JACC: CARDIOVASCULAR INTERVENTIONS VOL. 5, NO. 5, 2012

ISSN 1936-8798/$36.00

PUBLISHED BY ELSEVIER INC.

DOI: 10.1016/j.jcin.2012.03.005

Multicenter Evaluation of Edwards SAPIEN Positioning During Transcatheter Aortic Valve Implantation With Correlates for Device Movement During Final Deployment

Danny Dvir, MD,* Ifat Lavi, PhD,* Hélène Eltchaninoff, MD,† Dominique Himbert, MD,‡ Yaron Almagor, MD,§ Fleur Descoutures, MD,‡ Alec Vahanian, MD,‡ Christophe Tron, MD,† Alain Cribier, MD,† Ran Kornowski, MD*

Tel Aviv and Jerusalem, Israel; and Rouen and Paris, France

Objectives This study sought to evaluate the exact location of Edwards SAPIEN (Edwards Lifesciences, Irvine, California) devices in different stages of implantation and to quantify possible operator-independent device movement during final deployment.

Background Accurate device positioning during transcatheter aortic valve implantation is crucial in order to achieve optimal results.

Methods This multicenter study consisted of 68 procedures with reliable pacemaker capture. Device positions were assessed using fluoroscopic images and the C-THV system (Paieon Medical, Rosh Ha'Ayin, Israel).

Results The location after implantation was significantly higher than in the final stage of rapid pacing: 16.7 ± 16.3% of device height below the plane of the lower sinus border versus 32.6 ± 13.8%, $p < 0.0001$. Operator-independent device-center upper movement during final deployment was 2 ± 1.43 mm, range: −1.3 to 4.6 mm. Device movement was asymmetrical, occurring more in the lower part of the device than in its upper part (3.2 ± 1.4 mm vs. 0.75 ± 1.5 mm, $p < 0.001$), resulting in device shortening. Multivariate analysis revealed that moderate and severe aortic valve calcification had 49% higher upward movement than mild calcification ($p = 0.03$), and aortic sinus volume was negatively correlated with movement size ($r = -0.35$, $p = 0.005$). This movement was independent of device version (SAPIEN vs. SAPIEN XT), procedural access (transfemoral vs. transapical), and interventricular septum width.

Conclusions The final Edwards SAPIEN position is mostly aortic in relation to the lower sinus border. There is an operator-independent upward movement of the device center during the final stage of implantation. Anticipated upward movement of the device should influence its positioning before final deployment. (J Am Coll Cardiol Intv 2012;5:563–70) © 2012 by the American College of Cardiology Foundation

From the *Department of Cardiology, Institute of Interventional Cardiology, Rabin Medical Center, Beilinson Campus, Petach Tikva, Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; †Department of Cardiology, Charles Nicolle Hospital, University of Rouen, Rouen, France; ‡Department of Cardiology, Hôpital Bichat, Paris, France; and the §Department of Cardiology, Sha'are Zedek Medical Center, Jerusalem, Israel. The study was sponsored by Paieon Medical (Rosh Ha'Ayin, Israel). Dr. Almagor is a proctor for Edwards Lifesciences. Dr. Vahanian received honoraria from Edwards Lifesciences and is on the advisory board of Abbott, Medtronic, and Valtech. Dr. Cribier received significant honorarium as a consultant for Edwards Lifesciences and served as a certified TAVR proctor for Edwards Lifesciences and his interventional cardiology department received in 2011 a research grant ($3,000 only) from Paieon Medical company in Israel. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

Manuscript received December 20, 2011; revised manuscript received February 27, 2012, accepted March 2, 2012.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 5, NO. 5, 2012
MAY 2012:563–70

Transcatheter aortic valve replacement (TAVR) is an alternative treatment for severe symptomatic aortic valve stenosis in high-risk patients (1,2). To achieve optimal results and avoid complications, implanted valves must be precisely positioned (3,4). Significantly low implantation can cause severe paravalvular regurgitation, residual stenosis, mitral insufficiency, conduction abnormality, and in extreme cases, device drop into the left ventricular cavity, whereas considerably high implantation could result in paravalvular regurgitation, coronary flow obstruction, and device embolization (5–8). These complications could lead to patient instability and occasionally require further interventions, such as implantation of another device or an emergent surgery (9,10). Therefore, meticulous implantation technique is required to ensure precise positioning.

During implantation of an Edwards SAPIEN device (Edwards Lifesciences, Irvine, California), rapid pacing is performed to stabilize the device throughout balloon inflation and to prevent its ejection toward the aorta. This crucial stage is universally associated with temporary hemodynamic instability; hence, device positioning needs to be performed as quickly and safely as possible. However, conventional imaging modalities, mainly fluoroscopy, aortography, and echocardiography, have limited ability to guide the operator in accurate positioning of the prosthetic device in relation to the native valve (11). This becomes even more difficult in the presence of an extremely irregular anatomy, such as in highly tortuous aorta; in these cases, TAVR using non-repositionable devices carries a significant risk. Moreover, even in cases with optimal pacing performance, there may be some operator-independent movement of the device toward the aorta during final device deployment (4). This upward movement has not yet been quantified in a cohort of TAVR procedures, and the optimal position of the Edwards SAPIEN device before final deployment is as yet unknown.

Abbreviation and Acronym

TAVR = transcatheter aortic valve replacement

The objectives of the present study were to analyze Edwards SAPIEN devices positions in different stages of implantation and to quantify possible device movement during final deployment.

Methods

A cohort of 109 patients with severe symptomatic native aortic valve stenosis treated with Edwards SAPIEN TAVR procedures at 4 major medical centers from January 2010 to December 2010 were screened prospectively for this study (Charles Nicolle Hospital, Rouen, France; Hôpital Bichat, Paris, France; Rabin Medical Center, Petach Tikva, Israel; Shaare Zedek Medical Center, Jerusalem, Israel). Institutional committee on human research approved the study protocol. To prevent technical inaccuracies and to allow the use of quantitative processing techniques with improved reproducibility, only cases that met the following criteria were included: similar angiographic views during device positioning and implantation (<15° separation in all planes); aortographic contrast injection usage before and after device deployment; and appearance of a visible calcium spot during all measurement stages. In addition, reliable capture of the pacemaker at a rate of at least 180 beats/min, with loss of pulsatile flow was mandatory. Cases with operator-induced device movement during the rapid pacing stage were excluded.

Clinical and echocardiographic data were collected. Anatomic measurements of the ascending aorta and aortic root were collected using fluoroscopic images obtained before device implantation: sinus width, sinus height (between the level of the lower sinus border plane and the sinotubular junction plane), diameter of the sinotubular junction and the ascending aorta. Degree of aortic valve calcification was defined according to fluoroscopic images: no, no calcification visible; mild, calcification visible but does not include the entire valve plane; moderate, calcification includes the entire valve plane without the sinuses; and severe, calcification includes the entire valve plane and the sinuses. Estimation of sinus volume (cm^3) was calculated as: sinus height (mm) $\times \pi \times$ (annulus diameter [mm]/2)^2/1,000. Degree of aortic regurgitation was defined according to aortographic measurements in a scale of 1+ to 4+: mild regurgitation (1+) when only a small amount of contrast enters the left ventricle and does not fill the chamber; moderate regurgitation (2+) when the contrast faintly fills the entire ventricle and does not clear rapidly; moderate-severe (3+) when ventricle opacification is equal in density to the ascending aorta; and severe (4+) when it is greater than in the aorta.

Definition of device position. The virtual ring formed by joining the points of basal attachment of the aortic valve leaflets, representing the plane of the virtual aortic valve annulus, anatomic annulus (Fig. 1A), served as a reference for the location of the device. Device position was defined as the fraction below the anatomic annulus, in relation to the total prosthetic valve height (Figs. 1B–1D). After device implantation, when the virtual valve annulus is no longer at its original position, we used a fixed anatomic structure as the reconstructed line reference, namely, the sinotubular junction and the sinus curve complex constructs.

Measurements of device position. Position measurements were performed using the C-THV (Paieon Medical, Rosh Ha'Ayin, Israel) system to identify the device position offline. The C-THV is an imaging modality that creates a 3-dimensional reconstruction of the aortic root during Edwards SAPIEN TAVR procedures, and enables real-time device positioning in relation to a pre-defined target line (12–14). To accurately evaluate the position of the implanted device, 4 components of the native valve and the aortic root complex were marked during the planning stage:

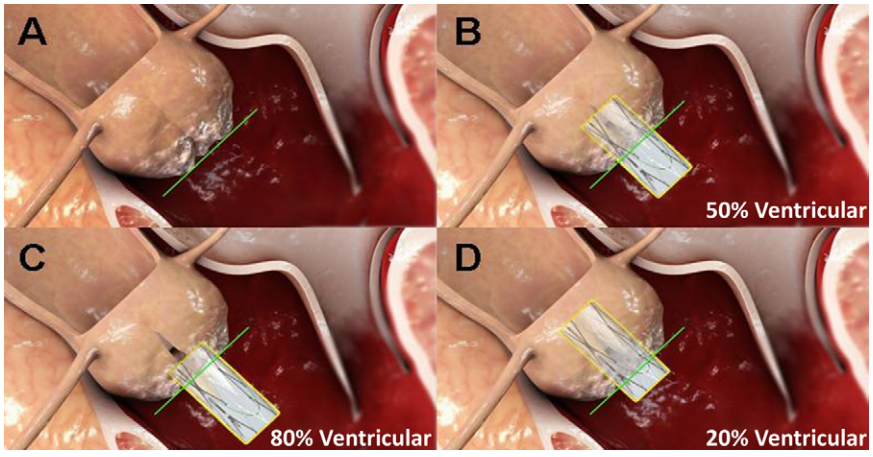

Figure 1. Edwards SAPIEN Device Positions

Edwards SAPIEN device in a closed configuration in several positions, defined as device fraction below the basal sinus border (anatomic annulus, **green line**) in relation to the total prosthetic valve height. **(A)** The anatomical annulus plane at the basal sinus border. **(B)** The device is centralized against the anatomic annulus (50% position). **(C)** The device is positioned very low (80% position). **(D)** The device is positioned very high (20% position).

the anatomic annulus at the base of the sinuses, the sinotubular junction, the aortic root complex, and a calcium spot. In each case, these components were verified by an independent observer blinded to initial selections. The plane of the aortic valve anatomic annulus was tracked until it was completely filled with contrast medium. This plane was used to identify the basal region of the sinuses. A visible calcium spot adjacent to the aortic root was identified as well. The stable position of this calcium spot and its fixed spatial relationship to the valve anatomic annulus allowed us to accurately recognize the plane of the aortic valve annulus and to evaluate device location without the need for additional contrast injection. Semiautomatic segmentation of the selected calcium spot was performed before and after device implementation.

We documented the prosthetic device positions in each patient at 4 stages during the procedure: 1) pre-deployment, before contrast injection (guided by the pre-selected calcium spot); 2) pre-deployment, during the last angiographic aortic contrast injection (guided by the aortographic image showing the fixed sinotubular junction and target line at the base of sinuses); 3) during rapid pacing, immediately before balloon inflation (guided by the pre-selected calcium spot); and 4) post-deployment, after device implantation (guided by the pre-defined fixed sinotubular junction and reconstructed target line). In each stage, we measured the following parameters in relation to the target line and the sinotubular junction: the fraction of the device below the anatomic annulus out of the total prosthetic device length, and the position of the upper, middle, and lower parts of the device.

Statistical analysis. Statistical analysis was performed with the SAS version 9.1 (SAS Institute, Cary, North Carolina). Continuous variables are presented as mean ± SD, and categorical variables as proportions and percentages. Differences in paired continuous variables were assessed by Student *t* test. Correlations between clinical parameters and device movement were calculated using Pearson correlation coefficients. Significance was set at $p < 0.05$.

Results

Sixty-eight patients (62% women) of mean age 82.9 ± 7.2 years were included in the analysis. There were no differences in background and clinical characteristics between patients who were included in the study and those excluded. Their clinical and anatomic characteristics, as well as early clinical results, are detailed in Tables 1 and 2. There were no cases of coronary ostial obstruction, a need for a second device implantation because of malpositioning, or an emergent cardiac surgery. Two patients (2.9%) required permanent pacemaker implantation after the procedure. Edwards SAPIEN devices were implanted in 36 patients (52.9%), and Edwards SAPIEN XT devices in 32 patients (47.1%). Transfemoral (43 cases, 63.2%) or transapical (25 cases, 36.8%) routes were used for access.

Before deployment, the fraction of device height below the anatomic annulus was 36.9 ± 21.5%, guided by the pre-selected calcium spot without aortic contrast injection, and 39 ± 14.7%, guided by the aortographic image with contrast injection. There was no significant difference between these values ($p = 0.51$).

Device position during rapid pacing, immediately before balloon inflation, was highly correlated with its position after deployment ($r^2 = 0.68$, $p < 0.001$) (Fig. 2). After deployment, the position of the device (16.7 ± 16.3% below

Table 1. Patient Characteristics (N = 68)

Baseline demographics	
Age, yrs	82.9 ± 7.2
Male	38.2
NYHA functional class I/II/III/IV	0%/4.4%/51.5%/44.1%
Diabetes mellitus	23.5
Hypertension	88.2
Peripheral vascular disease	33.8
Renal failure (GFR <60 ml/min)	39.7
Previous cardiac surgery	25
Logistic euroSCORE	23.2 ± 8.5
STS score	9.1 ± 4.2
Prosthesis size (23 mm/26 mm)	48.5%/51.5%
Device (SAPIEN/SAPIEN XT)	52.9%/47.1%
Vascular access (transfemoral/transapical)	63.2%/36.8%
30-day clinical and echocardiographic results	
Survival	94.1
NYHA functional class I/II/III/IV	35.3%/47.1%/16.2%/1.5%
Left-ventricular ejection-fraction	54.8 ± 13.5
Aortic regurgitation grade ≥2	17.7
Aortic-valve maximal pressure gradient, mm Hg	19.2 ± 9.5
Aortic-valve mean pressure gradient, mm Hg	9.8 ± 5

Values are mean ± SD or %.
GFR = glomerular filtration rate; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

the anatomic annulus) was significantly higher than during rapid pacing (32.6 ± 13.8%, p < 0.0001) (Figs. 3 and 4). In 91.2% of cases, final device location was <40% of the device height below the anatomic annulus. Absolute device movement toward the aorta between the final rapid pacing period and device deployment was 2 ± 1.43-mm upward movement of device center (range: −1.3 to 4.6 mm). This upward movement was asymmetrical and occurred mainly in the lower part of the device (3.2 ± 1.4 mm vs. 0.75 ± 1.5 in upper part, p < 0.001), resulting in device shortening (Fig. 5).

Table 2. Baseline Echocardiographic and Angiographic Characteristics (N = 68)

Aortic valve maximum pressure gradient, mm Hg	85.9 ± 22.9
Aortic valve mean pressure gradient, mm Hg	53.6 ± 18.1
Aortic valve area, cm^2	0.56 ± 0.13
Aortic regurgitation grade ≥2	29.4
Left ventricular ejection fraction, %	53.8 ± 12.6
Aortic valve annulus diameter, mm	22.1 ± 1.9
Proximal ascending aorta diameter, mm	31 ± 3.6
Intraventricular septum diameter, mm	13.5 ± 3.8
AV calcification (no/mild/moderate/severe)	0%/33.8%/48.5%/17.6%
Aortic root sinus width, mm	31.9 ± 5.9
Sinus root sinus height, mm	18.7 ± 4.2
Sinotubular junction width, mm	27.8 ± 6.7
Ascending aorta diameter, mm	33.6 ± 5.2
Aortic valve angulation,°	38.6 ± 10.9
Aortic sinus volume, cm^3*	7.2 ± 2.38

Values are mean ± SD or %. *Estimation of sinus volume (cm^3) was calculated as: sinus height (mm) × π × (annulus diameter [mm]/2)^2/1,000.
AV = atrioventricular.

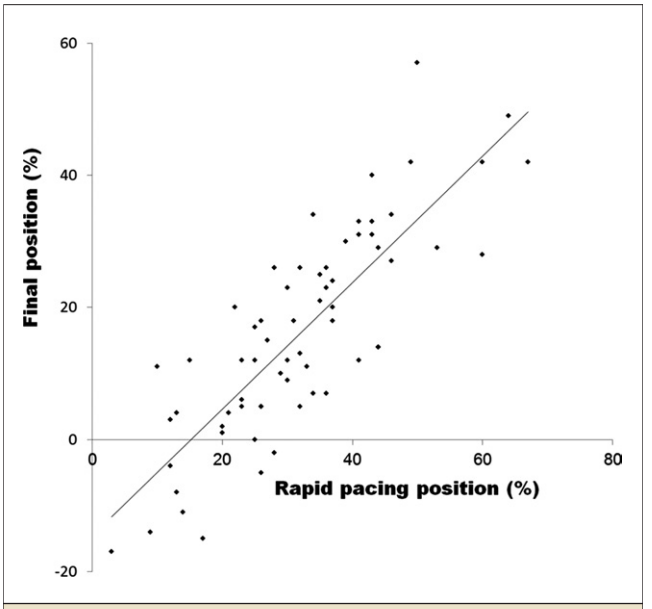

Figure 2. Edwards SAPIEN Device Position During Rapid Pacing and After Implantation

Correlation between Edwards SAPIEN device positions (defined as device fraction below the basal sinus border) during rapid pacing, immediately before implantation, and after deployment. $r^2 = 0.68$, $p < 0.001$.

Table 3 shows several correlations between device-center movement and clinical characteristics. The upward movement was independent of device type (Edwards SAPIEN vs. Edwards SAPIEN XT), size (23 vs. 26 mm), and procedural access (transfemoral vs. transapical). There was also no significant influence of baseline device position (high vs. mid/low position) on its movement. Significant (moderate or severe) aortic valve calcification was associated with a 49% higher upward movement than mild calcification (2.28 ± 1.15 mm vs. 1.53 ± 1.61 mm, p = 0.03). Aortic sinus volume was significantly negatively correlated with that movement (r = −0.35, p = 0.005), and a trend was found between that movement and either higher baseline aortic regurgitation severity (p = 0.07) or native aortic valve annulus (p = 0.09). There was no significant correlation between final device position and clinical or hemodynamic results.

Discussion

The present multicenter analysis of a cohort of TAVR procedures using Edwards SAPIEN devices yielded several findings. First, the position of the device during rapid pacing, before final implantation, was relatively higher (i.e., toward the aorta) than conventionally recommended (4). Average device location during rapid pacing was 32.6% of device height below the anatomic annulus and 67.4% above

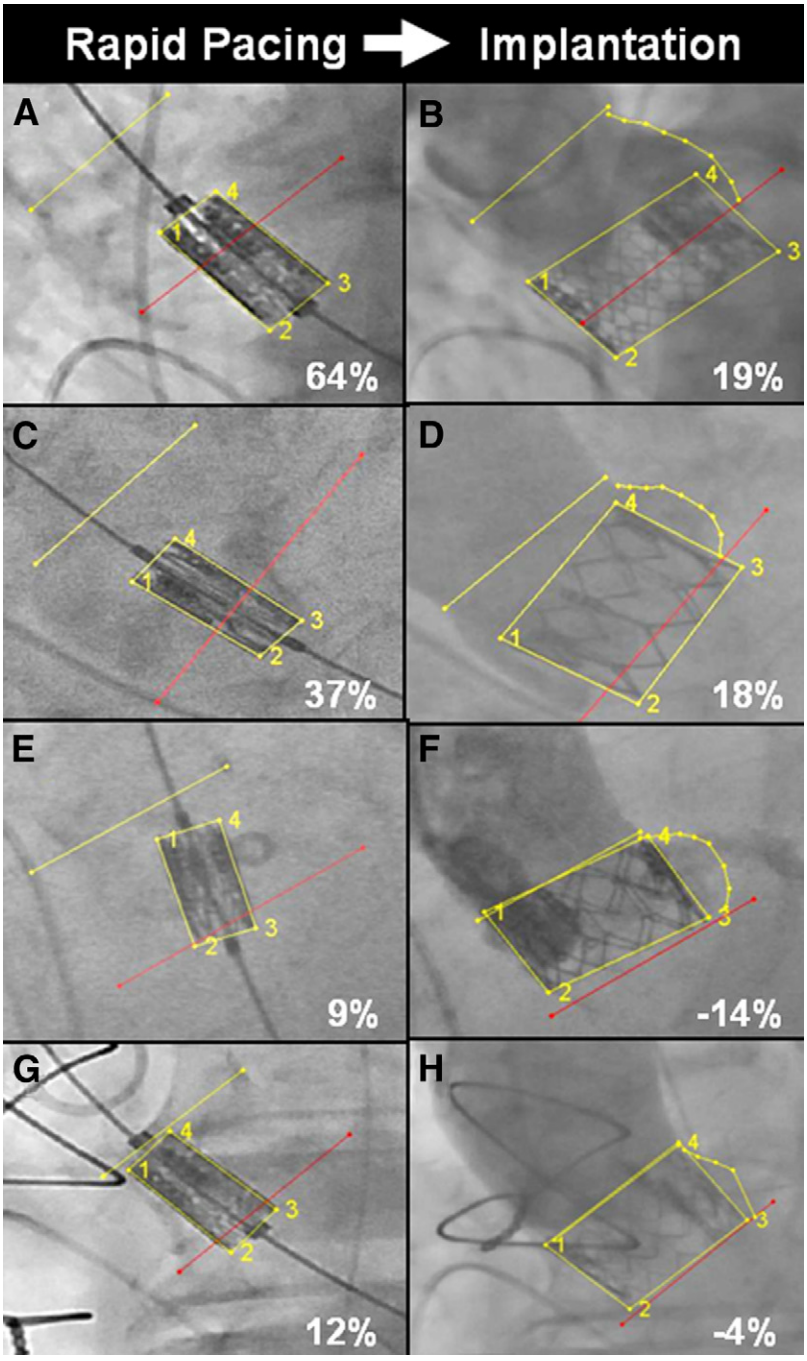

Figure 3. Case Examples

Operator-independent upward Edwards SAPIEN device movement between the final stage of rapid pacing, immediately before balloon inflation, and after device deployment. Numbers represent the fraction of the device below the basal sinus border (anatomic annulus, **red line**).

that plane. Nevertheless, early clinical results were satisfactory and comparable to contemporary registries of Edwards SAPIEN procedures in terms of patient survival, functional class, and valve hemodynamics (1,2,15,16). Second, even under proper rapid pacing, there is a considerable (average of 2 mm) upward, operator-independent movement of the device center during the final stage of implantation, which leads to an even higher location. This upward movement was more significant in cases of small aortic sinus volume and significant aortic valve calcification. Third, the lower

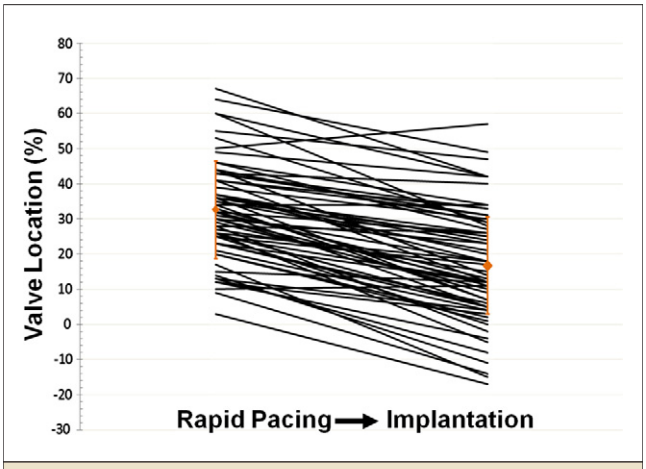

Figure 4. Edwards SAPIEN Device Positions

A graph displaying Edwards SAPIEN device locations of 68 patients in the final stage of rapid pacing, immediately before balloon inflation, and after deployment. Numbers represent the fraction of the device below the basal sinus border (anatomic annulus). There is a change in average device location from 32.6 ± 13.8% to 16.7 ± 16.3%.

portion of the device accounts for most of the upward movement (average of 3.2 mm), whereas the upper border of the device is relatively fixed (average of 0.75 mm), leading to device shortening (Online Video 1).

Device shortening and upper movement. Our study results support the manufacturer specifications of 2- to 3-mm device shortening from the crimped to open configuration (17). Although the exact shortening and upper movement mechanism is not clear, decrease in device height appears to be asymmetrical, where the upper device part is relatively fixed by the calcified leaflets, and the released lower part is moving upward. This differential movement might have some clinical benefits where upper movement of the lower device border could decrease the tension on the interventricular septum, and possibly reduce the rates of conduction defect after the procedure, whereas the relatively fixed position of the upper device border may decrease the risk of coronary ostia obstruction. Nevertheless, malpositioning could still result in significant valve regurgitation, and in extreme cases, may lead to device dislocation. According to our study results, the fixation of the upper part might be more pronounced in cases with significant valve calcification and small aortic sinus volume. It is conceivable that the impact of native valve calcification on device movement during deployment is dictated by the exact location and interplay between the device and calcification in a similar way that it may affect the degree of perivalvular leak after implantation (18). Nevertheless, an alternative mechanism of device movement could include symmetrical shortening of the device, from both upper and lower borders, followed by an upper device shift toward the aorta. However, this alternative hypothesis does not explain the relatively fixed position of the upper border of the device that was revealed in the study. Several clinical characteristics formerly thought to impact device stability during implantation were not found as such in

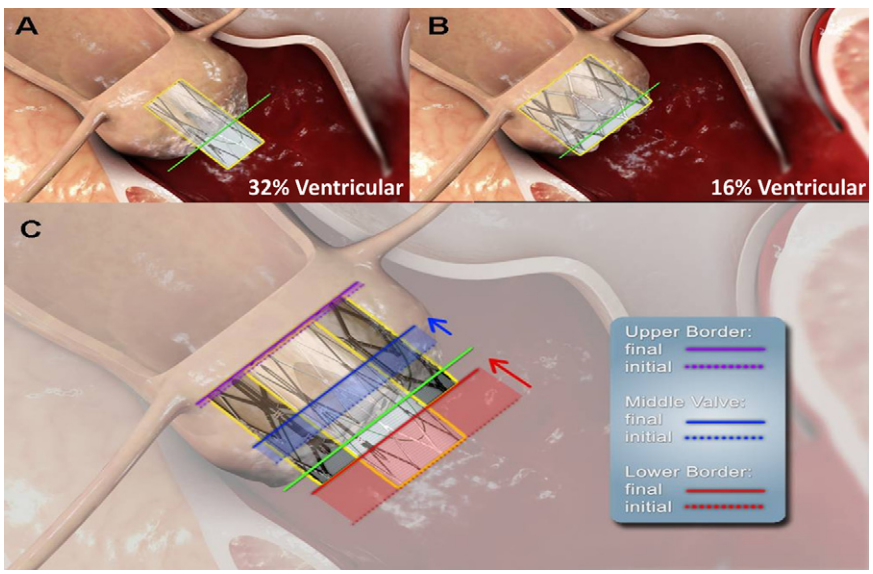

Figure 5. Illustration of Average Edwards SAPIEN Device Position and Operator-Independent Change During Final Implantation

(A) The device in closed configuration, during the final stage of rapid pacing, immediately before balloon inflation. It is positioned 33% below the basal sinus border (anatomic annulus, **green line**). **(B)** The device after deployment positioned 16% below the anatomical annulus. **(C)** Operator-independent device movement between the final stage of rapid pacing and deployment with 2 ± 1.43-mm upward movement of device center. Lower device border movement: 3.2 ± 1.4 mm; upper device border movement: 0.75 ± 1.5 mm. See Online Video 1.

Table 3. Device Movement During Final Deployment According to Clinical and Anatomic Parameters*

Parameter	Upward Device Movement (mm)	Pearson Correlation Coefficient	p Value
Baseline characteristics			
Aortic valve maximum pressure gradient, mm Hg		0.15	0.22
<85 (n = 34)	1.96 ± 1.76		
≥85 (n = 34)	2.04 ± 1.33		
Aortic valve area, cm^2		0.08	0.52
<0.55 (n = 33)	1.87 ± 1.57		
≥0.55 (n = 35)	2.13 ± 1.33		
Baseline aortic regurgitation grade		NA	0.07
<2 (n = 48)	1.81 ± 1.42		
≥2 (n = 20)	2.38 ± 1.4		
Intraventricular septum diameter, mm		−0.01	0.94
<13 (n = 35)	2.12 ± 1.58		
≥13 (n = 33)	1.88 ± 1.36		
Baseline left ventricular ejection fraction, %		−0.05	0.69
<60 (n = 36)	2.15 ± 1.51		
≥60 (n = 32)	1.83 ± 1.42		
Annulus diameter, mm		−0.21	0.09
<22 (n = 34)	2.2 ± 1.2		
≥22 (n = 34)	1.8 ± 1.55		
AV calcification		NA	0.03
No/mild (n = 23)	1.53 ± 1.61		
Moderate/severe (n = 45)	2.28 ± 1.15		
Aortic sinus volume, cm^3†		−0.35	0.005
<6.7 (n = 34)	2.43 ± 1.3		
≥6.7 (n = 34)	1.57 ± 1.45		
Aorta to aortic valve angulation,°		0.03	0.81
<50 (n = 34)	1.9 ± 1.45		
≥50 (n = 34)	2.11 ± 1.33		
Procedural characteristics			
Prosthesis type		NA	0.49
SAPIEN (n = 36)	2.12 ± 1.32		
SAPIEN XT (n = 32)	1.87 ± 1.55		
Prosthetic size			
23 mm (n = 33)	2.13 ± 1.21		
26 mm (n = 35)	1.86 ± 1.7	NA	0.21
Vascular access		NA	0.11
Transfemoral (n = 43)	1.78 ± 1.41		
Transapical (n = 25)	2.39 ± 1.43		
Device position during rapid pacing‡		0.11	0.18
<40% (aortic) (n = 48)	1.83 ± 1.33		
40%–60% (mid position/ventricular) (n = 20)	2.37 ± 1.63		

Values are mean ± SD. *Device movement is the operator-independent change in middle device position between the rapid pacing stage (immediately before balloon inflation) and deployed valve position. †Estimation of sinus volume (cm^3) was calculated as in Table 2. ‡Device position is defined as the device fraction below the basal sinus border.

AV = atrioventricular; NA = not applicable

our study (4). Specifically, a newer version of the SAPIEN device (SAPIEN XT) and the use of a transapical route of implantation did not decrease upper device movement. By contrast, a high degree of septal hypertrophy (i.e., bulging interventricular septum) was not associated with device instability. Nevertheless, the degree of pre-procedural aortic regurgitation tended to correlate with the degree of device movement.

Optimal deployment position. Even when a perpendicular view of the device is achieved, using the optimal projection method of the C-THV system, the optimal deployment location of the Edwards SAPIEN device is controversial. Most favorable results will probably be gained when full coverage of the aortic leaflets is obtained with secure anchoring at and below the level of the insertion of the native valve leaflets. Therefore, the conventional recommendation is to implant the device and 50% below and 50% above native leaflet insertion. However, the precise location of leaflet insertion is not easy to define using conventional real-time catheterization laboratory imaging, and an approximation of the aortic annulus location is usually made. However, the aortic annulus is not an anatomic structure, and the virtual basal ring, which commonly serves as the target line for implantation, forms at the plane of the base of the aortic sinuses, about 1 to 2 mm below the anatomic ventriculoaortic junction (leaflet hinge points) (3). Moreover, the skirt of the Edwards SAPIEN device surrounds mostly the lower part of the implanted device struts and not the upper part. Therefore, it seems reasonable to suggest that the final location of the middle region of implanted device will be 1 to 2 mm higher than the plane of the most basal part of the aortic sinuses. Our findings of slightly higher device implantations than the basal sinus border with satisfactory clinical results are compatible with this suggestion. Aiming for a slightly high valve position will decrease the risk of low malposition, a complication that may result in a severe complication of device drop into the left ventricular cavity with a subsequent need for emergent surgery. Slightly high valve position may also diminish the risk of conduction system abnormalities, although the correlation between implantation depth and a need for permanent pacemaker implantation after the procedure was studied mostly in patients undergoing CoreValve device (Medtronic, Minneapolis, Minnesota) implantation (19,20). Nevertheless, in patients with low left main ostia that are considered for transcatheter valve implantation (especially those <8 mm from the virtual basal ring), in addition to considering the use of a safety guidewire in the coronary artery, the operator should aim for a lower implantation to decrease the risk of ostial coronary occlusion.

Clinical implications. It seems that operators implanting Edwards SAPIEN devices need to be aware of the upper movement phenomenon. This operator-independent change in device position was as common in the new SAPIEN device version as in the previous version. In appropriate cases, operators should consider placing the

center of the device 1 to 2 mm below the target line for implantation during the rapid-pacing phase. The extent of compensation should probably be greater in patients with significant valvular calcification and/or small aortic sinus volume. Alternatively, considering the relatively fixed position of the upper device border, this location could be used as a reference for its final position. Otherwise, in complicated cases, prolonged and stepwise balloon inflation might be applied with minimal correction of device position.

Study limitations. Our study was limited for not being powered to evaluate possible correlation between device location and clinical results. The possible impact of device position on valve function should be examined in a larger group of patients with long-term follow-up. After device deployment, the anatomic annulus plane in the base of the native aortic sinuses is not in its original position, and any comparison of device location to the pre-deployment location was not direct, and some degree of bias could not be excluded. Nevertheless, we were guided by a fixed anatomic structure created by the sinotubular junction and the sinus curve complex. Moreover, as detailed in the results, we found no significant difference between pre-implantation device locations according to direct aortographic imaging and those performed indirectly using the calcium spot, supporting our method of analysis.

Conclusions

Our multicenter analysis of Edwards SAPIEN device positions included only cases with reliable capture of the pacemaker and no cases with operator-induced device movement during the rapid-pacing stage. Our analysis shows that there is an operator-independent upward movement of the device during the final stage of implantation, between the final stage of rapid pacing and deployment. This upward movement is asymmetrical, occurring mainly in the lower part of the device, and is more significant in highly calcified valves and those with aortic roots of small volume. Anticipated upward movement of the device center should influence its positioning before final deployment.

Acknowledgments

The authors are very grateful to Serge Goldstein and Ziv Qual from MD Simulation, Ltd. for preparing the images and video illustrations.

Reprint requests and correspondence: Dr. Ran Kornowski, Department of Cardiology, Rabin Medical Center, Beilinson Campus, 39 Jabotinski Street, Petach Tikva 49100, Israel. E-mail: rkornowski@clalit.org.il.

REFERENCES

1. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. N Engl J Med 2010;363:1597–607.
2. Smith CR, Leon MB, Mack MJ, et al. Transcatheter versus surgical aortic-valve replacement in high-risk patients with severe aortic stenosis. N Engl J Med 2011;364:2187–98.
3. Piazza N, de Jaegere P, Schultz C, et al. Anatomy of the aortic valvar complex and its implications for transcatheter implantation of the aortic valve. Circ Cardiovasc Interventions 2008;1:74–81.
4. Serruys P, Piazza N, Cribier A, Webb J, Laborde JC, de Jaegere P, editors. Transcatheter Aortic Valve Implantation: Tips and Tricks to Avoid Failure. New York, NY: Informa Healthcare, 2010.
5. Zahn R, Schiele R, Kilkowski C, Zeymer U. Severe aortic regurgitation after percutaneous transcatheter aortic valve implantation: on the importance to clarify the underlying pathophysiology. Clin Res Cardiol 2010;99:193–7.
6. Détaint D, Lepage L, Himbert D, et al. Determinants of significant paravalvular regurgitation after transcatheter aortic valve: implantation impact of device and annulus discongruence. J Am Coll Cardiol Intv 2009;2:821–7.
7. Stabile E, Sorropago G, Cioppa A, et al. Acute left main obstructions following TAVI. EuroIntervention 2010;6:100–5.
8. Kukucka M, Pasic M, Dreysse S, Hetzer R. Delayed subtotal coronary obstruction after transapical aortic valve implantation. Interact Cardiovasc Thorac Surg 2011;12:57–60.
9. Tay EL, Gurvitch R, Wijeysinghe N, et al. Outcome of patients after transcatheter aortic valve embolization. J Am Coll Cardiol Intv 2011;4:228–34.
10. Al Ali AM, Altwegg L, Horlick EM, et al. Prevention and management of transcatheter balloon-expandable aortic valve malposition. Catheter Cardiovasc Interv 2008;72:573–8.
11. Tops LF, Delgado V, van der Kley F, Bax JJ. Percutaneous aortic valve therapy: clinical experience and the role of multi-modality imaging. Heart 2009;95:1538–46.
12. Dvir D, Kornowski R. Percutaneous aortic valve implantation using novel imaging guidance. Catheter Cardiovasc Interv 2010;76:450–4.
13. Dvir D, Kornowski R. Real-time 3D imaging in the cardiac catheterization laboratory. Future Cardiol 2010;6:463–71.
14. Tzikas A, Schultz C, Van Mieghem NM, de Jaegere PP, Serruys PW. Optimal projection estimation for transcatheter aortic valve implantation based on contrast-aortography: validation of a prototype software. Catheter Cardiovasc Interv 2010;76:602–7.
15. Thomas M, Schymik G, Walther T, et al. One-year outcomes of Cohort 1 in the Edwards SAPIEN Aortic Bioprosthesis European Outcome (SOURCE) registry: the European registry of transcatheter aortic valve implantation using the Edwards SAPIEN valve. Circulation 2011;124:425–33.
16. Eltchaninoff H, Prat A, Gilard M, et al. Transcatheter aortic valve implantation: early results of the FRANCE (FRench Aortic National CoreValve and Edwards) registry. Eur Heart J 2011;32:191–7.
17. Transcatheter Heart Valve: The Edwards SAPIEN Transcatheter Heart Valve With the RetroFlex 3 Transfemoral System. Edwards Lifesciences website. Available at: http://www.edwards.com/products/transcathetervalve/Pages/THVcategory.aspx. Accessed December 20, 2011.
18. Ewe SH, Ng AC, Schuijf JD, et al. Location and severity of aortic valve calcium and implications for aortic regurgitation after transcatheter aortic valve implantation. Am J Cardiol 2011;108:1470–7.
19. Guetta V, Goldenberg G, Segev A, et al. Predictors and course of high-degree atrioventricular block after transcatheter aortic valve implantation using the CoreValve Revalving system. Am J Cardiol 2011;108:1600–5.
20. Fraccaro C, Buja G, Tarantini G, et al. Incidence, predictors, and outcome of conduction disorders after transcatheter self-expandable aortic valve implantation. Am J Cardiol 2011;107:747–54.

Key Words: aortic stenosis ■ transcatheter aortic valve implantation.

APPENDIX

For an accompanying video, please see the online version of this article.