Balloon sizing technique with TAVR in patients with severe aortic stenosis with degenerative bicuspid aorta

Implante valvular aórtico percutáneo con técnica de balloon sizing en anillo aórtico en pacientes mayores de 55 años con estenosis aórtica severa sintomática con válvula bicúspide degenerativa

Marco Gabriel Massano,[1] Sebastián Lerga,[1] Fabricio Torrent,[1] Lucas Gerbaudo,[2] Marcos De La Vega,[2] Leonardo Danduch,[2] and Juan Moreno[3]

ABSTRACT

Introduction and objectives: The indication on transcatheter aortic valve replacement (TAVR) has been increasing during the last years thanks to new prosthesis and technics on the implantation. The objective of this study is to show how the balloon sizing technic is effective in the election on the size of the prosthesis in patients with bicuspid aorta.
Methods. Balloon sizing technic was realized in 8 high risk patients with aortic stenosis and bicuspid aorta previous TAVR
Results. The implantation of the valve was 100% successfully. The 63% of the patients had indication N° 34 size Evolut R valve and 25% had indication N° 26 Evolut R. As regards the implanted valves, 38% had Evolut R 29, 38% Evolut R 26 and 25% Evolut R 23. The average on the implantation high was 2.5 mm ± 0.93, with a range between 1 and 4 mm. The access was 86% right femoral and 14% left femoral. Only one patient had a vascular complication. No death was register during the study. It´s important to remark that 5 N° 34 valve were suggested because of the CT scan and none N° 23 and thanks balloon sizing technic 2 N° 23 valve and none N° 34 were implanted. After the procedure mild or no aortic regurgitation was registered.
Conclusions. Balloon sizing is a complementary technic with CT scan and echocardiogram. It can be useful when there are doubts in the ring dimension, when the measure are in a "grey zone" between two valve sizes and when the anatomic situation are not helpful such as bicuspid aortic and septal lump.

Keywords: *balloon sizing, TAVR, bicuspid aorta.*

RESUMEN

Introducción y objetivos. El implante valvular aórtico percutáneo (TAVI) es un procedimiento que ha crecido exponencialmente en los últimos años y cuya indicación va aumentando a medida que se desarrollan nuevas prótesis y mejora su técnica de implantación. El objetivo de este pequeño estudio es demostrar que la técnica de *balloon sizing* es efectiva para colaborar con la elección del tamaño de la prótesis en pacientes con aorta bicúspide.
Métodos. Se le realizó *balloon sizing* a 8 pacientes de alto riesgo con estenosis aórtica y aorta bicúspide previo a la colocación de TAVI.
Resultados. El éxito técnico, definido como el implante de la válvula se logró en el 100%. El 63% tenía indicación de implante de válvula Evolut R 34 y el 25% Evolut R 26. Con respecto a las válvulas implantadas, el 38% tuvo válvula Evolut R 29, el 38% Evolut R 26 y el 25% Evolut R 23. Las válvulas fueron implantadas en una altura promedio de 2,5 mm ± 0,93, con un rango comprendido entre 1 y 4 mm. La vía de acceso en el 86% de los casos fue FD (femoral derecha); y solo en el 14% fue FI (femoral izquierda). Un solo paciente tuvo complicaciones vasculares, quien además registraba marcapasos definitivo previo al tratamiento. Tampoco se registraron casos de pacientes que fallecieran. Es importante remarcar que según el perímetro valvular por tomografía se sugirieron 5 válvulas N° 34 y ninguna N° 23, y gracias al *balloon sizing* se terminaron implantando 2 N° 23 y ninguna N° 34. La insuficiencia aórtica residual leve o ausente al final del procedimiento se observó en el 100% de los procedimientos.
Conclusiones. *Balloon sizing* es una técnica complementaria a MSCT y al tamaño de ETE convencional. Es especialmente útil cuando existe incertidumbre en cuanto a las dimensiones del anillo, cuando las mediciones caen en la "zona gris" entre dos tamaños de válvula y en las siguientes situaciones anatómicas poco claras: válvula aórtica bicúspide, bulto septal.

Palabras clave: *balloon sizing, TAVI, aorta bicúspide.*

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become the treatment of choice for patients with severe aortic stenosis considered inoperable and gives better results compared to conservative management including the aortic valvuloplasty. In another group of patients—those of high surgical risk—TAVI proved to be non-inferior to surgical aortic valve replacement (SAVR). In this registry we will be describing a series of successful procedures with the balloon sizing technique in patients with symptomatic severe aortic stenosis with degenerative bicuspid aortic valve and percutaneous valve implantations. We will also be reviewing the experience reported so far.

Theoretical framework

Currently, aortic stenosis (AS) is the most common valve disease in developed countries given the increased life expectancy. Mostly, it is associated with calcified AS in older patients (between 2% and 7% of the population over 65).[1] Surgical valve replacement is still the treatment of choice in patients with symptomatic severe AS (class I recommendation with level of evidence B, ACC/AHA clinical practice guidelines, *Circ.* 2008;118:e523-e661).º

Without surgery prognosis is extremely ominous with rates < 30% at the 3-year follow-up; however, in 33% of all patients > 75 with severe AS surgery is not an option.[2] The mortality rate of high-risk patients with symptomatic severe AS is > 50% to 60% at 2 years. A significant percentage of those who finally end up undergoing aortic valve replacement surgery has a high morbimortality rate associated with the procedure.[3]

1. Clínica Santa Clara, San Juan, Argentine Republic
2. Sanatorio El Salvador, Córdoba, Argentine Republic
3. Clínica Pasteur, Neuquén, Argentine Republic

✉ Correspondencia: *Marco Massano. marcogabmassano@gmail.com; marcomassano@hotmail.com*

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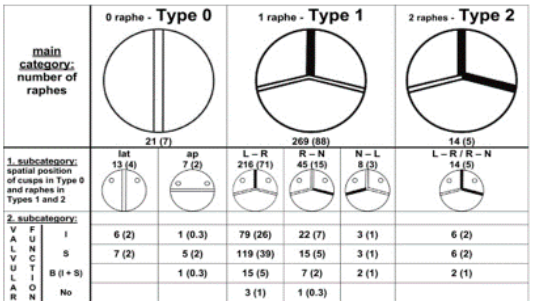
TABLE 1. Valve characterization.

Valve selection Después del ICP		CoreValve Evolut R		
Size	23 mm	26 mm	29 mm	34 mm
Annulus diameter (mm)	18-20	20-23	23-27	26-29
Annulus perimeter (mm)	56.5-62.8	62.8-72.3	72.3-81.7	81.7-94.2
Annulus area (mm2)	254.5-314.2	314.2-415.5	415.5-572.6	530.9-660.5
Diameter of ascending aorta (mm)	< 34	< 40	< 43	< 43
Diameter of Valsalva sinus (mm)	> 25	> 27	> 29	> 31
Height of Valsalva sinus (mm)	> 15	> 15	> 15	> 16



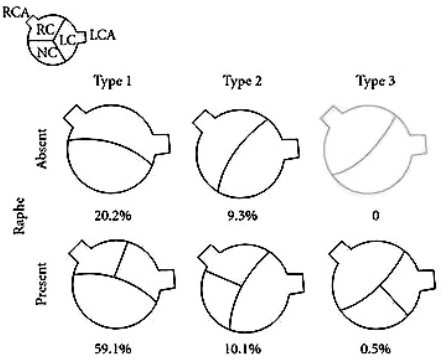


Figure 1. *A y B. Valve classification.*

The percutaneous balloon valvuloplasty was the first catheter-based technique to ever solve this problem. After the initial promising results,[4,5] the long-term follow-up data showed a high rate of restenosis and lack of significant clinical improvement in time.[6] For that reason, balloon valvuloplasty is considered an emergency option today as a bridging therapy to surgery or transcatheter aortic valve implantation (TAVI) and as compassionate treatment for some patients. TAVI, initially described by Andersen,[7] was first introduced in 2008 by Cribier for old patients of high surgical risk with symptomatic severe aortic stenosis.[8] The first single-center series showed the feasibility and efficacy of the balloon-expandable Sapien Edwards™ valve (Edwards Lifesciences LLC, Irvine, CA, United States)[9] and the self-expandable CoreValve™, now the Medtronic CoreValve™ (Medtronic Core-Valve, Irvine, CA, United States).[10-12] This was confirmed in a large multicenter Medtronic CoreValve registry.[13] The promising results across the world led to the wider use of this technique in the routine clinical practice with a rapid increase in the implantation rate of both valves.[14]

The right size of transcatheter heart valve (THV) is an important factor to minimize and prevent the complications associated with transcatheter aortic valve replacement (TAVR) such as valve embolization, aortic annulus rupture, paravalvular aortic regurgitation (PAR), and early or late valve thrombosis.

Transesophageal echocardiography (TEE) and multi-slice computed tomography scan (MSCT) are the imaging modalities used to measure the aortic annulus before the procedure, especially MSCT.[28,29]

Most of the actual THV systems require annular oversize for optimal adjustment purposes.[28] Inadequate oversizing can cause heart blockage, aortic root hematoma, and valve dysfunction or rupture. The balloon sizing technique is a valuable additional tool that should be included in the therapeutic armamentarium of TAVR. It can help establish the right size of THV in ambiguous cases of different valve sizes. The size of the balloon can also be used as an imaging modality regardless of the annular size/THV. Patsalis et al. confirmed that nearly 39% of their patients had borderline annular sizes as seen on the transesophageal Doppler echocardiography. They saw a significant reduction of PAR and 30-day and 1-year mortality rates with the use of the balloon sizing technique with aortography and conventional TEE.

Objective

The objective of this study is to show the early experience of a heart team with TAVI plus CoreValve Evolut R valve implantation using the balloon sizing technique in different centers of the inland regions of the country.

MATERIALS AND METHODS

Design

Descriptive, cross-sectional, observational study of 8 high surgical risk patients and an indication for TAVI due to degenerative bicuspid aortic valve.

The study population included a total of 8 patients > 55 years (5 males and 3 females) with symptomatic severe aortic stenosis, high surgical risk, and degenerative bicuspid valve treated with TAVI between May 2017 and March 2019 in different Argentinian hospitals of Córdoba (Sanatorio Del Salvador, Clínica Sucre, Clínica Fusavim), Villa María (Clínica Regional del Sud - Río Cuarto), San Juan (Clínica Santa Clara), and Neuquén (Clínica Pasteur). The decision to treat and perform TAVI was based on heart team consensus. All patients gave their informed consent prior to the procedure.

The study conducted prior to selecting the patients included general assessments and transthoracic echocardiography (TTE) performed by an operator to confirm the diagnosis. MSCT was performed too. Both imaging modalities—TTE

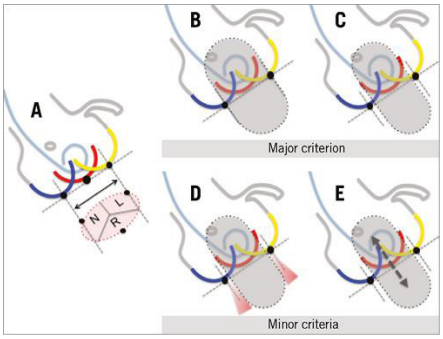


Figure 2. *Schematic view of major and minor criteria for the aortic annulus balloon sizing. A) Obtain the coaxial implantation view. Place the flexible cable catheter in the right coronary sinus and with a fast stimulation infuse 10-15 mL of contrast at a maximum flow rate of 10 mL/s. B) and C) The main criterion for balloon sizing describes the anatomical correlation between the sinus articulation sites and the balloon. In panel B, the balloon is big enough and it can reach the articulation sites; in panel C the balloon is smaller compared to the annulus and cannot reach the articulation sites. D) and E). Minor criteria for balloon sizing describe the functional correlation between contrast contraflow and the balloon movement in relation to the size of the annulus. Panel D shows contrast contraflow with a fully expanded balloon indicative of the insufficient seal of the annulus by the balloon. Panel E shows upward and downward movement of a fully expanded balloon indicative that the balloon is not properly anchored to the annulus.*

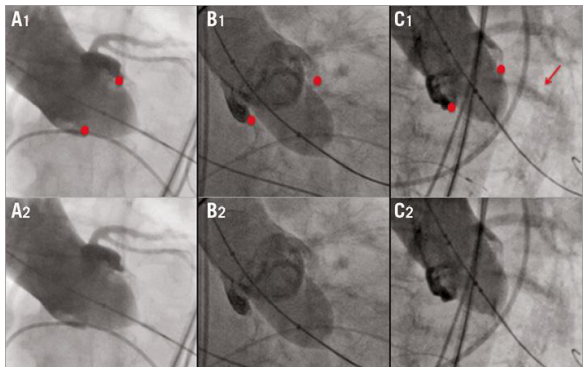


Figure 2. *Cine angiography imaging of major and minor criteria for the aortic annulus balloon sizing. A1/A2) Main criterion: the size of the balloon is able to reach the articulation sites; therefore, the balloon is big enough meaning that a same size THV can be picked. B1/B2) Main criterion: the size of the balloon is smaller compared to the annulus and cannot reach the articulation sites; therefore, the biggest THV of all should be picked here. C1/C2) Minor criterion: the balloon is borderline big, and it is uncertain whether it will be able to reach the articulation sites; however, there is contrast reflow around the balloon. Therefore, the biggest THV of all should be picked here.*

and MSCT—were used to assess the dimensions of the aorta and aortic valve, their morphology, and the degree and distribution of calcifications.

All patients underwent coronary angiography and aortography prior to the procedure in cases where revascularization with angioplasty and stent implantation was necessary. In 100% of the cases the valve was implanted without intraprocedural need for TEE, TTE or general anesthesia.

Techniques and procedures

Valve implantation was basically an elective procedure. Preoperative measurements of the aortic annulus using MDCT were taken followed by valve characterization (bicuspid or tricuspid) (**Table 1; Figure 1**). Cases of bicuspid valve were suspicious of excessive valve oversize with the corresponding complications involved.

During valve implantation it was suggested to use a certain percutaneous valve that matched the perimeter of the valve (bigger valve) and a smaller valve based on the result obtained using the balloon sizing technique.

The balloon sizing technique consists of performing an aortic valvuloplasty prior to valve implantation using a balloon catheter to differentiate the valve annulus and determine the size of the corresponding valve (**Figure 2A**). After a fast enough stimulation between 10 mL and 15 mL of contrast are infused at a flow rate of 10 mL/s to guarantee the optimal visualization of the valve annulus, the degree of anchorage of the balloon catheter, and the presence of regurgitation towards the left ventricle (LV) at maximum balloon catheter inflation pressure (**Figure 2A**).

To choose the right size for the THV when it falls within the "gray zone" between 2 different valve sizes, use balloons with a valve outer diameter that is smaller compared to the size of the balloon. Regarding the Evolut R Medtronic valve, for example, use a 25 mm-balloon when having to decide between a 29 mm or a 34 mm THV. If the 25 mm-balloon has good anchorage and there is no regurgitation towards the LV, a 29 mm-valve should be used. On the contrary a 34 mm-valve should be implanted.

In conclusion: contrast contraflow in the LV during valvuloplasty (**Figure 2D**) suggests that the balloon does not provide enough annular coverage. Therefore, it is advised to choose the biggest THV. Similarly, retrieving the balloon with movement during valvuloplasty (**Figure 2E**) is indicative of the inadequate anchorage of the balloon to the annulus. Therefore, choosing the biggest THV is recommended here.

Figure 3 shows angiographic examples of major and minor criteria for the aortic annulus size with balloon. **Figures 3A1, 3A2**, and motion-based image #1 show the main criterion where the size of the balloon is big enough to reach the articulation sites. In this scenario, a THV of the same size should be implanted. **Figures 3B1, 3B2**, and motion-based image #2 show the main criterion where the size of the balloon is smaller compared to the anatomy of the annulus and, therefore, not big enough to reach the articulation sites; here the biggest size of THV should be used. **Figures 3C1, 3C2**, and motion-based image #3 show the minor criterion where the size of the balloon is borderline big, and it is unclear whether it can reach the articulation sites. However, during the aortogram there is a contrast contraflow both around the balloon and in the LV; here the biggest THV should be used.

RESULTS

Technical success, defined as the implantation of the valve, was achieved in 100% of the cases. Mean age of the population was 70.3 ± 9.2 years and 63% were males. Mean peak transvalvular gradient was 76.17 ± 8.89 mmHg and the mean gradient was 50.83 ± 4.64. Mean valve area was 0.65 ± 0.16 mm (range: 0.5 mm to 0.95 mm). Mean angulation was 50.5 ± 15.77 ranging from 27 to 75; mean sinus size was 25.38 ± 14.98. One patient was already the carrier of a permanent pacemaker before the procedure. The remai-

TABLE 1. General characteristics

Variable	Mean	SD	Min	Max
Peak grad.	76.17	8.89	65	91
Echo pre-TAVI mean grad.	50.83	4.54	45	51
Area	0.65	0.16	0.5	0.95
Perimeter	79.38	9.02	65	90
Angulation	50.5	15.77	27	75
Mean sinuses	25.38	14.98	2	37

TABLE 4. Degrees of aortic regurgitation.

Classification	N	%
Mild	1	0.14
Pre mild - No post	1	0.14
Pre moderate – Post mild	1	0.14
Pre moderate – No post	1	0.14
No AR	2	0.29
No pre – Post mild	1	0.14

ning patients did not require a pacemaker after the implant (**Table 1**).

Sixty-three per cent had an indication for the implantation of the Evolut R34 valve, and 25% for the implantation of the Evolut R26 valve. Of the total, 75% had a raphe and 63% a type I valve (R-L). Twenty-five per cent of the patients had a type 0 valve and 13% a type II valve (R-NC). Regarding the valves implanted, 38% of the patients received the Evolut R29 device, 38% the Evolut R26 valve, and 25% the Evolut R23 valve (**Table 2**). Valves were implanted at a mean height in relation to the annulus of 2.5 mm ± 0.93 mm ranging from 1 mm to 4 mm. In 86% of the cases the surgical access route was the RFA (right femoral artery) and only in 14% of the cases the LFA (left femoral artery) was used. We should mention here that 34-mm valves were not used. Instead 23-mm valves were used whose size was changed after using the balloon sizing technique.

Only one patient, who was also the carrier of a permanent pacemaker, had minor vascular complications (access site hematoma). No cases of death were reported.

We should mention here that based on the perimeter of the valve according to the MSCT 5 different 34-mm valves and 0 23-mm valve were proposed. Thanks to the balloon sizing technique 2 23-mm valves per 0 34-mm valves ended up being implanted.

Residual aortic regurgitation was mild or absent at the end of the procedure in 100% of the patients. No severe aortic regurgitation was reported. When the degrees of aortic regurgitation were analyzed it was evident that the particular situation of each patient was different. Table 3 shows all cases seen.

DISCUSSION

The degenerative bicuspid aortic valve has been an absolute or relative contraindication for TAVI for quite some time now. This has been so because it took a long time it took to predict the behavior of the percutaneous valve in this type of complex valve annulus.

TABLE 3. Characteristics of the valve

Variable		N°	%
Perimeter-based valve	R26 R29 R34	2 1 5	25% 13% 63%
Raphe	With Without	6 2	75% 25%
Valve type	0 Type I (R-L) Type II (R-NC)	2 5 1	25% 63% 13%
Valve implanted using the balloon sizing technique	R 23 R 26 R 29	2 3 3	25% 38% 38%

The TAVI technique has been perfected over time and to this day some still say that the size of the valve to be implanted should only be based on the size of the valve perimeter as seen on the MDCT; currently, a group of interventional cardiologists is developing the balloon sizing technique specifically for these patients anticipating a possible excessive oversizing of much bigger valves and knowing that 20% to 30% oversizing is usually accepted for proper anchoring. This suspicion makes them use prior valvuloplasty with the post-dilatation balloon catheter of the aortic valve right underneath the perimeter-estimated valve with an aortogram simultaneous to balloon inflation.

With this technique, the valve orifice total occlusion using the balloon at maximum expansion can be seen, which involves the use of a smaller size valve. If not possible, an MDCT perimeter-estimated valve is used.

These case registries clearly show less use of bigger valves (34 mm) and much more use of smaller valves with respect to the MDCT planning.

CONCLUSION

The balloon sizing technique is complementary to the multi-slice computed tomography and the size of conventional TEE. This technique is especially useful when there is uncertainty around the annulus actual dimensions, when measures fall within the "gray zone" between 2 valve sizes, and in the following unclear anatomical situations: bicuspid aortic valve, septal bulge. The balloon size imitates valve implantation without having the valve in its actual place; it gives us additional anatomical information not available on the MSCT or TEE imaging. Balloon sizing allows us to assess visually how situations like severe and eccentric calcifications and the cusp volume will affect valve implantation, functional results, and associated complications. The patency of coronary ostia can also be seen during balloon sizing.

For the time being this has been a promising technique with good clinical results. However, since the studies conducted have used small size series, they have not produced a statistically significant impact to be able to recommend the use of this technique in the routine clinical practice.

For the time being the use of this technique that is still under study and research is left at the heart team's discretion.

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