Initial experience in Mexico with the Evolut™ R valve with direct aortic access

Experiencia inicial en México con la válvula Evolut™ R por abordaje aórtico directo

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Abstract

Background: Aortic stenosis (AS) is one of the most frequent valvulopathies in elderly patients. The treatment for AS is heart surgery; however, many patients do not benefit from this treatment because they are considered to be at high surgical or inoperable risk. Transcatheter aortic valve implantation (TAVI) was developed for these patients. **Objective:** To disseminate the feasibility and safety of other access routes for the implantation of transcatheter aortic valves and that it can also be performed in the hemodynamic laboratory. In addition to the rapid growth in technology and knowledge, there is a lot of experience with TAVI already. **Methodology:** One of the limitations is the diameter of the femoral, subclavian, and axillary vascular accesses. This is why other approaches such as the direct aortic approach are sought after, despite the invasive nature of mini-thoracotomy and aortotomy is technically feasible, familiar, and easy to learn for cardiac surgeons. **Results:** In addition, it has been associated with favorable outcomes and a lower rate of complications (bleeding and risk of myocardial injury) and shorter length of stay in the intensive care unit compared to surgery or transapical access. **Conclusions:** Our center successfully implanted the self-expandable aortic valve Evolut™ through direct aortic for presenting a dissection in transverse aorta with possibilities of embolization.

Key words: Aortic. Transcatheter. Direct. Self-expanding. Implantation. Mexico.

Resumen

Antecedentes: La estenosis aórtica es una de las valvulopatías más frecuentes en el paciente mayor. Su tratamiento es la cirugía de corazón, sin embargo, muchos pacientes no se benefician de este tratamiento por considerarse de alto riesgo quirúrgico o inoperables. Para estos últimos pacientes se desarrolló el implante de válvula aórtica transcáteter (TAVI). **Objetivo:** Dar a conocer la factibilidad y seguridad de otras vías de acceso para la implantación de válvulas aórticas transcáteter y que además se puede realizar en el laboratorio de hemodinámica. Además de un rápido crecimiento en tecnología y conocimientos, actualmente ya se tiene mucha experiencia con TAVI. **Metodología:** Una de las limitantes es el diámetro

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de los accesos vasculares femorales, subclavio y axilar. Es por esto por lo que se buscan otros accesos como el aórtico directo, a pesar del carácter invasivo de la minitoracotomía y aortotomía es técnicamente factible, familiar y fácil de aprender para los cirujanos cardíacos. **Resultado:** Se ha asociado con resultados favorables y una menor tasa de complicaciones (sangrado, riesgo de lesión miocárdica) y menor duración de la estancia en la Unidad de Cuidados Intensivos en comparación con la cirugía o el acceso transapical. **Conclusión:** Nuestro centro implantó con éxito la válvula aórtica autoexpandible Evolut™ vía aórtica directa por presentar una disección en la aorta transversa con posibilidades de embolización.

Palabras Clave: Aórtica. Transcatéter. Directa. Autoexpandible. Implantación. México.

Introduction

Aortic stenosis (AS) is the most common cardiac valve disease in developed countries. Its prevalence gradually increases with age: 0.2% at 50-59 years, 1.3% at 60-69 years, 3.9% at 70-79 years, and 9.8% at 80-89 years¹. Transcatheter aortic valve implantation (TAVI) has revolutionized the treatment of AS. TAVI is currently the treatment of choice for patients with high risk and inoperable AS and a therapeutic option for intermediate-risk patients².

The most commonly used access is transfemoral (TF), which is the first option in most centers; however, there is a group of patients in whom TF access is not possible due to the size, tortuosity, or calcification of the femoral vessel. As a consequence, non-TF access alternative routes have been developed, which include transapical, transaortic (TAo), axillary, subclavian, and transcarotid access^{3,4}. There are studies where femoral access was associated with a lower 30-day and 1-year mortality rate in comparison with non-TF access^{5,6}, while others compare TF access with TAo and transapical access, with higher 30-day and 1-year mortality being shown in the transapical group⁷. TAo access can be carried out in most cases except in patients with porcelain aorta, calcium in the catheter insertion area, inaccessible ascending aorta (anatomical deformation of the chest wall), and radiation to the chest^{8,9}. The TAo technique can be more complicated to learn, both in patient selection and implantation technique, which limits its use in low patient volume centers; however, it is a safe technique; the access is a variant of full sternotomy, and therefore, exposure of the aorta is a common skill for a surgeon. In addition, in both surgery and TAVI with TAo access, cannulation of the aorta with two cord sutures is performed, which makes access faster in case of any complication. Aortic rupture and dissections arising from said cannulation are extremely rare and are easier to treat than ventricular rupture. TAo access by mini-sternotomy without opening the pleural cavities is the best approach in patients with poor respiratory function. There is finer control on the positioning due

to proximity to the aortic annulus⁸. As an alternative access to an unfeasible TF route, there are three clear options today: transapical, axillary, and TAo access; it is not necessary to think on a favorite alternative option to TF, but carrying out an individual assessment for each patient is one of the tasks of the multidisciplinary team³.

Aortic access technique

One of the most important aspects of this access is the distance between the puncture on the aorta and the aortic valve plane since there must be enough distance to accommodate the valve during the release, it should be at least 6 cm apart from the annulus. Exposure of the ascending aorta can be carried out either by mini-sternotomy or through a right anterior thoracotomy. To decide the approach technique, computed tomography angiography (CTA) is used⁹: cross-sectional section at the level of the second right costal cartilage, a perpendicular line is drawn from the right border of the sternum, and the percentage of the aorta to the left or right of the midline is calculated. Then, the distance from the outer border of the costal cartilage to the upper outer surface of the aorta is calculated. A right anterior thoracotomy is the access of choice if the aorta is >50% in the midline. Sternotomy will be the approach of choice when the aorta is in the midline, when it is located deeper and when its course is vertical¹⁰⁻¹³.

- Mini-sternotomy: It implies a “J” sternotomy through the second or third right intercostal space or a T-sternotomy through the second intercostal space. The advantages of this technique include familiarity of surgeons with the procedure, the possibility to maintain the pleural space intact (it avoids complications such as pleural effusion), patient rapid recovery, and the possibility to quickly turn it into sternotomy if necessary. It is the best technique when the aorta is at the midline or deeper
- Right anterior thoracotomy: It is commonly performed through the second right intercostal space and is the

Figure 1. **A and B:** Femoral arteries angiography and abdominal and iliac aorta CTA with mild tortuosity and femoral arteries with >5 mm caliber. **C:** Oblique sagittal reconstruction image at the level of the aortic arch where a hypodense linear image is observed, which is projected in the aortic lumen in relation to a flap with punctate calcifications on an atheroma plaque. **D:** Axial section at the level of the sinus of Valsalva, where bicuspid morphology of the aortic valve with irregular calcifications is observed. **E and F:** Asymmetric aortic annulus measurements with diameters of 17 mm $\times$ 26 mm, perimeter of 72.86 mm, and area of 389.1 mm².

technique of choice if the patient has undergone previous sternotomy and has a mammary artery bridge, horizontal ascending aorta (lying down), the aorta is on the right and not far away from the rib cage.

Clinical case

A 68-year-old woman with low surgical risk according to the risk assessment scales (EuroScore II of 2.1 and STS of 3.3%), but at high risk of respiratory complications, with morbid obesity (weight of 93 kg, height of 1.52 m, and BMI of 40.2) and chronic lung disease, diagnosed with symptomatic critical AS. Transthoracic echocardiogram showed bicuspid aortic valve, indexed aortic valve area of 0.7 cm², mean gradient of 47 mmHg, maximum velocity of 4 m/s, and normal left ventricular systolic function. Coronary angiography showed no significant atherosclerotic disease of the coronary arteries. Angiography and CTA of peripheral vessels showed an iliac-femoral system with moderate tortuosity and calcification, but small caliber with 5-mm femoral arteries (Fig. 1A and B); with a dissection of the intima in the aortic arch where a flap is observed (Fig. 1C); native bicuspid aortic valve (Fig. 1D), with an asymmetric aortic annulus, 17 mm $\times$ 26 mm in diameter, with perimeter of 72.86 mm and an area of 389.1 mm², which are measurements that are compatible with an number 26

Evolut™ self-expanding aortic valve (Fig. 1E and F). Performing the procedure by direct aortic access was decided due to poor femoral accesses and to a dissection of the aortic arch with a risk of supra-aortic vessels embolization.

Procedure

The intervention was carried out under general anesthesia and mechanical ventilation. Unfractionated heparin (100 IU/kg) was administered to achieve an activated coagulation time of 200-250 s during the procedure. A pacemaker was placed on the right jugular vein. A 6F pig-tail catheter was inserted through the femoral artery for hemodynamic monitoring and reference aortic angiography. A mini-sternotomy was performed because it is the simplest technique and is the procedure our center has more experience with (Fig. 2A and B) because the aorta was found at a higher percentage toward the left side of the sternum, with a 5-cm incision from the suprasternal notch to the level of the third rib being made to expose the ascending aorta (Fig. 3A and B). Two 3-0 polypropylene concentric sutures were placed on the aortic wall at the desired insertion site ("tobacco bag" suture), with the center of these sutures being punctured with a standard needle and a 6-F introducer sheath with a 0.035" J-tipped wire

Figure 2. A: Computed tomography angiography axial slice, where a larger percentage of the aorta is observed on the left in relation to the sternum. The distance between the second intercostal space of the rib cage and the aorta is 4.4 cm, which makes mini-sternotomy feasible. **B:** Theoretical aortic point of puncture at a distance of 6.9 cm from the aortic valve annulus (red rectangle), which is sufficient for the valve to be deployed.

Figure 3. A: Marking of the surgical site for this minimally invasive surgery, where the area from the second intercostal space to the fourth intercostal space is taken into account. **B:** Exposure of the aorta for the insertion of the 18-F introducer sheath. **C and D:** The 18-F introducer sheath has a Foley catheter fragment placed at about 0.5-1 cm from the tip, which serves for fixation and as a reference for not introducing more than 0.5-1 cm of the introducer sheath into the aorta. **E and F:** Layered closure, with a 5-6 cm wound being left.

being inserted. The aortic valve was crossed with the extra stiff support wire guide placed in the left ventricle. The 18-F introducer has a Nélaton probe ring attached at the tip to prevent the 18-F catheter external part from penetrating the internal portion of the aorta and

damaging internal structures (Fig. 3C and D). The procedure was carried out in the usual way, with direct implantation of a No. 26 Medtronic CoreValve™ Evolut™ R transcatheter aortic valve; post-implantation peak-to-peak gradient was 12 mmHg and no aortic

insufficiency was detected on the aortogram. A transeophageal echocardiogram was performed in the same procedure, with minimal paravalvular leak and adequate expansion and symmetry of the already implanted valve being observed. At the end, the pouch sutures were knotted under direct vision, similar to decannulation, after cardiopulmonary bypass; wound closure was layered (Fig. 3E and F).

Discussion

With the increasing adoption of TAVI as a definitive treatment for severe symptomatic AS, an increase in the absolute number of non-TF cases has been observed, and many centers have focused on direct aortic or subclavian accesses¹⁴. This is a clinical case of a patient with high surgical risk, in whom the medical-surgical team agreed that the most feasible access was TAO, given that the patient had small peripheral vessels (both femoral and left subclavian vessels). This is one of the cases of non-TF access, where another access route has to be sought¹⁵. Studies have shown that mortality decreases with the TF access in comparison with the rest of access routes both at 30 days and 1 year¹⁶. Potential complications of the TAO route are the same as those of the TF route. Perforation of the left ventricle and various injuries resulting from the use of extra stiff guidewire have been described, but they are now very rare given the use of preformed guidewires and careful manipulation of the guidewire within the ventricular cavity¹⁷.

All centers should have experience in an access route other than TF, for those cases where carrying out the procedure through the femoral route is not feasible; however, studies support that the TF access route remains the first option in most centers. Regarding the non-TF accesses, it is necessary to properly select what type of access route is the most appropriate for the patient according to his/her anatomy and all his/her comorbidities, in addition to the technical experience of the valve implanting team.

In the case of our patient, the Evolut™ self-expanding aortic valve was successfully implanted using the TAO route, with its releasing system technically facilitating implantation, which makes it more precise and faster.

Conclusions

With the current data, TAVI can be claimed to be the treatment of choice for patients with severe

symptomatic AS considered inoperable or with high surgical risk. The first option for access route is TF, but the center should always be familiar with non-TF routes given the progressive increase in the use of this technique. Each one of the non-TF access routes has its peculiarities and should be appropriately chosen for each patient.

The TAO access should be considered as a safe alternative to TF access when peripheral vessels are small, highly calcified and with significant tortuosity, with similar success rates to those of the TF route. It is technically feasible despite the invasive nature of mini-thoracotomy and aortotomy and has favorable results, lower complication rate, and shorter stay in the intensive care unit in comparison with transapical access or surgery. New devices such as the Evolut™ self-expanding valve make the TAO access route a feasible and safe option, even in low-volume centers.

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Conflicts of interest

None.

Ethical disclosures

Protection of people and animals. The authors declare that no experiments were performed on humans or animals for this research.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appear in this article.

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