8.3%	0.17
Stroke	(2) 3.3%	(1) 1.7%	0.65
AF	(12) 20.0%	(4) 6.7%	0.031
Cardiogenic shock	(4) 6.7%	(1) 1.7%	0.173
Major vascular complications	(1) 1.7%	(5) 8.3%	0.095
Mortality	(2) 3.3%	(1) 1.7%	0.562
MI;myocardial infarction.AF;atrial fibrillation. $p < 0.05$ statistical significant.§;means not calculated			

As regard the post-procedure conduction disturbances, the total incidence represents 18.3% in SAVR and 48.3% in TAVI group ,there is significant increase in TAVI group in comparison to SAVR group ( $p$  valve = 0.0004)

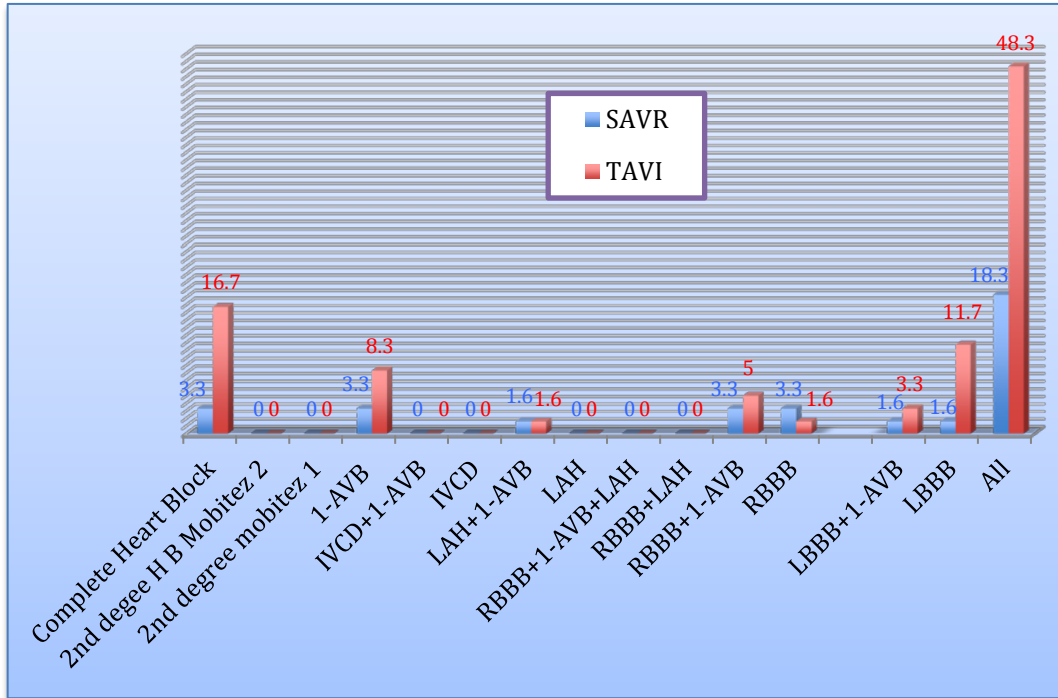
The incidence of LBBB was higher in TAVI group (11.7%) vs (1.6%) in the SAVR group and this higher incidence was a statistical significant factor ( $p=0.028$ )

The incidence of complete heart block was higher in TAVI group (16.7%) vs (3.3%) in the SAVR group and this higher incidence was a statistical significant factor ( $p=0.015$ ) as shown in figure (1)

Other conduction disorders such as ; LBBB+1-AVB , RBBB, RBBB+1-AVB , LAH+1-AVB and 1-AVB occured in incidence of (3.3% vs 1.6%, 3.3% vs 5%,1.6% vs 1.6% and 3.3% vs 8.3%) in SAVR group vs TAVI group respectively and theses incidences were



not a statistical significant factor between the two groups. Some conduction disorders did not occur in any group such as; RBBB+LAH, RBBB+1-AVB+LAH, LAH, LAH, IVCD, IVCD+1-AVB, 2nd degree mobitez 1 and 2nd degree mobitez 2.



**Figure (1) Post-procedure incidence of conduction disturbances.**

As regard the incidence of conduction disturbances after one month of the initial procedure, the total incidence represents 17.2% in SAVR and 35.8% in TAVI group, there is significant increase in TAVI group in comparison to SAVR group (p value = 0.0258).

The incidence of LBBB was higher in TAVI group (9.4%) vs (1.7%) in the SAVR group. Due to resolution of 2 cases in TAVI group from those observed after the procedure, this incidence was not a statistical significant factor. The incidence of complete heart block was higher in TAVI group (1.9%) vs (0%) in the SAVR group and this incidence was not a statistical significant factor (p=0.297) as shown in figure (2).



Figure (2) one month incidence of conduction disturbances.

Other conduction disorders such as ; LBBB+1-AVB , RBBB, RBBB+1-AVB , LAH+1-AVB and 1-AVB occurred in incidence of (3.4% vs 1.9%, 3.4%vs 5.6%,1.7% vs 1.9% and 5.2% vs 13.2%) in SAVR group vs TAVI group respectively and these incidences were not a statistical significant factor between the two groups.

Some conduction disorders did not occur in any group such as; RBBB+LAH, RBBB+1-AVB+LAH, LAH, IVCD, IVCD+1-AVB, 2nd degree mobitez 1and 2nd degree mobitez 2

**Discussion**

The main findings of this study are as follows: (A) The incidence of postprocedural new-onset LBBB was 6.7% and LBBB was significantly more frequent after TAVI than SAVR (11.7% vs 1.6%), which decreased after one month to 5.4% and LBBB after one

month was more frequent after TAVI than SAVR (9.4% vs 1.7%) but this frequency was insignificant due to resolution in 2 TAVI patients.

**(B)** The incidence of post-procedural new-onset CHB was 10% and CHB was significantly more frequent after TAVI than SAVR (16.7% vs 3.3%), which decreased after one month to 1% and CHB after one month was more frequent after TAVI than SAVR (1.9% vs 0%) but this frequency was insignificant after one month from the initial procedure due to exclusion of cases with CBH resolution and PPI (2 in SAVR and 9 in TAVI). The high rate of conduction abnormalities post-TAVR remains a concern and probably represents one of the main limitations of this treatment compared with cardiac surgery.

The real clinical effect of conduction abnormalities and the need for permanent pacemaker (PPM) implantation following TAVR remain controversial. Although limited data suggest a potential effect on mortality, studies assessing the outcomes of conduction abnormalities after TAVR have yielded conflicting results (12). Unfortunately, to date, no specific features have been incorporated into transcatheter heart valve (THV) systems to reduce the risk for these complications. On the contrary, an increased rate of conduction abnormalities has been reported associated with the use of most newer THVs, suggesting that the clinical relevance of these complications may increase in the near future (12).

The prevalence of AF in TAVI patients has been reported to be 10–41% and its incidence after TAVI 5–10%, corresponding well with our findings (8-10).

It is very likely that the prevalence of AF would be even higher if screening for AF before TAVI would have been performed. On the contrary, we found a higher incidence of AF after SAVR as reported in another study comparing AF incidence after TAVI and SAVR.(10) Depending on the methods and AF definition used, a similar rate has been reported after cardiac surgery in general (11).

In this study, we found similar rates of new LBBB after TAVI as described in the literature. Rates of complete AV-block remained high after TAVI and low after SAVR. Our data add further evidence that a significant amount of new AVCA may resolve

within one month after the procedure, indicating a transient interference with the infra-Hisian conduction system.

In a recent study, Mauri et al. (13) looked carefully at the technical and anatomic predictors of PPM implantation in patients receiving the SAPIEN 3 THV (Edwards Lifesciences, Irvine, California). A total of 33 of 229 patients with no previous pacemakers (14.4%) received PPMs following the TAVR procedure. In addition to the presence of pre-existing right bundle branch block (RBBB), important calcification of the left ventricular outflow tract at the level of the left and right coronary leaflets and a deep implantation of the valve, defined as >25.5% of the stent frame below the aortic annulus at the level of the posterior leaflet on angiography (odds ratio: 15.7;  $p < 0.001$ ), were independent predictors of PPM implantation. Importantly, patients with none of these risk factors had a rate of PPM placement of 1.1%, and reducing the depth of valve implantation by 3 mm resulted in a decrease of 52% in the need for PPM, without increasing the incidence of paravalvular leaks. Although other technical changes may have influenced such results, this study suggests that the increased rate of PPM implantation with the SAPIEN 3 THV appears to be driven mainly by technical rather than device-related factors and that significant reductions in the rate of PPM implantation can be obtained by modifying the implantation technique. The confirmation of these results in larger multicenter studies will represent a major step forward in reducing the rates of PPM associated with this new THV. However, the potential risks (i.e., valve embolization) of a high (more aortic) valve implantation strategy should not be underestimated.

In Roten et al. the rate of PPM implantation after TAVI was 20% compared to only 4% after SAVR. Only 4% of TAVI patients received a PPM due to complete AV block and 16% due to new LBBB in combination with AF or first degree AV block, representing a prophylactic indication. (14) In the surgical literature, rates of PPM implantation of 3–4% are reported and are comparable with our findings. In octogenarians undergoing SAVR, rates of PPM implantation up to 11% have been published (15).

A recent meta-analysis including more than 7,000 patients (16) and the majority of previous studies of TAVR did not find a negative effect of PPM implantation after TAVR or cardiac surgery in all-cause mortality (17–20). Moreover, longer periods of follow-up (definitely longer than 1 year) have been necessary to detect the detrimental effect of long-term pacing in patients with heart failure (21).

### **Study limitations**

(1) The present study was not a randomized controlled trial, and a selection bias may have existed. (2) Small sample size, which reduces the statistical validity of some of the differences between the groups. (3) Long follow-up durations are needed to capture enough events to reveal more meaningful patterns in the data. (4) The economic burden of TAVI is an important limitation and a major obstacle. (5) Older age of the patients made the follow up more difficult. (6) The relative lack of flexibility in providing TAVI data by hospitals. (7) Population under this study (elderly with severe aortic stenosis and no conduction disturbance at baseline) is a relatively hard to find.

### **Conclusion**

Transcatheter aortic valve implantation is frequently followed by the development of new conduction defects mainly the third-degree atrioventricular block (AV block) demanding for permanent pacemaker implantation and left bundle branch block in comparison to surgical aortic valve replacement.

### **Conflict of interests**

No financial or nonfinancial conflicts of interests related to the subject matter or materials discussed in the manuscript.

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