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Valve-In-Valve–Tavi Procedure in Multivalvular Disease Future Perspectives on Young Patients

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Abstract:- Young patients with rheumatic disease almost invariably develop the multivalvular disease. In general, patients with multivalvular disease are more severely for conventional surgical procedures. With the advent of less invasive transcatheter treatment, patients with more than one valve disease are part of the Heart Team's discussion, so that their peculiarities are better understood.A 32-year-old, female patient refers that without having performed any physical effort, he suddenly felt short of breath during walks with a very fast "pulse" and "gasping" when talking.The patient had undergone multivalvular surgery 16 years ago: replacement of the aortic valve with a biological prosthesis (23 mm), and mitral valve annuloplasty with a prosthetic ring (26 mm).Clinical examination showed a pale patient, breathless, and tachycardic. BP: 130 x 55 mmHg, HR: 100 b x min. He had a systolic murmur ++/4+; a diastolic murmur ++/4+, in aortic focus.Doppler echo images showed significant aortic regurgitation, with a flap from one of the cusps of the prosthesis, prolapsed into the cavity of the left ventricle and mild mitral regurgitation. The final diagnosis was: a rupture of the biological aortic prosthesis, followed by acute aortic insufficiency, after the 16th year of follow-up.The patient underwent aValve in Valve (ViV) - TAVI procedure. A Sapien 3 ultra valve, measuring 23 mm, was implanted through a femoral approach inside the dysfunctional biological prosthesis. The procedure was performed successfully, and the patient was discharged from the hospital 2 days later.

Conclusion: ViV-TAVI has become an attractive alternative to redo SAVR in young patients with failed bioprostheses. If there is any limitation to expanding the indications for TAVI or ViV-TAVI procedures for all ages, it is linked to the durability of the prostheses.New expandable synthetic stent valve is already shown in vitro and in vivo tests, greater durability and is free from calcification.

I. INTRODUCTION

Over the past decade, TAVI has changed the management of symptomatic aortic valve dysfunction. TAVI has already been approved in patients with severe symptomatic aortic stenosis across all surgical risk profiles and for patients with failed bioprosthetic valves (BVs). ViV-TAVI[1] has emerged as an alternative to surgical aortic valve replacement (SAVR) in patients at high operational risk, now representing approximately 5% of all TAVI procedures performed in the United States. BVs are increasingly being used for young patients, in preference to mechanical valves, and this will result in a large increase in re-interventions in the near future.

II. CASE REPORT

A 32-year-old woman refers thatwithout having performed any physical effort, has suddenly felt short of breath during walks with a very fast "pulse" and "gasping" when talking.She was admitted to a hospital for clarification of diagnosis and treatment.

A. Previous history.

The patient reports that at the age of 14, she presented with a fever lasting 14 days, which subsided after treatment with antibiotics.Months after this episode, she developed dyspnea on exertion and a heart murmur was detected, and aortic and mitral valve dysfunction was diagnosed. The Doppler echocardiographic study confirmed: Moderate Aortic and Mitral Regurgitation.

With a diagnosis of compatible heart valve disease of rheumatic etiology, she was medicated with Captopril, 25 mg/daily, and Bencetazil (1,200,000 u), every 21 days.

At the age of 16, she has dyspnea intensified, passed to medium efforts, and dizziness. The Doppler echocardiographic study showed dilatation of the left atrium, and left ventricle, due to increased left ventricle end-diastolic and systolic volumes (LVEDV, LVESV). Table 1.

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Personal data	
Height:	158 cm
Weight:	50 kg
Body surface:	1.49 m2
Structural Parameters	
Aorta	28 mm
Left Atrium	48 mm
LV End-diastolic diameter:	66 mm
LV End-systolic diameter:	39 mm
LV End-diastolic volume:	287 ml
LV End-systolic volume:	59 ml
LV Ejection fraction - Teicholz	68 %
LV mass:	175 g x m2

Table 1: Doppler echocardiographic study: Structural parameters. (November 24, 2006)

Doppler echo images showed significant aortic regurgitation and moderate mitral dysfunction. Figure 1.

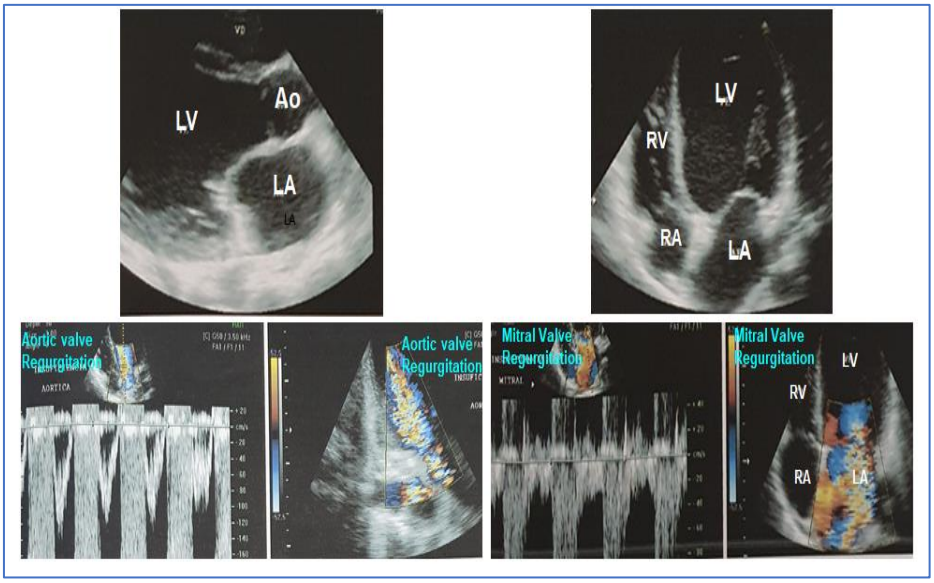

Fig. 1: Echo-Dopplercardiographic study: Moderate Aortic and Mitral regurgitation. (November 24, 2006).

The patient had undergone multivalvular surgery: replacement of the aortic valve with a biological prosthesis (Carpentier - Edwards - Mod. Magna), of 23 mm, and mitral valve annuloplasty with a prosthetic ring (Carpentier-Edwards), of 26 mm.The patient had an excellent recovery and she was discharged from the hospital on the 4th postoperative day.

The echo - Dopplercardiogram performed 13 days after surgery showed: a significant reduction in LVFDD: 46.9 mm, LVFSD: 28.0 mm, LVFDV: 97 ml, LVFSV: 21 ml. The LV-Ao gradient was: 26 mmHg (M:16 mmHg) and LA - LV was: 12 mmHg (M: 7 mmHg). Mitral valve repair proved to be effective, with no restrictions in opening and competent in closing.

The patient was well known, at ourInstitution's outpatient clinic, to have a biological aortic prosthesis and plastic of the mitral valve. She had been followed by echo-Doppler Cardiography, for 16 years, keeping in functional class I (NYHA). During this period, she had 2 pregnancies, without intercurrences, and 2 daughters were born naturally. (5 y, 1 y of age).

B. Clinical examination.

OnSeptember 20, 2022, duringa clinical examination, the patient was pale, breathless, and tachycardic. Blood Pressure: 130 x 55 mmHg, heart rate 100 bxmin. He had a systolic murmur ++/4+; a diastolic murmur ++/4+, in aortic focus.

a) Echo-Dopplercardiographic study
The transthoracic echo-Dopplercardiographic study, showed increased left ventricular area: LVEDV=167 ml, LVESV= 51 ml and left ventricular diameters: LVDD = 58 mm, LVSD=35 and preserved Ejection Fraction= 62%.Table 2

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Personal data	
Height:	158 cm
Weight:	47 kg
Body surface:	1.47 m2
Structural Parameters	
Aorta	29 mm
Left Atrium	48 mm
LV End-diastolic diameter:	58 mm
LV End-systolic diameter:	35 mm
LV End-diastolic volume:	167 ml
LV End-systolic volume:	51 ml
LV Ejection fraction - Teicholz	62 %
LV mass:	203 g x m2

Table 2: Echo-Dopplercardiographic study: Structural parameters. (September 22, 2022)

Doppler echo images showed significant aortic regurgitation, with a flap from one of the cusps of the prosthesis, prolapsed into the cavity of the left ventricle and mild mitral valve regurgitation. The final diagnosis was: a rupture of the biological aortic prosthesis, followed by acute aortic insufficiency, after a follow-up of the 16th year. Figure 2.

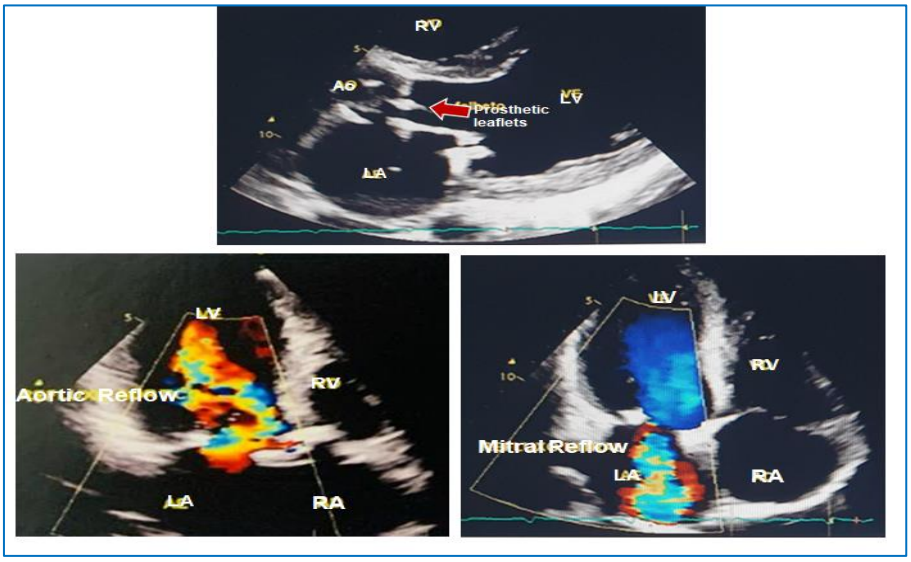

Fig. 2: Doppler echocardiographic study: Important acute Aortic valve insufficiency (Prosthesis rupture) and moderate Mitral valve Insufficiency. (September 22, 2022).

C. Computed Tomography Angiography study.

Computed tomography angiography (CTA) uses an injection of contrast material, into your blood vessels and CT scanning to help diagnose, and obtain anatomical information for the evaluation of the aortic prosthesis structure, internal diameter, position, and height of the coronary Ostia. Figure 3

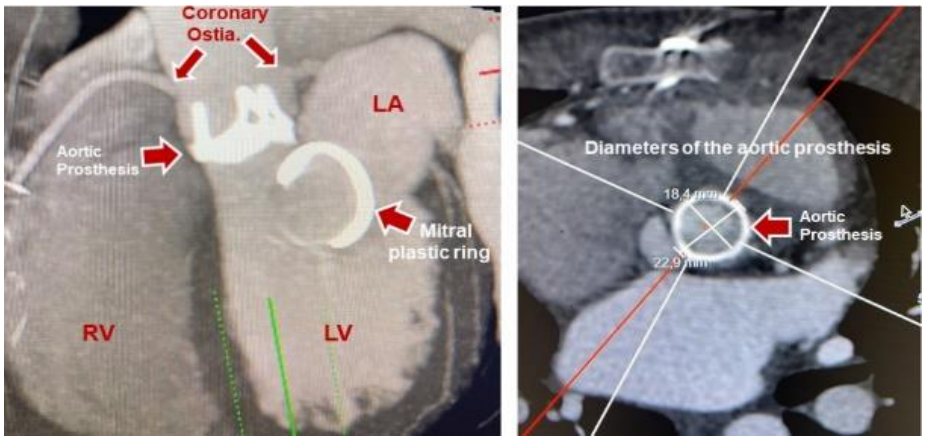

Fig. 3: Computed Tomography Angiographic images show the aortic route, aortic prosthesis, coronary Ostia position, and mitral annuloplasty. (September 22, 2022)

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The young patient was referred to the Heart Time Group, with a diagnosis of multivalvular dysfunction, and it was agreed to proceed with an urgent ViV-TAVI procedure, in accordance with AHA and ACC guidelines.

According to the recommendations and guidelines of these associations, our 32-year-old patient would have the indication of a conventional surgical procedure, to replace a biological aortic prosthesis with a mechanical prosthesis, but several questions were discussed to indicate a valve in valve procedure - TAVI, such as 1- Family factor: mother of 2 small children, one of whom is breastfeeding; 2- Type of heart disease: multivalvular patient (ruptured Aortic Prosthesis + Mitral valve repair, with insufficiency), with the possibility of a new intervention, in a short period of time; 3- Procedure performed: valve in valve TAVI technique, in a low-profile biological prosthesis, with an internal diameter of 18.4 mm; 4- Patient decision: Patient preference for this type of intervention.

The patient underwent an Interventional hemodynamic procedure, Valve-in-Valve (ViV)-TAVI procedure, under general anesthesia and controlled mechanical ventilation.The procedure was monitored with transesophageal echo-Doppler and radioscopic images.

After heparinization, and by means of a puncture of the right radial artery, a Sentinel-type filter system was placed in the brachiocephalic trunk and in the left carotid artery.

Then, under the puncture of the right femoral artery, a 15 FR introducer catheter was placed.By puncturing the right femoral vein, a temporary pacemaker wire was passed and positioned in the right ventricular cavity.

After being chosen, the Sapien 3 ultravalve, measuring 23mm, was conditioned in the balloon catheter and submitted to crimping.

A 23 ml balloon catheter was advanced to the aortic prosthesis to dilate its cusp, preparing the stent valve implantation site, introduced, and navigating through the aorta. With radioscopic and Doppler echocardiographic control, the stent-valve was positioned at the same height as the aortic prosthesis, followed by the activation of the pacemaker, maintaining the heart rate at a rate of 180 b x min. The balloon was expanded with saline and radiopaque barium solution and then expanded within the biological prosthesis route.

A prosthesis positioning test was performed, measuring gradients left ventricle/aorta, assessment of the presence or absence of paravalvular leak, and the success of the procedure was confirmed. Figure 4

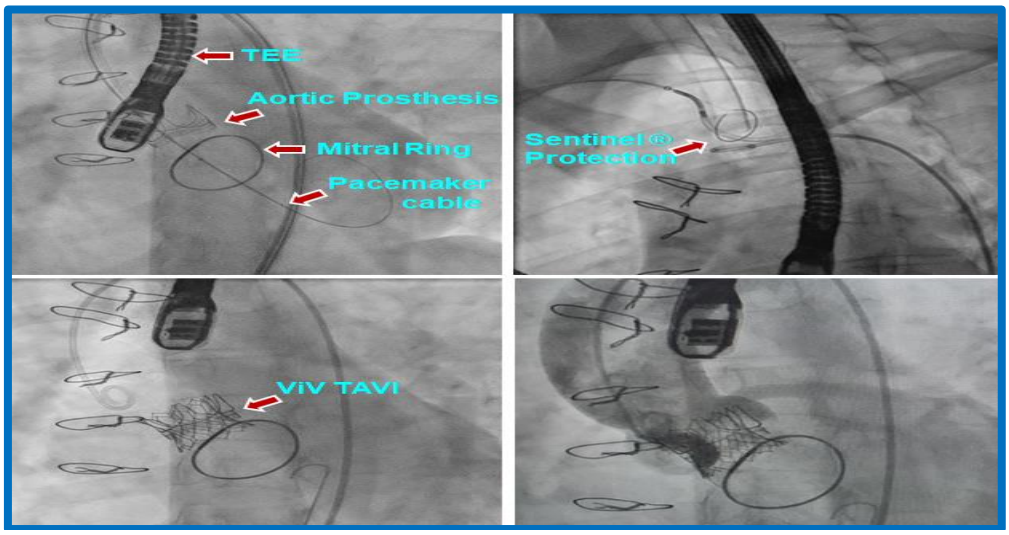

Fig. 4: Radioscopic images of the Valve in Valve (ViV) procedure,Transcatheter Aortic Valve Implant (TAVI). Monitoring with transesophageal echo-Doppler (TEE). Embolization protection with the Sentinel® system

The procedure was concluded, by turning off the pacemaker and removing balloons and catheters, and closing the femoral arteriotomy with a suture system.

The use of percutaneous occlusion devices makes it possible to occlude the access route without the need for surgery, using the Pro Glide device.

After the diameters were completed and the hemodynamic procedure was successfully performed and without complications, the patient was taken to the ICU, in stable hemodynamic conditions, in spontaneous breathing.

The patient was then transferred to the intensive care unit for observation and discharged to the ward the following day, with a remaining sinus rhythm.

One month after the procedure, she showed normal sinus rhythm andremained asymptomatic.

Post-TAVI, Three-dimensional echocardiographic study showed a well-functioning aortic valve with trivial valvular insufficiency. The ejection fraction was 70% with a mean peak and gradient after TAVI of 22/13 mmHg, with a reduction in left ventricular diameters and volumes LVDD: 43 mm, LVSD: 29 mm. The Mitral valve repaired showed mild regurgitation. Figure 5.

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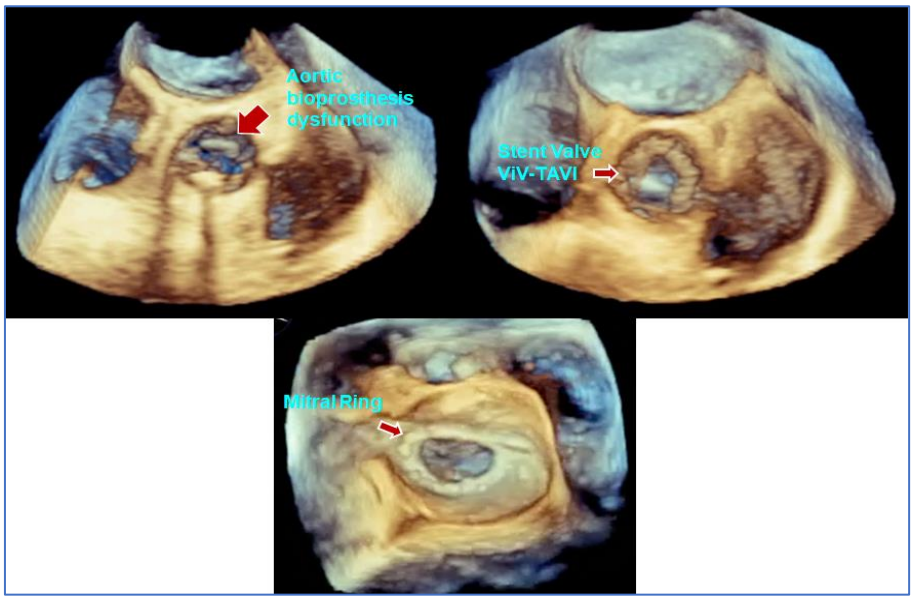

Fig. 5: Postoperative Three-dimensional echocardiographicimagesshow competent stent-valve

III. COMMENTS

With the release of the Partner (Placement of Aortic Transcatheter Valves) 3[2] and Evolut Low-Risk trials[3], TAVI procedures will increasingly include younger, low-risk patients, which could lead to an issue regarding the future management path for patients, with acute aortic prosthesis dysfunction.

Transcatheter aortic valve-in-valve implantation (ViV-TAVI) has become an attractive alternative to redo surgery in patients with failed aortic bioprosthetic valves.[4]

A recent publication, Majmundar et al[5]show that 6,769 procedures were performed, 3,724 (55%) patients underwent ViV TAVI, and3,045 (45%) underwent repeat SAVR. ViV-TAVI was associated with lower in-hospital all-cause mortality (odds ratio [OR] 0.42, 95% confidence interval [CI]: 0.20-0.90, p=0.026) and a higher rate of 30-day (hazard ratio [HR] 1.46, 95% CI: 1.13-1.90, p=0.004) and 6-month all-cause readmission (HR 1.54, 95% CI: 1.14-2.10, p=0.006) compared with repeat SAVR. All secondary outcomes were comparable between the two groups.

Thomas Cuisset[6]read with interest the work of Majmundar et al, published recently by EuroIntervention. Interestingly, a large, matched comparison of valve-in-valve transcatheter aortic valve implantation (ViV-TAVI) versus redo surgical aortic valve replacement (SAVR). He says, we have to congratulateMajmundar and colleagues for providing their updated work, the largest propensity analysis on this subset of patients. Indeed, the number of patients presenting with a failed aortic bioprosthesis is increasing along with life expectancy. Therefore, those patients represent a new challenge for the physician. Recent European guidelines recommend redoing surgery as a first-line treatment in case of failure.

Aortic interventions remain the most effective treatment for severe aortic stenosis. In recent years, advances in bioprosthetics and newer data have reduced the cut-off age for the use of bioprosthetic valves in younger patients, but the debate on whether to favor mechanical valves in younger patients remains a constant, especially with the undesired effects and considerations of anticoagulation therapy with vitamin K antagonists in this age group. Other options like the Ross procedure are gaining traction, despite still being undervalued and necessitating expertise centers.[7]

Hemodynamic considerations and durability of these options are important to consider, especially in this age group. Regardless of the choice of prosthesis, patient-informed consent is paramount since the decision affects the lifetime management of their initial condition, and the expectations given must remain realistic.

Data are mainly available for elderly patients at increased surgical risk. Large registries demonstrated that the procedure can be safely performed in this patient group. Overall mortality at 30 days was 4.6% of 1168 patients in the Valve-in-Valve International Data Registry (VIVID).[8]

In the setting of patients with multi-valve disease(MVD), not only is the timing of the intervention important but even more so is the type of intervention. In the Euro Heart Survey, in-hospital mortality for treatment of MVD was 6.5%, compared with 0.9–3.9% for single-valve disease[9] In the Society of Thoracic Surgeons database, the operative mortality of patients with MVD was twice as high as for patients with the single-valve disease (10.7% versus 5.7%, respectively; p=0.0001)[10]. Furthermore, long-term mortality and, in particular, valve-related mortality in patients undergoing aortic and mitral valve replacement are high.[11]This higher risk must be taken into account when evaluating patients and deciding on the treatment strategy. The possibility of a single-valve operation as an incomplete surgical correction in order to reduce the risk for selected patients should be taken into account. Conversely, a percutaneous intervention may be a lower-risk single-valve treatment.[12]

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Computed tomography would have added significant diagnostic information to influence the treatment plan. Computed, using limited injections of contrast to the coronary, aortic root, and peripheral bed provided the details needed to plan the ViV-TAVI procedure. In addition, non-invasive imaging with echocardiography has been used pre, during, and post-procedure.

The valve position was carefully adjusted, guided by intraoperative imaging with aortic radicular injections. The large distance from the coronary Ostia did not determine the need for dedicated coronary protection procedures. There was no need to recapture the new valve that was perfectly positioned on the first try. No arrhythmia occurred, and good valve function with only a trivial insufficiency wasdemonstrated on echocardiography performed immediately after Sapien 3 valve placement. The patient was hemodynamically stable and did not require inotropic support.

New models of stent valves made entirely with synthetic materials (polyurethane leaflets), have already shown in vitro and in vivo tests, greater durability, and free from calcification. A new design of these synthetic valve stents allows the approach of congenital valve stenosis, being implanted during the correction of heart defects, in patients from 1 year of age (diameter = 14mm). These prostheses can be expanded, in a programmed way, by percutaneous approach, with balloons of increasing sizes, to avoid mismatch.[14]

These new prosthetic models, with biocompatibility tests and FDA certification (Humanitarian Use Device Program), are sterilized with gamma radiation and dry preserved[15], and will soon begin a clinical trial for implantation in pediatric patients, by surgical and adults, by catheter, approach.

ViV-TAVI has become an attractive alternative to redo SAVR in patients with multivalvular dysfunction and failed bioprostheses, in young patients. It can be performed with low procedural risk, but not frequently achieves more favorable hemodynamic results than redo surgery. This may be particularly performed in the case of regular valve sizes and result in longer survival for the patient. Therefore, based on currently available data, the following guidelines should be considered:To facilitate the ViV-TAVI procedure, after bioprostheses dysfunction, surgeons should aim to implant the largest possible valve size, enlarging the aortic annulus when necessary.

IV. CONCLUSION

- The ViV-TAVI procedure, has its limitations when the diameters of the valve annulus do not allow obtaining gradients of less than 30 mmHg. In these cases, the indication of SAVR, will be mandatory.
- Companies should offer prostheses with a fractured valve ring or expandable stents, to get smaller gradients, inViV-TAVI implants.
- The guidelines of the AHA, ACC consider good results with the TAVI or ViV-TAVI procedure, this is sufficient evidence to expand the indications for young patients, currently limited to patients over 65 years of age.
- With the new generation of valve stents, which promise greater durability, it will be possible to offer the TAVI and ViV-TAVI procedure, without limitations, as a less invasive technique, for young, multivalve patients with contraindications to the use of anticoagulants, reducing the number of interventions and a longer and better quality of life for the patient with valvular heart disease.

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