ORIGINAL ARTICLE

High Self-expandable Valve Implantation with the Cusp-Overlap Technique, a Strategy to Reduce the Need for Pacemaker in Transcatheter Aortic Valve Implantation. 30-day Outcome

Implante alto de las válvulas autoexpandibles con la técnica de "Cusp-Overlap", una estrategia para disminuir la necesidad de marcapasos en el implante percutáneo de válvula aórtica. Evolución a 30 días

OSCAR MENDIZ[1], CARLOS FAVA[1], GASPAR CAPONI[1], LEÓN VALDIVIESO[1], GUSTAVO LEV[1], PAUL GAMBOA[1], HUGO FRAGUAS

ABSTRACT

Background: The aim of this study was to analyze whether higher transcatheter aortic valve implantation with self-expandable valves using the right and left cusp overlap strategy decreases the need for permanent pacemaker.
Methods: A total of 164 consecutive patients undergoing TAVI with self-expandable valves were analyzed: 101 (61.6%) implanted with the conventional technique (CON) using the three-cusp coplanar view, and 63 (38.4%) using the right and left cusp overlap (COVL) technique. The primary endpoint (PEP) was the need for permanent pacemaker (PPM) at 30 days.
Results: Mean age, prevalence of male gender, hypertension, prior coronary artery bypass graft surgery (CABG), and history of stroke, kidney function or hemodialysis was not different between groups. Patients in the COVL group had more diabetes, coronary percutaneous transluminal coronary angioplasty (PTCA) and prior infarct, and pre-TAVI PTCA was similar, with higher STS score (6.3±2.2 vs. 5.8±2.4; p=0.05). The presence of atrial fibrillation was greater in the COVL group, without differences in right or left bundle branch or atrioventricular block.
There was no difference in aortic valve area, mean gradient and left ventricular ejection fraction.
At 30 days, the need of PPM was significantly reduced with the COVL technique (6.3%% vs. 17.8%; p=0.03). No difference was observed in mortality, stroke, major bleeding, acute myocardial infarction or aortic regurgitation, and the presence of new-onset complete left bundle branch block was lower in the COVL group (4.8% vs. 12.9%; p=0.08).
Conclusions: Use of the COVL technique, which allows higher self-expandable valve implantation during TAVI, was feasible and safe, decreasing the need for PPM without increasing complications.

Key words: Aortic Valve Insufficiency - Self Expandable Metallic Stents - Transcatheter Aortic Valve Replacement - Follow-Up Studies

RESUMEN

Objetivo: Analizar si el implante más alto en el implante percutáneo de válvula aórtica (TAVI) con válvulas auto-expandibles utilizando la superposición de las cúspides derechas e izquierdas disminuye la necesidad de marcapasos definitivo.
Material y Métodos: Se analizaron 164 pacientes consecutivos que recibieron TAVI con válvulas auto- expandibles; en 101(61,6%) de ellos se implantaron utilizando la vista coplanar de las tres cúspides, a la cual llamamos técnica convencional (CON) y en 63 (38,4%) utilizamos la técnica COVL, con superposición de las cúspides derecha e izquierda. El punto final primario (PFP) fue la necesidad de marcapasos definitivo (MCPD) a 30 días.
Resultado: No hubo diferencias entre los grupos en la edad media, prevalencia de sexo masculino, hipertensión, cirugía de revascularización previa, antecedente de accidente cerebrovascular (ACV), función renal, o hemodiálisis. Los pacientes en el grupo COVL tuvieron más diabetes, angioplastia coronaria (ATC) e infarto previo. La ATC pre-TAVI fue similar, con mayor score STS (6,3±2,1 vs. 5,8±2,4 vs; p=0,05). La presencia de fibrilación auricular fue mayor en el grupo COVL sin diferencia en bloqueo auriculoventricular, de rama derecha o izquierda.
No hubo diferencia en el área valvular aórtica, gradiente medio y fracción de eyección ventricular izquierda.
A 30 días se observó una reducción significativa del PFP en la estrategia COVL, (6,3% vs. 17,8%, p=0,03). No hubo diferencia en mortalidad, ACV, sangrado mayor, infarto agudo de miocardio o regurgitación aórtica. Hubo tendencia a menor presencia de nuevo bloqueo competo de rama izquierda en el grupo COVL (4,8% vs 12,9%, p=0,08) respectivamente.
Conclusiones: El uso de la técnica de COVL, que permite un implante más alto en el TAVI con válvulas autoexpandibles, demostró en esta serie ser factible y seguro, con disminución de la necesidad de MCPD sin aumento de las complicaciones.

Palabras clave: Insuficiencia de la Válvula Aórtica - Stents Metálicos Autoexpandibles - Reemplazo de la Válvula Aórtica Transcatéter - Estudios de Seguimiento

Rev Argent Cardiol 2022;90:106-112. http://dx.doi.org/10.7775/rac.v90.i2.20481

Address for reprints: Oscar A Mendiz. Avda. Belgrano 1746, CABA. (1093) Argentina. - E-Mail: omendiz@ffavaloro.org

Received: 10/23/2021 – *Accepted:* 01/09/2022

This work received the 2021 Berconsky Award

[1] Department of Interventional Cardiology, Instituto de Cardiología y Cirugía Cardiovascular, Hospital Universitario Fundación Favaloro

Abbreviations

vAF	Atrial fibrillation	**IS**	Implant success
AMI	Acute myocardial infarction	**LBBB**	Left bundle branch block
CABG	Coronary artery bypass graft surgery	**PEP**	Primary endpoint
CO	Conventional strategy; 3-cusp coplanar view	**PPM**	Permanent pacemaker
COVL	Right and left cusp overlap	**PTCA**	Percutaneous transluminal coronary angioplasty
CS	Clinical success	**RBBB**	Right bundle branch block
ECG	Electrocardiogram	**TAVI**	Transcatheter aortic valve implantation

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has shown its benefit in high-risk or inoperable patients (1,2), those at intermediate risk (3,4) and also in low-risk patients (5,6). Although with higher experience and the development of technology complications have been decreasing, conduction disorders and the need for permanent pacemaker (PPM) implantation are still an important limitation for self-expandable valves, associated with higher mortality rate, (7) in addition to the need for generator change and the risk, though low, of infective endocarditis or severe tricuspid regurgitation. (8)

The development of new-onset complete left bundle branch block (LBBB) after TAVI has also been related to worse long-term outcomes. (9)

Conduction disorders, lack of durability beyond 10 years and costs are perhaps the ultimate limitations for a massive use of this technique.

OBJECTIVES

In this analysis we compared the need for PPM or new-onset LBBB after self-expandable valve implantation using the conventional coplanar implantation technique with 3-cusp view (CON), versus the recently described technique of a higher implant in the left ventricular outflow tract using a radiological view at the time of implantation where the right and left cusp are overlapped, called Cusp-overlap (COVL). This strategy allows a better view of the left ventricular outflow tract, and hence greater precision at the time of device deployment, reducing the need for PPM at 30 days and the development of new-onset LBBB, due to less interaction with the conduction system.

METHODS

A total of 164 consecutive patients receiving TAVI with self-expandable valves from August 2019 to May 2021 were analyzed. They were divided into two groups: the first 101 patients (61.6%) received implants with the conventional technique (CON) and the following 63 (38.4%) using the COVL strategy. Patients with surgical bioprosthesis, prior PPM, bicuspid aortic valve or TAVI with balloon-expandable valve were excluded from the study.

Implant success (IS) was defined as gradient <10 mmHg at the end of the procedure in the absence of severe regurgitation and clinical success (CS) as IS in the absence of death, acute myocardial infarction (AMI), stroke or urgent valve surgery.

The primary endpoint (PEP) was the need for PPM at 30 days, and in addition, mortality and the incidence of AMI, stroke, major vascular complication, major bleeding, moderate or severe aortic regurgitation, new-onset LBBB and hospital length of stay were analyzed. Events were defined according to the Valve Academic Research Consortium criteria. (10,11)

All patients were evaluated by the hospital "Valve Heart Team", with echo Doppler, coronary angiography with aortogram, and a multi-slice computed tomography angiography with 3D reconstruction of aortic valve, thoracic aorta, abdominal aorta, and subclavian, iliac and femoral arteries with intravenous contrast material.

An ECG was recorded prior to TAVI, repeated at 24 hours and another at 30 days.

Anesthesia was conscious sedation, except for those in whom a percutaneous femoral access was used, where general anesthesia was employed. All patients received dual antiplatelet therapy with aspirin and clopidogrel, except in cases receiving anticoagulants, where only clopidogrel was indicated. Anticoagulation with heparin 100 U/Kg was used during the procedure, with values controlled during its course.

In patients receiving CON strategy implants, the valve was positioned and implanted using the coplanar 3-cusp projection according to the computed tomography angiography and usually corrected by left anterior oblique, slightly cranial, angiographic projection. The implantation was performed having as objective an implant depth of approximately 4 mm below the aortic annulus, under high stimulation frequency (180 bpm) with temporary pacemaker, at the operator's discretion.

In those receiving the COVL strategy implant, a previous detailed analysis of the computed tomography angiography was performed, identifying the projection where there was right and left cusp overlap, in opposition to the non-coronary cusp, and this was chosen as the implantation projection. In case of difficulties or differences, corrections were made according to the previous angiography. When this was not feasible, positioning was performed using two pigtail or Amplatz AL2 catheters placed in the right and left sinuses, and then the angiographic projection showing cusp overlap was sought.

The objective was the implantation approximately 2-3 mm below the aortic annulus with respect to the non-coronary sinus. At the time of deployment, overstimulation with temporary pacemaker at 120 beats per minute was used to achieve system stability.

Both pre-dilation with balloon diameter below that of the aortic annulus, as post-dilation, were performed according to the operator´s criterion.

A PPM was implanted in patients presenting complete atrio-ventricular block (AVB) 24 hours after implantation or in those presenting conduction disorders, including complete right bundle branch block (RBBB) and first-degree AVB, and who after the implantation presented high-degree

AVB that did not reverse after 24 hours.

Clinical follow-up was performed in the outpatient clinic, requiring an ECG and color Doppler echocardiogram.

Ethical considerations

The study was conducted according to the Declaration of Helsinki principles and the International Conference on Good Clinical Practice regulations. In addition, all patients signed the informed consent of the Hospital to perform the procedure.

Statistical analysis

Continuous variables are presented as mean and standard deviation and categorical variables as absolute value and percentage. Student's t test was used to compare continuous variables and the chi-square test or Fisher test for categorical variables. Statistical significance was established for $p < 0.05$.

RESULTS

Groups were similar in age (79.8±7.9 years in the CON group vs. 80.4±6.7 years in the COVL group) and prevalence of male gender (48.5% vs. 53.9%). Presence of diabetes, prior percutaneous coronary intervention and atrial fibrillation (AF) was greater in those receiving the COVL strategy, while the presence of previous infarction was higher in those receiving the CON technique.

The STS score was 5.8±2.4 in the CON group vs. 6.3±21.2 in the COVL group (p=0.05), and no significant differences were found in left ventricular ejection fraction (LVEF), aortic valve area, transvalvular gradients, and LV outflow tract calcification, though aortic valve calcification was greater in those receiving the COVL strategy according to the computed tomography evaluation (3289.7±925.6 vs. 3231.2±1040 Agatston U)

Femoral access was used in all patients of the CON group and in 61 of the COVL group; in two patients of the latter group a subclavian access was used. Predilation was more frequently employed in the COVL strategy (79.3 % vs. 57.4% , p=0.0003) without differences in the use of post-dilation.

All valves implanted were self-expandable (Table 2). Percutaneous closure was used for the vascular access in 99% vs. 95% (PROSTAR XL® ABBOTT Vascular, Santa Clara, California and Proglide®, ABBOTT Vascular, Santa Clara, California) of patients. There were no cases of valve displacement towards the aorta after final deployment ("Pop-Out") (Table 1). Table 2 describes the type and number of the valve implanted in each strategy.

Implant success was achieved in all cases and CS in 95.1% vs. 92.1% (p=0.43). At 30 days, the PEP occurred less frequently in the COVL strategy (6.3% vs 17.8%; p=0.03) (Figure 1). Comparing CON vs. COVL, mortality was 4.9% vs. 4.8% (p=0.95), stroke 0% vs. 1.6% (p=0.2), major bleeding 2% vs. 1.6% (p=0.85), vascular complications 2% vs. 4.8% (p=0.31), moderate aortic regurgitation 2% vs 1.6% (p=0.85), and new-onset LBBB 12.9% vs. 4.8% (p=0.08) (Figure 2). No patient presented AMI or severe aortic regurgitation (Table 3).

Among the four patients who required PPM in the COVL group, one presented prior trifascicular block, one AF plus complete RBBB, one AF plus complete LBBB and one sinus rhythm without conduction abnormalities.

DISCUSSION

According to different publications, the need for PPM after TAVI with self-expandable valve implantation has been reported between 10% and 34%, depending on the valve type and generation, the operator's and center experience, prior conduction abnormalities, especially complete RBBB, anatomical characteristics, as calcification severity, and procedure characteristics, among which implant depth (>6 mm) use of post dilation and larger diameter valves (34 mmm) stand out, all of which have prompted until now its no-recommendation in young patients or in those at low surgical risk. (12-14)

In our series, a high implant using the COVL technique for self-expandable valve implantation was related to a lower need for PPM and lower presence of LBBB, without increasing major complications or aortic regurgitation, coronary occlusion or valve embolization.

In patients requiring PPM after the implant, three presented rhythm abnormalities and bundle branch blocks prior to the implant, and only one was in sinus rhythm without baseline electrocardiographic abnormalities.

It is important to avoid PPM implantation, since in addition to increasing long-term mortality according to some reports, (15) it generates increased costs and an additional procedure to that of TAVI. Also, not using a PPM not only reduces the need for new procedures to change the generator, and hence the costs, but also the risk of infective endocarditis and eventually the presence of tricuspid regurgitation caused by the cables, (8) which may sometimes be severe or massive. As we know, this situation is complex and usually requires hospitalizations by right heart failure producing limitations to the pharmacological treatment, in some cases with the requirement of surgical repair or eventually percutaneous treatment, which is currently under development without robust evidence to support it.

The reduction in the need for pacemaker is essential, as TAVI indications are progressing for the treatment of lower-risk groups and younger patients. (16-18)

Different analyses have shown that implant depth and presence of LV outflow tract calcification are related to greater need for PPM, and thus a better visualization of the LV outflow tract in the COVL group allows a more accurate implantation, reducing the incidence of a deep implant (19,20)

Our analysis also showed greater pre-dilation in

Table 1. Population characteristics

	CON 101 patients	COVL 63 patients	
Age (n, %)	79.8±7.9	80.4±6.7	0.41
Male gender (n, %)	49 (48.5)	34 (53.9)	0.37
Hypertension (n, %)	90 (89.1)	58 (92.1)	0.53
Diabetes (n, %)	21 (20.8)	22 (34.9)	0.04
Dyslipidemia (n, %)	69 (68.3)	52 (82.5)	0.04
Prior infarction (n, %)	23 (22.7)	9 (14.3)	0.0007
Prior CABG (n, %)	19 (18.8)	11 (17.5)	0.82
Prior PTCA (n, %)	32 (31.7)	31 (49.2)	0.001
Pre TAVI PTCA (n,%)	22 (21.8)	20 (31.7)	0.99
COPD (n, %)	19 (18.8)	13 (20.6)	0.77
Stroke (n, %)	5 (4.9)	3 (4.8)	0.61
GFR (ml/min), mean±SD	60.1±19.3	61.3±17.9	0.4
Dialysis (n, %)	3 (3)	1 (1.6)	0.57
STS score, mean±SD	5.8±2.4	6.3±2.1	0.05
Atrial fibrillation (n, %)	16 (15.8)	22 (34.9)	0.004
1st degree atrio-ventricular block (n, %)	17 (0.9)	1 (1.6)	0.73
RBBB (n, %)	10 (9.9)	6 (9.5)	0.93
LBBB (n, %)	10 (9.9)	6 (9.5)	0.93
Aortic valve area, cm^2, mean± SD	0.71±0.15	0.69±0.14	0.4
Mean gradient, mm Hg, mean± SD	40.8±10.7	41.5±10.1	0.35
Severe LVOT calcification (n, %)	6 (5.9)	3(4.8)	0.78
AVC (Agatston U) mean± SD	3231.2±1040	3289.7±925.6	0.08
Femoral access (n, %)	101 (100)	61 (95.2)	0.07
Subclavian access (n, %)	-	2 (3.17)	0.07
Pre-dilation (n, %)	58 (57.4)	50 (79.3)	0.0003
Implanted valve (n,%)			
Evolut® - Evolut. Pro®	101 (100)	51 (80.9)	0.000005
Portico®	-	8	0.0002
Accurate Neo®	-	4	0.01
Post-Dilation (n, %)	25 (24.5)	16 (25.3)	0.92
Pop-Out (n, %)	-	-	-
Percutaneous closure (n, %)	100 (99)	60 (95.2)	0.12

CON: conventional technique. COVL: right and left cusp overlap. CABG: coronary artery bypass graft surgery. PTCA: percutaneous transluminal coronary angiography. TAVI: transcatheter aortic valve implantation. COPD: chronic obstructive pulmonary disease. GFR: glomerular filtration rate. STS: Society of Thoracic Surgeons. AVB: atrioventricular block. RBBB: right bundle branch block. LBBB: left bundle branch block. LVOT: left ventricular outflow tract. AVC: aortic valve calcification. SD: standard deviation

those receiving the COVL strategy, something performed in many centers around the world, since it has demonstrated not increasing stroke risk, and facilitates implantation with lower need for post-dilation. This additional maneuver could have increased conduction abnormalities, but it was not observed.

The development of new-onset LBBB and its persistence added to the need for PPM implantation has been associated with higher mortality and rehospitalizations for heart failure. Therefore, using strategies that minimize risks of conduction abnormalities is favorable for the reduction of these events and costs. (21,22).

Presence of RBBB and pre-dilation of self-expandable valves were identified as strong predictors of post-implant PPM. (23) For this reason, some investigators suggest not using these valves in these conditions, (24,25) but preliminary reports show that using this new strategy could overcome this limitation. (26)

In our series, pre-dilation was greater in patients receiving COVL, without difference in post-dilation. This group showed lower need for PPM and a trend to lower incidence of new-onset LBBB.

Coronary occlusion could be a limitation in the case of higher implants; in our case, there was only one, probably not associated with valve positioning and deployment, as it was an acute occlusion of the right coronary artery stent in a patient who had undergone angioplasty of that artery with two long stents before TAVI, and was possibly related to a hypotensive episode during the procedure. Coronary access was easy and the event was resolved with implantation of two additional stents.

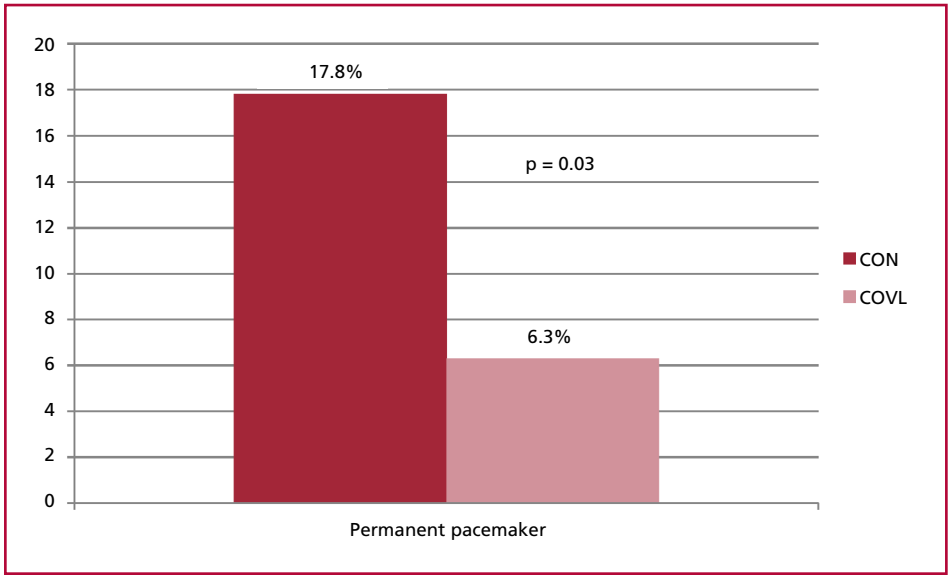
We believe that this strategy offers benefits, since

Table 2. Type and size of the implanted valve

	CON n (%)	COVL n (%)	
Evolute®/Evolute Pro®			
23 n (%)	3 (3)	-	0.16
26 n (%)	18 (17.8)	7 (11.1)	0.24
29 n (%)	58 (57.4)	26 (41.3)	0.005
34 n (%)	22 (21.4)	18 (28.6)	0.3
Portico®			
25 n (%)	-	2 (3.2)	0.07
27 n (%)	-	3 (4.8)	0.02
29 n (%)	-	3 (4.8)	0.02
Accurate®			
Medium	-	4 (6.3)	0.01

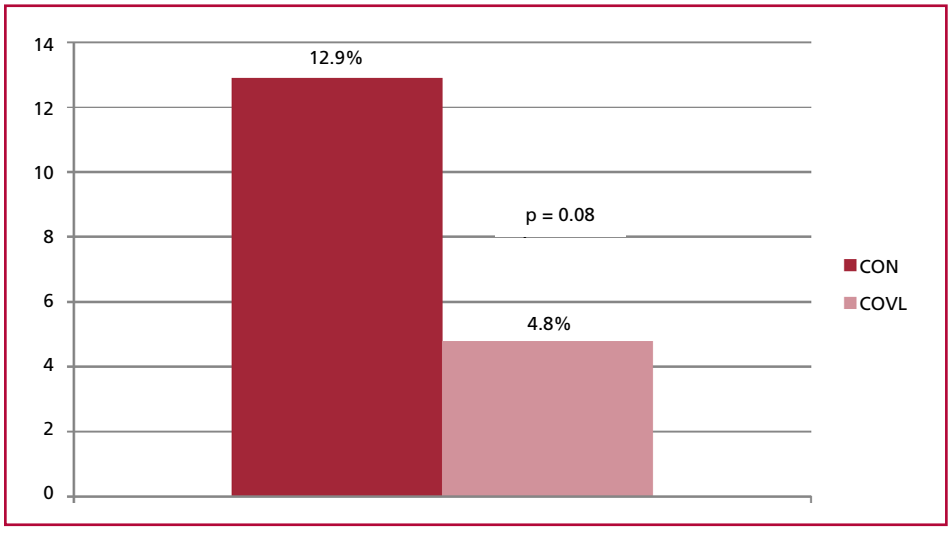
CON: conventional technique. COVL: right and left cusp overlap.

Fig. 1. Primary endpoint



CON: conventional technique. COVL: right and left cusp overlap

Fig. 2. New-onset left bundle branch block



CON: conventional technique. COVL: right and left cusp overlap

Table 3. 30-day results

	CON n (%)	COVL n (%)	
Technical success (n, %)	101 (100)	63 (100)	-
Clinical success (n, %)	96 (95.1)	60 (92.1)	0.43
PPM (n, %)	18 (17.8)	4 (6.3)	0.03
Death (n, %)	5 (4.9)	3 (4.8)	0.95
AMI (n, %)	-	1 (1.6)	0.2
Coronary occlusion (n, %)	-	1 (1.6)	0.2
Stroke (n, %)	-	1 (1.6)	0.2
Major bleeding (n, %)	2 (2)	1 (1.6)	0.85
Vascular complication (n, %)	2 (2)	3 (4.8)	0.31
Moderate regurgitation (n, %)	2 (2)	1 (1.6)	0.85
Severe regurgitation (n, %)	-	-	-
LBBB (n, %)	13 (12.9)	3 (4.8)	0.08
Hospital length of stay, days, mean±SD	2.9±1.1	2.7±1.3	0.3

CON: conventional technique. COVL: right and left cusp overlap. PPM: permanent pacemaker. AMI: acute myocardial infarction. LBBB: left bundle branch block. SD: standard deviation

it reduces hospital costs due to lower need of PPM implantation and its eventual complications, and it avoids the need for generator replacement, infective endocarditis and tricuspid regurgitation associated with PPM, that could be severe or massive, during follow-up

Limitations

Among the limitations of our study, it is necessary to point out that it was not a randomized study, but a consecutive series of patients from a single center. In addition, although we have some data showing greater implantation height with the COVL strategy, we do not have a contrast injection in both projections (CON and COVL) in all patients. Therefore, we have not reported these values, as this projection was not used in most patients of the CON series and the left oblique projection of the CON group was not performed in many patients of the COVL series, due to restrictions in the use of contrast material in elderly patients, many of whom had prior kidney disease.

As it was a consecutive series of cases, the learning curve could have had some effect on the results; however, all cases were managed by the same operators with an experience of more than 400 cases at the beginning of the series.

Although the technique was initially described for the Evolute® valve (Medtronic Inc. Minneapolis, MN), in our series we have extended it to other self-expandable systems.

CONCLUSION

In this study, high implantation of the percutaneous aortic valve using the COVL technique was feasible and safe, with lower need for PPM at 30 days and a trend to lower incidence of new-onset LBBB. Further research is necessary to support the routine use of this strategy.

Conflicts of interest

Oscar Mendiz is proctor for Medtronic, BSCI. The rest of the authors have no conflicts of interest. (See authors' conflicts of interest forms on the website/Supplementary material)

REFERENCES

1. Gleason TG, Reardon MJ, Popma JJ, Deeb GM, Yakubov SJ, Lee JS, et al. 5-Year Outcomes of Self-Expanding Transcatheter Versus Surgical Aortic Valve Replacement in High-Risk Patients. J Am Coll Cardiol 2018;72:2687–96. https://doi.org/10.1016/j.jacc.2018.08.2146

2. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. Transcatheter versus Surgical Aortic-Valve Replacement in High-Risk Patients. N Engl J Med 2011;364:2187-98. https://doi.org/10.1056/NEJMoa1103510

3. M.J. Reardon, N.M. Van Mieghem, J.J. Popma, et al. Surgical or Transcatheter Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med 2017;376:1321-31. https://doi.org/10.1056/NEJMc1706234.

4. Makkar RR, Thourani VH, Mack MJ, Kodali SK, Kapadia S, Webb JG,et al. Five-Year Outcomes of Transcatheter or Surgical Aortic-Valve Replacement. N Engl J Med 2020;382:799-809. 10.1056/NEJMoa1910555

5. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al.. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med 2019;380:1695-705. https://doi.org/10.1056/NEJMoa1814052

6. Jørgensen TH, Thyregod HGH, Ihlemann N, Nissen H, Petursson P, Kjeldsen BJ. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J 2021;42:2912-9. https://doi.org/10.1093/eurheartj/ehab375.

7. Faroux L, Chen S, Muntané-Carol G, Regueiro A, Philippon F, Sondergaard L, et al. Clinical impact of conduction disturbances in transcatheter aortic valve replacement recipients: a systematic review and meta-analysis.. Eur Heart J 2020;41:2771-81 https://doi.org/10.1093/eurheartj/ehz924

8. Diab Mutlak, Jawad Khalil, Jonathan Lessick, et al. Risk Factors for the Development of
Functional Tricuspid Regurgitation and Their Population-Attributable Fractions. JACC Cardiovasc Imaging 2020;1313:1643-51. https://doi.org/10.1016/j.jcmg.2020.01.015

9. Jørgensen TH, De Backer O, Gerds TA, Bieliauskas G, Svendsen JH, Søndergaard L.et al. Mortality and Heart Failure
Hospitalization in Patients With Conduction Abnormalities After

Transcatheter Aortic Valve Replacement. J Am Coll Cardiol Interv 2019;12:52–61. https://doi.org/10.1016/j.jcin.2018.10.053

10. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH, et al .Updated standardized endpoint definitions for transcatheter aortic valve implantation: the valve academic research consortium-2 consensus document (VARC-2). Eur J Cardio Thoracic Surg 2012;42:S45–S60. https://doi.org/10.1093/ejcts/ezs533

11. Mehran R, Rao SV, Bhatt DL, Gibson CM, Caixeta A, Eikelboom J, et al., Standardized bleeding definitions for cardiovascular clinical trials. Circulation 2011;123:2736–47 https://doi.org/10.1161/CIRCULATIONAHA.110.009449.

12. Fadahunsi OO, Olowoyeye A, Ukaigwe A, Li Z, Vora AN, Vemulapalli S, Elgin E,, et al. Incidence, Predictors, and Outcomes of Permanent Pacemaker Implantation Following
Transcatheter Aortic Valve Replacement Analysis From the U.S. Society of Thoracic Surgeons/ American College of Cardiology TVT Registry. JACC Cardiovasc Interv
2016;9:2189-99. https://doi.org/10.1016/j.jcin.2016.07.026

13. Jilaihawi H, Zhao Z, Du R, Staniloae C, Saric M, Neuburger PJ,, et al. Minimizing Permanent Pacemaker Following Repositionable Self-Expanding Transcatheter Aortic Valve Replacement. J Am Coll Cardiol Intv 2019;12:1796–807. https://doi.org/10.1016/j.jcin.2019.05.056

14. Thyregod HG, Steinbrüchel DA, Ihlemann N, Nissen H, Kjeldsen BJ, Petursson P,, et al. Transcatheter Versus Surgical Aortic Valve Replacement in Patients With Severe Aortic Valve Stenosis: 1-Year Results From the All-Comers NOTION Randomized Clinical Trial. J Am Coll Cardiol. 2015 May 26;65(20):2184-94. https://doi.org/10.1016/j.jacc.2015.03.014

15. Jørgensen TH, De Backer O, Gerds TA, Bieliauskas G, Svendsen JH, Søndergaard L. Mortality and heart failure hospitalization in patients with conduction abnormalities after transcatheter aortic valve replacement. JACC Cardiovasc Interv 2019;12:52–61. https://doi.org/10.1016/j.jcin.2018.10.053.

16. Auffret V, Lefevre T, Van Belle E, Eltchaninoff H, Iung B, Koning R, et al.Temporal trends in transcatheter aortic valve replacement in France J Am Coll Cardiol 2017;70:42-55. https://doi.org/10.1016/j.jacc.2017.04.053.

17. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low risk patients. N Engl J Med 2019;380:1706-15. https://doi.org/10.1056/NEJMoa1816885.

18. Vahanian A, Beyersdorf F, Praz F, Milojevic M, Baldus S, Bauersachs J, et al. 2021 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J 2022;43:561-632. https://doi.org/10.1093/eurheartj/ehab395.