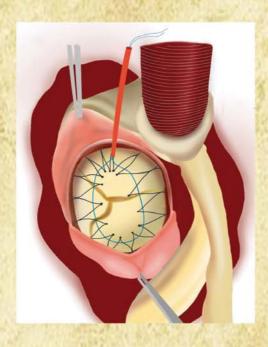
# CIRUGÍA CARDIACA EN MÉXICO

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### CIRUGÍA CARDIACA EN MÉXICO

Official Journal of the Sociedad Mexicana de Cirugía Cardiaca, A.C. and the Colegio Mexicano de Cirugía Cardiovascular y Torácica, A.C.



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#### **CONTENIDO / CONTENTS**



Volume 9 • Issue 3 • July-September 2024

#### **EDITORIAL / EDITORIAL**

77 Surgical aortic valve replacement after TAVR: are we dropping a clanger or meeting a challenge?

Reemplazo protésico aórtico quirúrgico después de TAVR fallido: ¿estamos cayendo en un grave error o enfrentando un desafío?

Ovidio A. García-Villarreal

#### ORIGINAL ARTICLE / ARTÍCULO ORIGINAL

79 An anti-calcifying system. An option against calcification of bioprostheses *Un sistema anticalcificante. Una opción contra la calcificación de las bioprótesis*Alejandro Juárez-Hernández,
Felipe A. Masso-Rojas

#### CASE REPORT / REPORTE DE CASOS

87 Endocarditis post-TAVR treated by surgical aortic valve replacement. Case report Endocarditis post-TAVR tratada mediante reemplazo protésico aórtico. Reporte de caso

Reynaldo J. Jiménez-González, Raúl M. Guillén-Ramírez, Rigoberto Marmolejo-Rivera, Manuela I. Rodríguez-Quezada, Ovidio A. García-Villarreal

91 Valve in TAVR: surgical explantation of transcatheter aortic valve

Válvula en TAVR: explantación quirúrgica de la válvula aórtica transcatéter

José J. Parra-Salazar,

Elizabeth Vera-Domínguez

96 Pulmonary artery banding: An alternative treatment in heart failure. Case report Bandaje de la arteria pulmonar: Un tratamiento alternativo en la insuficiencia cardíaca. Reporte de caso

Carlos Alcántara-Noguez, Alejandro Bolio-Cerdán, Sergio Ruiz-González, Patricia Romero-Cárdenas, Luis E. Martínez-Ortega, Víctor Villadozola-Molina, Manuel Vera-Canelo

101 Atypical presentation of late pulmonary vein obstruction, following the repair of total anomalous pulmonary venous connection. Case report Presentación atípica de obstrucción de venas pulmonares tardía posterior a corrección de conexión anómala total de venas pulmonares. Reporte de caso

Carlos Alcántara-Noguez, José A. Juárez-León, Diana V. Mejia-López, Alejandro Bolio-Cerdán, Alejandra Contreras-Ramos

#### SURGICAL TECHNIQUE / TÉCNICA QUIRÚRGICA

105 Total coronary revascularization via left anterior thoracotomy: a novel approach to achieving comprehensive coronary revascularization

Revascularización coronaria total a través de toracotomía anterior izquierda: un nuevo enfoque para lograr una revascularización coronaria completa

Gustavo A. De La Cerda-Belmont, Arturo Garza-De La Maza, María G. Cepeda-Flores, Jorge A. Chávez-De La Mora, Claudia E. González-Zúñiga, Roberto M. Vázquez-González, César A. Morales-Marín, Fabiola Buelna-Gaxiola, Gerardo M. Flores-Morín, Eliasib Pedroza-Solís



#### **EDITORIAL**

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# Surgical aortic valve replacement after TAVR: are we dropping a clanger or meeting a challenge?

Reemplazo protésico aórtico quirúrgico después de TAVR fallido: ¿estamos cayendo en un grave error o enfrentando un desafío?

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**Keywords:** aortic stenosis, aortic valve, surgical aortic valve replacement, transcatheter aortic valve replacement, TAVR.

Palabras clave: estenosis aórtica, válvula aórtica, reemplazo quirúrgico valvular aórtico, reemplazo transcatéter valvular aórtico, TAVR.

In August 2019, the U.S. Food and Drug Administration approved transcatheter aortic valve replacement (TAVR) for low-risk patients. However, it states that "the long-term durability of transcatheter heart valves compared to surgically implanted valves has not been established. Patients, especially younger ones, should discuss available treatment options with their heart care team to select the therapy that best meets their expectations and lifestyle". This new approval expanding the scope of TAVR, has increased, beyond a shadow of a doubt, the number of patients being candidates for this percutaneous approach.

Although it is true that the latest generation TAVR prostheses are expected to have greater efficiency, the sizeable growth of TAVR usage in the last years brings to the table the issue related to the unknown long-term durability of TAVR, mainly when the patient's life expectancy may turn out longer than this durability.

The reported incidence of TAVR-explant is approximately 0.5 to 2% of the series, which will most likely increase in the upcoming years due to the inclusion of low-risk TAVI and younger patients with the inherent risk of structural valve deterioration.<sup>2</sup> The two alternatives available to treat TAVR failure are redo-TAVR (TAVR-TAVR) or TAVR-explant

(SAVR after TAVR). However, not all patients are susceptible to redo-TAVR, requiring surgical removal of TAVI (TAVR-explant). Redo-TAVR/TAVR-explant ratio has been reported as 1.19, being redo-TAVR more frequently used than TAVR-explant.<sup>3</sup> The main worry is that TAVR-explant is currently associated with high risk of mortality and morbidity.

With the STS database (STS ACSD) having 97% implementation among adult cardiac surgery programs in the US, this registry is highly representative of daily practice in the real world.<sup>4</sup> The results of post-TAVR cardiac surgery using the STS ACSD have recently been released. Between 2012 and 2023, 5,457 post-TAVR operations were registered. Of these, 54.4% were surgical aortic valve replacement (SAVR) after TAVR (TAVR-explant), and 45.5% were non-SAVR after TAVR. The net percentage increase was 4,235.3% throughout the study period, with a constant annual increase of 144.6%. This increase has grown especially since 2019, the year in which the use of TAVR was approved in patients with low surgical risk.<sup>5</sup>

The group of patients undergoing SAVR after TAVR (TAVR-explant) deserves special attention. The operative mortality rate was 15.8%, stroke 4.5%, renal failure 11.1%, combined mortality and morbidity 39%, and permanent

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pacemaker implantation 14.6%. Importantly of note is the high rate of need for some aortic root procedure at 28.8% (13.4% as total aortic root replacement), of which 14.8% had aortic dissection as the primary indication for reintervention. The indication for reoperation SAVR after TAVR (TAVR-explant) was due to endocarditis in 36% of cases, and structural valve deterioration in 64%. Aortic stenosis by echocardiographic study was present in 50.2% of TAVR cases with failure.<sup>5</sup>

In turn, among patients undergoing non-SAVR after TAVR, the most common cause of surgery was coronary artery bypass grafting (33.8%), mitral valve surgery (28.3%), tricuspid valve surgery (9.1%), and ablation procedure (6.6%). Of course, these concomitant procedures seen during reintervention as non-SAVR after TAVR raise the issue of the presence of other cardiac pathologies in the process of TAVR selection, which may not have been efficiently assessed as part of the comprehensive management of TAVR patients.

The low correlation that exists between observed/expected mortality calculated through the current STS-PROM risk scores is truthfully striking. While standard SAVR represents an operative mortality of 1-2%, in SAVR after TAVR (TAVR-explant) the operative mortality rate was 15.8%. That is, the risk for mortality and major morbidity increased between 5 and 10 times. In the case of SAVR after TAVR (TAVR-explant), the EXPLANTORREDO-TAVR International Registry reported a 30-day operative mortality rate of 13.6%, and 32.4% at 1 year.<sup>3</sup> Hawkins et al. reported 17% of operative mortality, which was 1.7 times higher for SAVR after TAVR (TAVR-explant) patients than for redo SAVR patients.<sup>6</sup>

In stark contrast, current data by Narayan et al. have demonstrated that operative mortality was 3.1% for redo SAVR.<sup>7</sup> Survival after SAVR in low-risk patients is currently 92.5% at five years. Furthermore, when STS-PROM was lower than 1%, the survival rate was 95% at eight years.<sup>8</sup> These facts take special importance especially in the era of alternative catheter-based therapies.

In conclusion, SAVR after TAVR (TAVR-explant) involves challenges and special situations, as demonstrated by the fact that 28.8% of the series required some aortic root procedure.<sup>5</sup> In this framework, special surgical techniques

to approach SAVR after TAVR (TAVR-explant) have been properly described.<sup>2</sup> The necessity for cardiac surgery after TAVR is becoming the fastest growing adult cardiac procedure nowadays, with increased risk for mortality and major morbidity between 5 and 10 times when compared to standard SAVR.

In this issue, Parra-Salazar et al. and Jiménez-González et al. publish two cases of SAVR after TAVR (TAVR-explant). It is very presumable that this new reality has already reached us. After analyzing the foregoing, the question arises: are we dropping a clanger or meeting a challenge?

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#### ORIGINAL ARTICLE

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# An anti-calcifying system. An option against calcification of bioprostheses

### Un sistema anticalcificante. Una opción contra la calcificación de las bioprótesis

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#### **ABSTRACT**

Bioprosthetic heart valves are currently the best option for replacing a damaged heart valve. It has been known for several years that calcification (mineralization) represents the main drawback of bioprosthesis. Accordingly, to address this issue, our institution -over 35-year experience in bioprosthesis production-performed research and developed an anticalcification system for bioprosthesis. Our bioprostheses were initially made of duramater and, afterwards, of bovine pericardium. The latter was treated for preservation with glutaraldehyde, a solution that optimally prepares the biological tissue; however, it attracts calcium. The proposed and tested system consists of adding glycine, a simple amino acid, to the general treatment. This treatment prevents calcium from adhering to the biological tissue, which results in a longer functional lifetime than that achieved with traditional treatment. Following satisfactory in vitro and in vivo studies, we proceeded to the clinical phase with 1,362 prostheses successfully implanted so far in all positions within a 10-year period.

**Keywords:** anticalcification treatment, cardiac bioprosthesis, bovine pericardium, duramater, glutaraldehyde, glycine.

In general terms, the use of cardiac prostheses can be considered relatively new, when compared to other types of surgeries. It also applies for cardiac bioprostheses. Since the 1970's, given the multiple problems of mechanical

#### RESUMEN

Las bioprótesis cardiacas son en la actualidad la mejor opción para sustituir una válvula cardiaca enferma. Desde hace varios años se sabe que el principal problema de las bioprótesis es la calcificación (mineralización). Por tanto, en nuestra institución, donde se tiene ya experiencia de 35 años en la elaboración de bioprótesis, se investigó v desarrolló un sistema para tratar de proteger nuestras bioprótesis de este problema. Nuestras prótesis originalmente se hicieron con duramadre y posteriormente con pericardio bovino preservadas con glutaraldehído, solución que prepara bien al tejido biológico, pero que tiene el inconveniente de atraer calcio. El sistema propuesto y probado fue el de agregar un aminoácido sencillo, glicina, al tratamiento general. Este tratamiento impide la adhesión de calcio al tejido biológico, permitiéndole un tiempo de vida funcional más prolongado que con el tratamiento convencional. A partir de estudios in vitro e in vivo muy satisfactorios, se pasó a la etapa clínica, en donde hasta el momento se han implantado 1,362 prótesis en todas las posiciones con excelentes resultados a 10 años.

**Palabras clave:** tratamiento anticalcificante, bioprótesis cardiacas, pericardio bovino, duramadre, glutaraldehído, glicina.

prostheses, homografts were considered as an option in the treatment of some heart valve diseases.<sup>1,2</sup> Over the years, from a hemodynamic point of view, bioprostheses have shown superior qualities than mechanical prostheses. The latter ones

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have a series of drawbacks and limitations, such as the fact that, because of not operating with a single and central outlet flow, they cause exaggerated shear stress (turbulence),<sup>3-7</sup> which finally may be the origin of thrombus formation, with inherent consequences such as impingement on the prosthetic tilting discs, and systemic embolism.<sup>8,9</sup>

On the other hand, anticoagulation can lead to the opposite effect, resulting in risk of hemorrhages. <sup>10-12</sup> These problems can sometimes be a small one, such as those called strands, <sup>13-16</sup> a phenomenon that involves the formation of threads or strands of thrombi that may become emboli and migrate toward the brain. This is particularly important since it has been shown that a large clot is not mandatory at all to produce brain injury. Lifelong anticoagulation has been used in order to avoid this serious problem. In our socio-economic environment, all the above mentioned represents a serious drawback. Not all patients who receive this type of prosthesis have the economic capacity and knowledge to be disciplined in the use of oral anticoagulation. By the same token, a large number of patients with cardiac valve prostheses live in remote locations, with difficult access to medications, in addition to poor INR monitoring.

Furthermore, mechanical prostheses that were initially reputed to be "eternal" have shown important weaknesses in their structure and functioning. In addition to the foregoing, the prosthetic discs do not open and close simultaneously, but often move at different times, increasing the degree of turbulence and therefore the possibility of thrombosis.

Opposed to normal heart valves, mechanical valves do not have a single flow channel, but rather have several and this favors turbulence. Hence, the possibility of thrombosis with this type of prosthesis is notably increased.

To complicate the matter, they may suffer a structural deterioration called cavitation, <sup>17-20</sup> where the coating of the discs is damaged, causing an irregularity in that place that, in turn, is the focus of platelet adhesion and ultimately of thrombi.

There also exists another abnormal phenomenon which is the growth of a new tissue adherent to the ring of the prosthesis with extension towards the mobile discs of the mechanical prostheses, called pannus.<sup>21-25</sup> Limited and even impeded excursions of the tilting discs may result in collapse of the valve function and fatal consequences.

On the contrary, cardiac bioprostheses practically maintains the normal flow of the natural leaflets, providing a single, central, and Newtonian-type flow. All the above prevents all the consequences noted for mechanical prostheses. Furthermore, in cases of structural failure, the possibility for acute failure is somehow minimal, and it allows the patient to have a period of several days to go to a medical center to be treated. Anticoagulation is not essential in patients who are carriers of biological prosthesis. Thus, the quality of life is better than those with mechanical prosthesis.

Much has been written about the durability of both types of prostheses. It was previously suggested that mechanical prostheses were for the whole life of the patient, and biological prostheses had a very short useful life, mainly due to the calcification of the leaflets. However, advancement in bioprosthesis design, by having better preparation, by using new materials for their support apparatus, and especially by adding a protection system, has ended up in a longer lifespan, as much as or even better than mechanical prosthesis. It might as well be the main reason why nowadays mechanical prostheses have been replaced by biological ones practically all over the world.

A few countries, including Mexico unfortunately, cling to the outdated idea that mechanical prostheses are better and more durable. However, experience has shown the opposite. In fact, mechanical prostheses have been replaced by the undeniable advantages of biological prostheses, to the extent that very serious entities such as the American College of Cardiology (ACC) and the American Heart Association (AHA) accept that the most recommended and judicious is to use bioprostheses in the majority of cases, even in young people, <sup>26</sup> as demonstrated by the very recent work of a series of hospitals in England and Ireland, currently being used in almost 80% biological versus 20% mechanical. According to AHA/ACC, in the period spanning from 1999 to 2002, the proportion of implanted mechanical prosthetic decreased from 41 to 33%, with a consequent increase in biological prosthesis from 50% to 65% in the same time frame.<sup>27</sup>

Another rigorous demonstration about this change from mechanical to biological prostheses is represented by Starr's work in 2007. Between 2003 and 2005, the trends reached 80% for the use of bioprostheses in aortic position. Unfortunately, in our country, the situation regarding the use of bioprostheses is exactly the opposite, something totally unexplainable and unjustifiable. An important exception to the above can be found in our institution, where the proportion in recent times for biological prostheses usage is roughly 80%.

In the history of cardiac prostheses, various stages were-described as a part of the development of biological prostheses; namely, heterografts (porcine), <sup>29,30</sup> homografts, <sup>31,32</sup> duramater, <sup>33-35</sup> fascia lata, <sup>36-39</sup> antibiotic-based preparations, <sup>40</sup> and other substances such as chromium mercury, formalin, glycerol <sup>41,42</sup> with somewhat discouraging results. In the 70's, Dr. Alain Carpentier used glutaraldehyde (GA) as a mechanism to more safely prepare these biomaterials. <sup>43,44</sup>

Bovine pericardium is the biological raw material most frequently used for the manufacture of cardiac bioprostheses. The main component of the pericardium is type I collagen, an extracellular matrix protein belonging to a large family of proteins, closely related to each other, known as the collagen superfamily, of which to date have been described in detail at least 17 different genetic types. In the particular

case of type I collagen, there is a generic composition that can be described as the repetition of the Gli X-Y sequence, where the X position is almost always occupied by a proline or hydroxyproline residue, and the Y position is frequently occupied by lysine or hydroxylysine; although this Y position is more variable and can be occupied by other amino acids. Of these 17 types of collagen, 6 are the most important and frequent, and of them, type I is the most numerous and frequent one. Given the evidence that the biological tissues in bioprostheses end up calcifying, many researchers have taken on the task of investigating the causes of the above as well as the shorter duration of bioprostheses. These investigations have clarified several points; nonetheless, not all the mechanisms leading to the aforementioned calcification are totally known. Even so, much progress has been made in this field. 45,46

GA has been identified as a good tissue preparer. It helps to fix and align collagen fibers, making it less antigenic, more resistant and maintaining elasticity.<sup>47</sup> Additionally, it sterilizes biological tissue.

At the same time, alongside these beneficial effects of GA, it is now known that its molecules that remain in the tissues attract calcium that ends up fixing to the bioprosthesis. 48,49 The GA solution aims to fix the tissue, so this solution acts mainly on lysine, hydroxyline, proline and hydroxyproline residues, forming Schiff bases and causing cross-linking of collagen molecules (chemicals bridges) which gives it greater resistance. However, the aldehyde groups that did not react remain free and can react very easily with primary amino groups present in practically all proteins. The secondary amino groups are predominantly found in cationic form at neutral pH and therefore the changes in the net charge of the protein are considerably smaller, making them less reactive.

With this preparation, which guarantees that the collagen fibers are aligned in the tissue and chemical bridges are formed between the various layers of it in the pericardium, it is ensured that the tissue prepared with GA is ductile and resistant, in addition to being sterilized in prostheses manufactured with this treated tissue, but they will always have the threat of calcification.

Due to the process currently followed for the conservation of the pericardium used for bioprostheses, the presence of reactive aldehyde groups, at the time of application, is imminent. For these reasons, these groups function as centers in which molecules present in the plasma, including some cations, can be easily deposited. Therefore, one of the main problems that bioimplants currently present is their tendency to calcify relatively easily and out of control. This calcification could be due, at least partially, to the mechanism explained above.

On the other hand, the use of GA as a protein coupler is widely known and used in a wide variety of biochemical and

immunological techniques. A prime example is the method described by Avrameas to conjugate enzymes to antibodies, or that described by Kishida to couple ferritin or that used by Nicholson to also conjugate hemocyanin to antibody molecules. In all these processes it is essential to eliminate the functional aldehyde groups that remain after conjugating the proteins, given that in most cases, these conjugates will be placed in the presence of other proteins that are potentially reactive due to the presence of free amino groups, chiefly primary aminos. To avoid this undesirable reaction, the aldehyde groups must be blocked. This can be achieved by means of using various amino acids, proteins or substances containing free primary amino groups. This is possible thanks to the presence of amino groups in high concentrations, which interact and completely exhaust the reactive aldehyde groups.

With this preparation, which guarantees that the collagen fibers are aligned in the tissue and bridges are formed between the various layers of it in the pericardium, it is guaranteed that the tissue prepared with GA is ductile and resistant in the prostheses manufactured with this treated tissue, but they will always have the threat of calcification. For this reason, we focused on searching for a protective mechanism by experimenting both in vitro and in vivo by adding to the tissue after preparation, an amino acid, glycine, which is the simplest of the amino acids since it only has one free aldehyde, and by covalent substitution with the GA of the bovine pericardium, eliminates the possibility that its free aldehydes can bind to other substances as they are saturated and neutralized with glycine and there are no free aldehydes in the pericardium where calcium or other substances could be fixed (calcium, cholesterol, iron, lipids, etc.). Therefore, it inhibits calcification, thereby prolonging the lifetime of the prostheses treated in this way.

In light of these data and with the previous clinical experience that bioprostheses do indeed calcify, it exists a current consensus that these prostheses must be protected against calcification. Structural valve deterioration conditions, such as leaflet thickening, failure in movement, and even rupture are factors that may promote the need for reoperation. Figure 1 shows a bioprosthesis with thickened leaflets, calcified and even with rupture of one of them. Thus, it is clear that since biological prostheses are not protected against calcification, they will inevitably end up suffering structural deterioration and shorter lifespan. When some type of protection is used, the clinical follow-up of bioprostheses treated with some anti-calcifying system has shown good results. The durability of bioprostheses with this treatment has significantly improved. In the 80's, when bioprostheses had fewer years of implantation and no anti-calcification system was included, the average survival of bioprostheses was 8-10 years. By improving the designs, materials and, by adding an anti-calcification system, this survival is spanning today



Figure 1: Dysfunctional bioprosthesis.

between 15 and 18 years after implantation, almost 2-fold as a result of the application of all these systems.

At our institution, with the application of this method and 1,362 prostheses placed in 10 years, none of these prostheses has suffered clinical deterioration requiring reoperation. Our results are similar to those previously reported in the literature. Up to date, several techniques have been developed and used to mitigate, reduce or avoid the calcification of bioprostheses. In clinical practice, four major ideas and methods have been applied for this purpose. These methods can be grouped as follows:

- 1. Removal of lipids (phospholipids, cholesterol, etcétera).
- 2. Covalent substitution (INC).
- 3. Detergents.
- 4. Removal of GA (INC investigation).

The first of them (A) is important because the normal lipid components in the pericardium and practically any tissue can attract calcium from the bloodstream, initiating the first stage of calcification, nucleation. The substances most used for this purpose are ethanol, methanol and chloroform.

The second one (B) is also highly important, since the GA with which the pericardium is impregnated, through a chemical reaction, can unite its free amino groups with those of the circulating calcium, thus causing the beginning (nucleation and continuation) of the phenomenon of dystrophic calcification. If these possible unions are covered with other substances (in this case an anti-calcifying system), they can no longer be used by calcium. The most used substances for this purpose

are iron, aluminum and some amino acids. This mechanism is possibly the best and most effective to avoid calcification.

The third of them (C) has a similar purpose to the previous one and the most used substances are sodium dodecyl sulfate, aminoleic acid and L-glutamic acid. Its effect is not as comprehensive as the previous one.

The fourth one (D) is another mechanism to remove practically all the GA from the beginning, seeking to ensure that the possibility of calcium adhesion is minimal. This method implies i) leaving the GA in the tissue for the shortest possible time and therefore the GA concentration will be lower, which means that the possibility of calcium adhesion is minimal, ii) use glycine from the beginning, and iii) do not store the bioprosthesis in aldehyde until its clinical use (which can last months or years and therefore redeposit more aldehyde in the tissue) a method that as a whole protects it from having aldehyde on its surface again and therefore less possibility of calcification. Currently, all the commercial brands that use any of the anticalcification methods, even if they apply it in a professional and strict manner, all end up storing their product in some aldehyde until its clinical use. However, when the prostheses are placed again for months or years in aldehyde, the amount of this that adheres to the tissue easily exceeds the level of protection it previously had, and again there are many suitable amino sites to bind calcium. Finally, the protective effect turns out to be no longer effective.

#### MATERIAL AND METHODS

The method to follow was to carry out the process for this protocol *in vitro* and also *in vivo*. In the *in vitro* process, the tissue used (bovine pericardium) was placed in a 0.5% glutaraldehyde solution at a pH of 7.2 at time intervals that were 24 hours, 7 and 15 days; once prepared with GA, the pericardium was washed with 0.9% physiological solution and then treated with a 5% glycine solution for 24 hours at a temperature of 4 °C. The pericardium was cut into segments of 1 cm square and was stored in a solution with 50% glycerin at room temperature until subcutaneous implantation in guinea pigs *(in vivo)*, which were divided into four groups of six animals each with the treatment shown in *Table 1*.

Table 1: Treatment of the pericardium in subcutaneous implantation in Guinea pigs.

Group	Treated with 0.5% glutaraldehyde	Treated with 0.5% glycine, (hours)
A	24 hours	24
B	07 days	24
C	15 days	24

Two groups of experimental animals were formed. The first of them included 3 subgroups (A, B, C) in which all the samples that were implanted were treated with GA: group A was in it for 24 hours, group B for seven days and group C for 15 days. The twenty-four female Hartley strain guinea pigs were six-week-old with a weight of 375 g on average. On the same day, all animals were anesthetized with ether and an incision was made in the mid-dorsal part of approximately 1 cm, through which the sample was placed subcutaneously; A mark was made for each group of animals according to the implant. The permanence period of the implant was 30, 90 and 180 days, sacrificing two animals from each group in each of these periods and thus removing the implant for its corresponding study.

#### **RESULTS**

The following is shown in *Figure 2*: in *Figure 2A* a rectangular segment of bovine pericardium treated only with GA is observed. *Figure 2B and C* show how the glycine-based treatment completely eliminates the amount of glutaraldehyde that can subsequently be a potential source of calcium fixation.

The analysis of these *in vitro* tests showed that the amount of GA molecules that remain in the tissue thus treated and that can potentially attract other calcium molecules once placed in the patient, practically disappear with the glycine-based treatment. As shown in *Figure 2A*, the amount of GA accumulated in the tissue is very important and the staining demonstrates this. Exposure time of this pericardium was 24 hours, treated only with GA. In *Figure 2B*, exposure time to glutaraldehyde was 7 days, but when it was also treated with glycine for 24 hours, it is shown how the amount of residual glutaraldehyde has decreased considerably. In *Figure 2C*, where the time of exposure to GA was 15 days, when it is

subjected to the anti-calcifying treatment with glycine, the residual GA is practically zero.

Next step was to extract the pericardium segments implanted in the guinea pigs in order to analyze whether calcium had been deposited in them. This is done in equipment (atomic absorption photometer) with a special preparation, which reports the amount of calcium that has accumulated in each pericardium sample. The results were reported in mg/g of dry tissue, based on the previously found basis that the pericardium contains, per se, 2.83 mg/g, as shown in *Table 2*.

The results in *Table 2* demonstrate that in group A, treated only with GA but without the base of the anticalcifying system (glycine) from the beginning, despite the short permanence time of the tissue in GA, the amount of accumulated calcium is already a little higher than that of the pericardium (2.98 versus 2.83) and these quantities increase after 14 days to 9.35 in the animals that had the sample for a month. From group B, the pericardium was also treated only with GA for thirty days, the samples showed even higher figures, 3.96, 8.12 and 12.15. In group C sacrificed at six months, these measurements of the amount of accumulated calcium were 4.83, 15.25 and 22.05, which is much greater than the original of the tissue, an unequivocal sign of the attraction mechanism of both the tissue itself and the GA remaining in the pericardium.

On the contrary, in the pericardium group treated with GA, but with the addition of the anti-calcifying system (glycine), these figures were surprisingly lower. In the first group (A), sacrificed after a month, the calcium report was only 0.399, 0.670 and 1.03, figures that, as can be seen, are even below normal. At three months, these figures have increased slightly to 0.61, 0.927, and 1.20, being this observation the same as for the one-month group. And finally, with the group sacrificed at six months, the samples report calcium quantities of 0.69, 1.01 and 1.52, respectively.

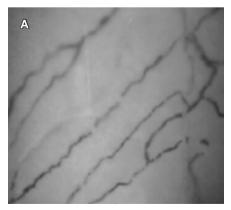






Figure 2: A) (24 hours) shows a rectangular segment of bovine pericardium treated only with 0.5% glutaraldehyde. B) 7 days. C) 15 days with the treatment based on 0.5% glycine for 24 hours. Residual glutaraldehyde is practically zero.

Guinea pigs sacrificed at	Exposure time to glutaraldehyde	Pericardium treated with glutaraldehyde without glycine	Pericardium treated with glutaraldehyde with glycine
One month	24 hours	2.98	0.399
	7 days	4.03	0.67
	14 days	9.35	1.03
Three months	24 hours	3.96	0.61
	7 days	8.12	0.927
	14 days	12.15	1.26
Six months	24 hours	4.83	0.69
	7 days	15.25	1.01
	14 days	22.05	1.52

Table 2: Calcium concentrations\*.

#### **DISCUSSION**

There is no doubt about the preponderant role played by GA in the preparation of biological tissues. On the one hand, it allows the fixation of collagen, making the tissue strong and ductile enough to be used in cardiac bioprostheses. In addition, it sterilizes the tissue, a discovery by Carpentier in porcine bioprostheses, and later asserted by many others in bovine pericardium. <sup>43,44</sup> At the same time, while ensuring these properties, GA entails the peril of becoming a pole of attraction for calcium, and this will translate into rigidity of the prosthesis, even rupture, which considerably reduces the useful life of the biological prostheses (*Figure 1*).

Beyond a shadow of a doubt, bioprostheses have excellent hemodynamics, due to their ability to maintain a central and unique flow, which leads to a quality of life very close to normal, without noise that disturbs the patient (as happens with mechanical prostheses), without the mechanical gradient, without the absolute need for anticoagulation (which is one of the several serious drawbacks that make mechanical prostheses undesirable, or at least riskier). On the other hand, as formerly mentioned, there is the always latent danger for bioprosthesis, especially in young patients, of the aforementioned calcification.

Therefore, finding a mechanism that ensures that bioprostheses do not calcify, or at least that it happens as late as possible, is a premise today. With this procedure that we present here, it is clearly shown, both *in vitro* and *in vivo*, how glutaraldehyde, in addition to fulfilling its purpose of preparing and sterilizing biological tissue, is practically eliminated. In this way, it prevents calcification of biological prostheses. Thus, the real possibility opens up for the use of this type of prosthesis in both young as well as in older patients, with the certainty that the feared phenomenon of calcification has decreased dramatically.

#### CONCLUSION

We can say that bioprostheses are hemodynamically superior than mechanical prostheses. Nevertheless, their useful life can be shortened due to the calcification process caused by the attraction of calcium ions due, in turn, to the use of glutaraldehyde for their preparation and deposited into their collagen. This system developed at our institution (INC) and tested in vitro and in vivo, reduces the possibility of calcium aggregation in such a way that calcification is minimal or at least considerably stopped, thereby lengthening the useful life of the bioprostheses. Notably important is to highlight the fact that this system described herein makes bioprosthesis available and appropriate even for young patients. This procedure has now moved into the clinical stage. In the last 10 years, 1,362 prostheses treated with this system have been placed, without any reoperation due to calcification having been reported so far. This will be the subject of another further report.

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<sup>\*</sup> Calcium amounts are expressed in mg/g of dry tissue.

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#### CASE REPORT

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# Endocarditis post-TAVR treated by surgical aortic valve replacement. Case report

Endocarditis post-TAVR tratada mediante reemplazo protésico aórtico. Reporte de caso

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#### **ABSTRACT**

The current ever-increasing use of TAVR to treat aortic stenosis through all ranges of surgical risk, as well as in younger patients, has begun to pay the price of the challenge, with the complications inherent to such a procedure. Infective endocarditis has been identified as one of the causes for TAVR failure. Even when the overall incidence of infective endocarditis is around 2%, surgical aortic valve replacement to treat such complication is underused in real-world practice. We describe here the case of a 76-year-old male patient diagnosed with post-TAVR endocarditis, who underwent surgical aortic valve replacement for TAVR removal.

**Keywords:** aortic valve disease, aortic stenosis, infective endocarditis, surgical aortic valve replacement, TAVR, TAVR failure.

ortic stenosis (AS) is the most frequent valvular disease in developed countries. As a matter of fact, aortic valve diseases are responsible for 61% of all valvular heart disease deaths. The prevalence of AS increases with increasing age of the population. It ranges around 0.2% at 50 to 59 years,

#### RESUMEN

El uso actual cada vez mayor de TAVR para tratar la estenosis aórtica en todos los rangos de riesgo quirúrgico, así como en pacientes más jóvenes, ha comenzado a pagar el precio del desafío, con las complicaciones inherentes a dicho procedimiento. La endocarditis infecciosa ha sido identificada como una de las causas del fracaso del TAVR. Incluso cuando la incidencia global de endocarditis infecciosa es de alrededor de 2%, el reemplazo quirúrgico de la válvula aórtica para tratar dicha complicación está infrautilizado en la práctica del mundo real. Describimos aquí el caso de un paciente masculino de 76 años con diagnóstico de endocarditis post-TAVR, sometido a reemplazo valvular aórtico quirúrgico para remoción de TAVR.

Palabras clave: enfermedad valvular aórtica, estenosis aórtica, endocarditis infecciosa, reemplazo valvular aórtico quirúrgico, TAVR, TAVR fallido.

1.3% at 60 to 69 years, 3.9% at 70 to 79 years, and 9.8% at 80 to 89 years of age.<sup>2</sup> The current American clinical guidelines for the treatment of valvular heart disease establish a series of recommendations to treat AS. Transcatheter aortic valve replacement (TAVR) or surgical aortic valve replacement

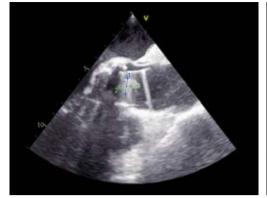
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Echocardiographic study that shows a large vegetation on transcatheter aortic valve replacement endoprosthesis.

(SAVR) are recommended as class of recommendation I Level of Evidence A in AS symptomatic patients between 65 and 80 years of age, while TAVR is recommended as indication IA over SAVR in patients older than 80 years-old.<sup>3</sup> Thus, TAVR has quickly surpassed the usage rates of traditional SAVR, with a relation TAVR:SAVR as 3.4:1 in 2019.<sup>4</sup>

Figure 1:

With the increasing rise in TAVR usage, the complications inherent to this technique have been constantly increasing. Causes of SAVR after TAVI failure are multifactorial; degenerative, physical or infectious factors can be identified. The incidence of early infective endocarditis (IE) after TAVR has been reported as 0.86%, late IE of 1.3% (mean follow-up of two years) and overall IE of 2.0% (mean follow-up of 3.4 years).<sup>5</sup> Although the incidence of IE is very similar in TAVR and SAVR, overall mortality has been reported higher in TAVI patients (43%) than in SAVR patients (32.8%).<sup>6</sup> Moreover, annular abscess is described in 34%, and mitral valve involvement in 31% of cases of IE after TAVI. Also, mitral valve replacement has been reported as necessary in 22% of the series. Postoperative in-hospital mortality for SAVR after TAVR for IE is described in 28%. Opposed to the above, medical management entails overall hospital mortality of 47%, and 66% at 1-year follow-up. Heart failure and septic shock have been identified as factors associated with increased in-hospital mortality.8 Hence, SAVR after TAVR failure due to IE seems to be the preferable treatment of choice, particularly if severe TAVR failure, heart failure, or local extension of the infection are present. Despite this fact, SAVR after TAVR is performed in only approximately 20% of series.9

We describe here one case of IE after TAVR, which was successfully treated by means of SAVR.

#### **CASE DESCRIPTION**

We present herein the case of a 76-year-old male patient diagnosed with post-TAVR endocarditis. In August 2023 he underwent TAVR for symptomatic aortic stenosis. The patient

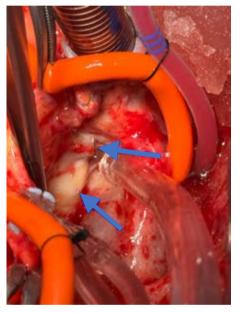


Figure 2:

Intraoperative view of the aortic root. Blue arrows indicate the unexpected finding of aortic wall perforations due to transcatheter aortic valve replacement stented struts emerging through aortic root.

was admitted for repetitive dizziness and anemia, which required treatment with a transfusion of 4 red blood cells. Due to clinical neurological data, after a screening protocol, hematoma versus left occipital frontal subdural empyema was diagnosed. Given the presence of a diastolic murmur in the aortic focus, the patient was studied by echocardiographic study demonstrating the presence of moderate-severe aortic regurgitation, without significant transaortic gradient, and the presence of multiple vegetations in the aortic endoprosthesis (TAVR), the largest of which was 1.3 by 1.5 cm in diameter (*Figure 1*).

On April 2024, the surgery was performed through standard sternotomy, with extracorporeal circulation and aortic cross-clamping times of 151 minutes and 118 minutes, respectively. Intraoperative findings were three lacerations in the aortic wall (*Figure 2*), aortic endoprosthesis (TAVR) with multiple vegetations on the entire surface of all the three leaflets

(*Figure 3*), a heavy calcified native valve and annular abscess that extended to the ostium of the left coronary artery. The endoprosthesis (TAVR) was removed (*Figure 4*). In addition, annulus repair and native valve removal were performed, combined with aortic root repair with ePTFE patch and pericardium to repair the lesions caused by the endoprosthesis (TAVR) (*Figure 5*). The postoperative course was uneventful, being discharged on the 9th day after surgery. The patient has been checked in the output clinic, with full recovery and free from any major adverse cardiac event.

#### COMMENT

As the use of TAVR expands, complications related to this transcatheter technique become more common.

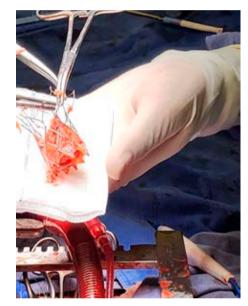
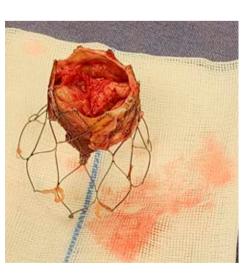


Figure 3:

Transcatheter aortic valve replacement endoprosthesis explanted.

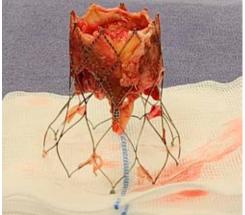


According to data coming from 2019, the most frequently seen complications after TAVR are as follows: in-hospital mortality of 1.3%, 30-days mortality of 2.5%, 1-year mortality of 16%; in-hospital stroke of 1.6%, 30-days stroke of 2.6%; 30-days permanent pacemaker of 10.8%; 30-days moderate-severe regurgitation of 1.6%. Overall incidence of infective endocarditis has been described as 2%.

Although there are two treatment options for TAVR failure, SAVR after TAVR (TAVR-explant) and redo TAVR have been used in fairly similar proportions. The reported incidence of TAVR-explant is approximately 0.5 to 2% of the series. Out of them, the indication for reoperation SAVR after TAVR (TAVR-explant) is due to endocarditis in 36% of cases, and structural valve deterioration in 64%.<sup>10</sup>

As formerly described yet, SAVR after TAVR failure due to IE is indicated particularly if severe TAVR failure, heart failure, or local extension of the infection are present. Our case presented here showed sepsis clinical data including persistent fever and anemia requiring several red bold packs. Although the patient had dizziness, no evidence of AV block or any other electrocardiographic abnormality was documented. The presence of a heart murmur indicative of aortic regurgitation in the presence of TAVR several months before, led us to an echocardiographic study, whose main findings were vegetations in the TAVR endoprosthesis (one of them > 1 cm in diameter, with a high probability of embolism), in addition to moderate-severe aortic regurgitation.

In our case, both echocardiographic findings were indicative for SAVR after TAVR (TAVR-explanted). Of note, in cases of IE of TAVR, despite operative mortality is much better with early surgery compared to conservative medical management (28 vs 43%), no additional benefit was found in the previous literature. In fact, only roughly 20% of cases for IE after TAVR undergoes SAVR after TAVR (TAVR-explanted). We are convinced that the management of IE in



Transcatheter aortic valve replacement endoprosthesis explanted with multiple vegetations and signs of edema on all prosthetic leaflets.

Figure 4:

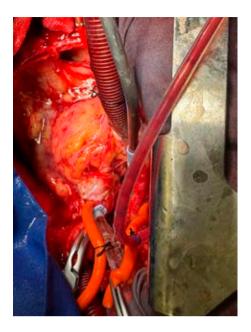


Figure 5:

Final view of the aortic root after repair using PTFEe and pericardial patch.

TAVR should be the same as that applied in cases of prosthetic valve endocarditis: uncontrollable infection, extravalvular extension, severe prosthetic failure, heart failure, and presence of vegetations at risk of embolism. In this case, one vegetation > 1 cm in diameter was present and at high risk of embolism. In addition, severe TAVR failure as severe aortic regurgitation was also indicative for surgery.

Some other findings not seen at the echo were also observed in the operating room. Multiple vegetations on all three aortic leaflets of TAVR endoprosthesis, and periannular abscess extended towards one of the coronary ostia. The unexpected finding of three aortic wall perforations due to TAVR stented struts made aortic root surgery necessary, together with the installation of an aortic prosthesis, just as previously described by Bodwish et al. in 28.8% of cases for SAVR after TAVR (TAVR-explant). <sup>10</sup>

When compared to previously described in TAVR de novo complications,<sup>4</sup> SAVR after TAVR (TAVR-explant) is more dangerous, with operative mortality rate of 15.8%, stroke of 4.5%, renal failure of 11.1%, permanent pacemaker implantation of 14.6%, and the need for some aortic root procedure of 28.8%.<sup>10</sup> Although our case had a complication-free postoperative evolution, operative mortality in these

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cases has been reported to be 15.8%. <sup>10</sup> That means an increase between 5 and 10 times when compared to standard SAVR.

#### CONCLUSIONS

It is important to remark, when thinking in expanding the use of TAVR in low-risk and younger patients, the unnecessary risk of a disproportionate increase in terms of morbidity and mortality. SAVR after TAVR (TAVR-explant) should be highlighted as a real and definite treatment in cases of IE after TAVR.

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#### CASE REPORT

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# Valve in TAVR: surgical explantation of transcatheter aortic valve

Válvula en TAVR: explantación quirúrgica de la válvula aórtica transcatéter

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#### **ABSTRACT**

Aortic stenosis is the most common valve disease in the population. The treatment of excellence has been surgical valve replacement. In recent years, new prostheses have been developed for patients at high surgical risk through the transcatheter approach. We present the case of a man who underwent transcatheter valve replacement; five years later, he developed febrile symptoms that did not remit with antibiotic therapy. After the studies performed, the transcatheter device was surgically explanted due to prosthetic infective endocarditis.

**Keywords:** transcatheter aortic valve replacement, TAVR associated infective endocarditis, surgical explantation of TAVR.

ortic stenosis (AS) is the most prevalent valve disease worldwide. Their prevalence increases with age. The prevalence is important mainly in the elderly. It affects 0.2% of people between 55 and 64 years of age and about 2-7% of those over 65 years of age. Given that the prevalence increases as the population ages, it is expected to increase in the coming years. By 2030, it is estimated that approximately 4.5 million people will suffer from this valve disease.

The etiology is mainly due to congenital and acquired causes. The most common cause of acquired AS is degenerative. It is mainly due to calcification and thickening of the aortic valve which reduces flow.<sup>3</sup> Congenital bicuspid

#### RESUMEN

La estenosis aórtica es la valvulopatía más frecuente en la población. El tratamiento de excelencia ha sido la sustitución valvular quirúrgica. En los últimos años se han desarrollado nuevas prótesis para pacientes con riesgo quirúrgico alto a través de abordaje transcatéter. Presentamos el caso de masculino quien se sometió a reemplazo transcatéter; cinco años después desarrolla cuadros febriles que no remiten ante antibioticoterapia. Después de estudios realizados, se realiza explantación quirúrgica de dispositivo transcatéter por endocarditis infecciosa protésica.

Palabras clave: reemplazo valvular aórtico transcatéter, endocarditis infecciosa asociada a TAVR, explantación quirúrgica de TAVR.

aortic valve hinders blood flow, which increases the development of early AS and calcification. Typically, the aortic valve area normally measures 3.0 to 4.0 cm<sup>2</sup>. When a significant reduction of the valve orifice area below 1.5 cm<sup>2</sup> occurs, an increase in transvalvular gradient is generated.

Treatment consists of a choice between surgical aortic valve replacement (SAVR) or transcatheter aortic valve replacement (TAVR). Surgical risk stratification of the patient plays an important role in the management that the patient will receive in this pathology. Identification of patient risk status is performed using the Society of Thoracic Surgeons-Predicted Risk of Mortality (STS-PROM).<sup>4</sup> SAVR has been

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the standard for treating severe and symptomatic AS for a long time, although in the last decade the transcatheter technique has been implemented.<sup>5</sup> SAVR is recommended in younger patients who are at low risk for surgery.

TAVR has taken relevance as management for patients with AS who are inoperable or who are at high (> 8%) or intermediate (> 4%) risk according to STS-PROM.<sup>6</sup> Its preference is recommended above all in older patients (> 75 years) and especially in patients at high risk (STS-PROM > 8%) or unsuitable for surgery. As in SARV, the characteristics of each patient should be considered, such as: previous cardiac surgery, especially in cases where there are coronary artery bypass grafts that may be injured during repeated sternotomy, elderly patients with severe fragility, assessment of the possibility of an adequate transfemoral approach or the condition of the aorta (porcelain aorta).<sup>7</sup>

Due to the increase in TAVR, it is important to consider the possible complications that may occur after the procedure. Five common periprocedural complications have been described that affect the long term after transcatheter valve replacement. The five complications mainly described are stroke, acute renal failure, moderate to severe paravalvular leakage, vascular complications, and conduction disturbances.<sup>8</sup>

In recent years, the indications for the use of TAVR have expanded, which has led to an increase in the number of complications. TAVR-associated infective endocarditis (TAVR-IE) is an uncommon complication, but is associated with high morbidity and mortality. Regarding the comparative occurrence of TAVR-IE or in SAVR, in an analysis of the PARTNER 1 and PARTNER 2 trials, the incidence and mortality in both groups were analyzed. The incidence of occurrence was similar in both groups, presenting 4.10 cases per 1,000 person-years in the SARV group, while in the TAVR group it was 5.21 cases per 1,000 person-years. <sup>10</sup>

With regard to the TAVR-IE presentation, there is little concrete information on its presentation. There is growing interest in infections occurring after TAVR. Kaur, et al<sup>9</sup> in their single center cohort study analyzed risk factors, microbiological

patterns and assessed the average time in which TAVR-IE developed. They established the time of onset of the disease according to early (one year) onset, as well as the predominant risk factors and microbiological patterns. In the cohort studied, ten of the 494 cases studied corresponded to TAVR. The incidence was predominantly in women. The presentation according to temporality was intermediate onset in 60% of the cases. The most common organism isolated was staphylococcus aureus in 66.6% of the cases. Mortality was present in 40% of the cases. In patients with early and intermediate onset it was 25% and in the late-onset group it was 100%.

#### **CASE DESCRIPTION**

76-year-old male patient with a history of pacemaker implantation 17 years ago secondary to third-degree atrioventricular block. 5 years ago with a diagnosis of severe aortic stenosis (severe aortic stenosis (valve area 0.65 cm²). Percutaneous implantation of Core Valve Evolut R 24 mm aortic valve was performed.

The current condition started one year ago with febrile episodes of up to 41 °C. He received private care with empirical antibiotic treatment with partial improvement in one month. After this first febrile condition, presented again different symptoms that required multiple hospitalizations, receiving various antibiotic regimens without clinical improvement. Seven months after the onset of symptoms, he presented febrile symptoms accompanied by adynamia and weight loss of 10 kg. Cultures were taken and staphylococcus sanguinis was reported, and antibiotic schedules with levofloxacin and clindamycin were started. Subsequently, he presented new febrile symptoms, performing cultures in particular media, with no isolated pathogen.

A transesophageal echocardiogram was performed in which vegetation attached to the electrode crossing the tricuspid valve was observed in the right atrium. It presents motility, occasionally entering the right ventricular cavity and measures  $31 \times 17$  mm with an area of  $4.6 \text{ cm}^2$ . At the

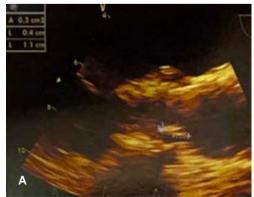




Figure 1:

Preoperatory ecocardiogram.

A) Image suggestive of vegetation in mechanical prosthesis in aortic position of probable periaortic abscess of anterior location. B) Image suggestive of vegetation attached to ventricular pacemaker electrode crossing tricuspid valve.





**Figure 2: A)** Intraoperative image demonstrating collapse of the distal nitinol frame of the prosthesis supported by circumferential placement of Kelly clamps. **B)** Transcaterer prosthesis (Core Valve type) explanted with evidence of endothelialization throughout its frame.

level of the aortic prosthesis there is an image suggestive of vegetation extending into the anterior portion of the aortic root suggesting a probable periaortic abscess, on Doppler analysis with no evidence of rupture (*Figure 1*). Severe left ventricular dysfunction was reported, left ventricular ejection fraction of 29%, so it was decided to perform cardiothoracic surgery.

For surgical resolution, a median sternotomy approach was performed. Pericardial opening and marsupialization of the edges is performed. The pericardial was opened and subsequent marsupialization of edges. Purse-string is placed in the aorta, right atrium and right superior pulmonary vein for cannulation. Subsequently, aortic clamping was performed and cardioplegia was administered until electromechanical arrest. For the resection of the valve prosthesis, aortotomy was performed, finding the valve prosthesis in a ortic position. The prosthesis is removed. Four kelly smith clamps are placed circumferentially on the nitinol frame for collapse (*Figure 2A*). Once the distal end of the prosthesis has collapsed, careful blunt dissection of the remainder of the prosthesis from the aortic wall is performed. The prosthesis was fully explanted (Figure 2B). Post-extraction remodeling of the valve site is identified. The native valves were resected and decalcification of the annulus was performed. A PTEF felt patch is placed over the aortic annulus and a 2-0 ethibond valve suture is placed. Edwards lifesciences perimount magna ease aortic biological valve number 25 mm is measured, descended and knotted. After valve replacement, the distal pacemaker leads are removed. The distal portion of the leads were successfully removed and a definitive epicardial pacemaker was placed. Raffia and subsequent aortic unclamping is performed.

Decannulation and cessation of extracorporeal circulation without complications. Hemostasis, drainage placement, and plane closure are verified. Extracorporeal circulation time was 152 minutes and aortic clamping time was 115 minutes. A total of 20,000 IU of heparin and 324 mg of protamine are used.

After surgery, required 11 days of hospitalization, without complications. Two months later, a control echocardiogram was performed. A normal functioning mechanical prosthesis was reported, with adequate mobility of the valve, without the presence of masses or thrombi adhered to its surface. Without presence of paravalvular leak. Maximum gradient 17 mmHg.

#### **COMMENT**

Aortic stenosis is one of the most prevalent valve diseases worldwide. Due to this, the development of new devices and techniques for its treatment is essential. Transcatheter aortic replacement is a less invasive option that is preferred to be performed in high surgical risk patients with valvular disease. The treatment of choice has been based on surgical replacement of the valve through median sternotomy or through minimally invasive techniques. The new valve replacement management options have been adapted more frequently in most cardiovascular care centers and to the population. It is preferred in elderly patients with high and intermediate surgical risk, with adequate anatomy.<sup>9</sup>

We present the first case of transcatheter device explantation in our institution. The development of endocarditis in the post-TAVR setting is feared and rare. In a 2020 review by Ostergaard, et al<sup>11</sup> reported the incidence to be between 0.7-3.0% per person per year. Fifty percent or more of patients presenting with TAVR-IE had surgical indication, only 16.4% or less underwent resolutive surgery.

The surgical explantation of aortic valve bioprostheses is increasing and its clinical impact is substantial in patients who require it. It is of great importance to assess the clinical and stability of the patient at the time of diagnosis of TAVR-IE. In surgery for transcatheter valve explantation, the possible damage and anatomical modification that the area has undergone must be analyzed. This leads the cardiothoracic surgeon to face scenarios of uncertainty and requires difficult decisions to be made when treating these patients.

In a retrospective case study by Fukuhara, et al<sup>12</sup> where they analyzed surgical explants of transcatheter bioprostheses. Seventeen patients were included. Once the data were analyzed, the indications for explantation were found to be: the main paravalvular leak in seven patients (41.2%), followed by structural valve degeneration in 4 (23.5%), valve migration in 2 (11.8%), intraoperative coronary obstruction in 2 (11.8%), prosthetic valve endocarditis in 1 (5.9%). Postoperative mortality was 11.8%. This retrospective review provides important information regarding the surgical

technique used in the different explants. It is important to mention that this review not only describes the surgical technique for explantation due to endocarditis, but also deals with explantation due to different etiologies. This provides a comprehensive overview of the appearance of the valve at the time of its removal. All explants were performed in a single center. The approach was via median sternotomy, regardless of whether concomitant cardiac surgery was required. The aortotomy was oblique or transverse. The instrument that was essential for the surgery consisted of the use of a Kocher clamp. The use of the clamp made it possible to keep the nitinol frame compressed by means of a crushing maneuver to facilitate extraction. Depending on the time of implantation, different compromises of the anatomy were found. In prostheses implanted < 6 months, there were few adhesions at the level of the stent frame and the aorta. Their release was achieved by eliminating the radial force of the prosthesis to the annulus using a Kocher clamp. No damage to the aortic annulus, anterior mitral leaflet or left ventricular outflow tract was identified. In prostheses older than 1-year, aortic neo endothelialization was observed throughout the prosthesis. The prosthetic leaflets were heavily calcified. Endothelialization predominated at the aortic root and sinotubular junction. Release of the prosthesis required endarterectomy to separate the prosthesis from the aortic wall.

Several techniques have been described in the literature on retro transcatheter prosthesis. Of the first reports in the literature is the one described by Albes, <sup>13</sup> he describes the removal due to paravalvular leak. He proposes that after

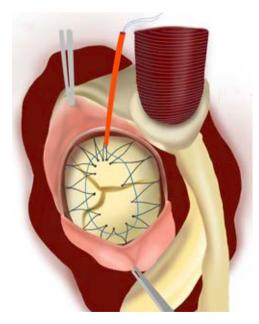
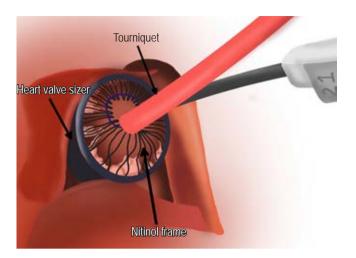


Figure 3: Graphical representation of the "tourniquet technique" for valve prosthesis collapse.



**Figure 4:** Graphic representation of the "heart valve sizer technique" for transcatheter valve prosthesis explantation.

aortotomy, the prosthesis should be bluntly dissected. After widening the access, a braided suture is passed through the nitinol frame in the form of a tobacco pouch and a tourniquet is placed, "tourniquet technique" (*Figure 3*). In this technique, when the tourniquet is placed, it collapses the frame and allows easier manipulation of the rest of the prosthesis.

Another more recent publication by Corona, et al<sup>14</sup> proposes a technique of explantation with the support of heart valve sizer. This case report presents a 68-year-old male patient with a diagnosis of critical stenosis in whom a transcatheter aortic prosthesis was placed. This report corresponds to the first case of transcatheter prosthesis explantation in Mexico. At six months follow-up, the patient presented severe paravalvular leakage requiring explant of the prosthesis 137 days after its placement. It was replaced by a biological prosthesis surgically. The proposed technique consists of using a circumferential suture through the nitinol frame and with the support of a tourniquet the distal end of the prosthesis is collapsed. For the extraction, a heart valve sizer was slid in. This allowed a progressive collapse of the annular portion, "heart valve sizer technique" (*Figure 4*).

#### **CONCLUSIONS**

According to this literature, explantation of transcatheter prostheses is a challenge for the cardiothoracic surgeon. Most of the techniques described did not involve endocarditis of the prosthesis as in our case. With respect to our case, the development of endocarditis in our case occurred five years, 1971 days after transcatheter prosthesis placement. During explantation in our case, Kelly smith forceps were used. The attachment of the proximal portion and the advanced neo endothelialization process made its extraction difficult. The

objective of exposing various techniques of transcatheter prosthesis explantation, allows us to know the possibility of techniques that we can use. Although we do not have a standard norm for explantation, knowing what has been done allows us to have shortcuts for future cases. Each case must be individualized and the surgeon must use the tools at his disposal at the appropriate time depending on the modification of the anatomy involved. In our case, the advanced process of endothelialization and remodeling of the valvular site was a challenge. In addition, the time since prosthesis placement was a factor against facilitating explant.

#### **ACKNOWLEDGMENTS**

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#### CASE REPORT

Vol. 9 No. 3 July-September 2024 doi: 10.35366/116099



# Pulmonary artery banding: An alternative treatment in heart failure. Case report

Bandaje de la arteria pulmonar: Un tratamiento alternativo en la insuficiencia cardíaca. Reporte de caso

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#### **ABSTRACT**

Terminal heart failure is a significant cause of morbidity and mortality in the pediatric age group. The definitive treatment is a heart transplant; the limited availability of organs in the pediatric age group necessitates exploring treatment alternatives as a bridge to transplant. Pulmonary artery banding with good right ventricular function becomes an option. We present the case of a 12-year-old female patient who, at the age of two, was admitted to our center with a diagnosis of dilated cardiomyopathy and good right ventricular function. It was decided to perform a pulmonary artery banding, which resulted in the recovery of biventricular function during a 10-year follow-up.

**Keywords:** congenital heart disease, heart failure, heart transplant, pulmonary artery banding.

eart failure represents a cause of morbidity and mortality in the pediatric age group, with many causes, predominantly congenital and genetic. Treatment remains a challenge in this age group; however, we now know that heart transplantation is the definitive treatment.

#### RESUMEN

La insuficiencia cardíaca terminal es una causa significativa de morbilidad y mortalidad en el grupo de edad pediátrica. El tratamiento definitivo es un trasplante de corazón; la limitada disponibilidad de órganos en el grupo de edad pediátrica hace necesario explorar alternativas de tratamiento como puente al trasplante. El bandaje en la arteria pulmonar, con buena función del ventrículo derecho, se convierte en una opción. Presentamos el caso de una paciente de 12 años que, a los dos años, fue ingresada a nuestro centro con un diagnóstico de miocardiopatía dilatada y buena función del ventrículo derecho. Se decidió realizar un bandaje en la arteria pulmonar, lo que resultó en la recuperación de la función biventricular durante un seguimiento de 10 años.

Palabras clave: cardiopatía congénita, insuficiencia cardíaca, trasplante de corazón, bandaje de la arteria pulmonar.

In the course of managing end-stage heart failure, we have some treatment alternatives; however, the results are still uncertain. Only Ventricular Assist Devices (VADs) and heart transplantation have an optimal level of evidence.

In our setting, VADs have a high cost, and availability is still limited for many patients. Regarding heart transplantation, we

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are aware that donations are scarce in the pediatric population, so local statistics indicate that 50% of listed patients die while awaiting a heart.

Pulmonary artery banding (PAB) is a technique described over 60 years ago and is still used today to restrict blood flow in the pulmonary artery and balance systemic-pulmonary circulations in cases of complex ventricular shunts. This old surgical technique is also employed in patients with a morphological right ventricle (VD) in the systemic circulation who are candidates for a biventricular anatomical repair. PAB in corrected congenital transposition of the great arteries is used not only to retrain the subpulmonary left ventricle but also as an early prophylactic approach in newborns to prevent severe tricuspid insufficiency associated with the systemic position of the right ventricle.<sup>1</sup>

Some surgical management strategies for heart failure have been described, one of them being Pulmonary Artery Cerclage proposed in 2007 by the Giessen Working Group. Reversible CAP has been reinvented as an alternative surgical option for children affected by dilated cardiomyopathy (DCM) with preserved right ventricular (RV) function. Drawing lessons from the subpulmonary ventricle retraining in congenitally corrected transposition of the great arteries, the rationale for PAB in DCM is to promote positive ventricular-ventricular interactions and supposed molecular interference [activating the potential for myocardial repair]. As a result, PAB could represent a true "regenerative surgery" for children affected by terminal heart failure.<sup>2</sup>

#### **CLINICAL CASE**

We present here the case of a 12-year-old female patient with a diagnosis of non-compacted myocardium, which has been present since birth. She has a stay of two months in the neonatal intensive care unit before being transferred to our center at the age of 1-year and 4-months, where the diagnosis was confirmed. A study protocol for heart transplantation was conducted, and she was subsequently enlisted.

At two years of age, she was readmitted to the hospital due to decompensation of heart failure. Echocardiography revealed dilated cardiomyopathy, mild mitral insufficiency, and dilated left ventricle. MV E/A ratio > 200 mmHg, biplane LVEF 38%, synchrony index 36%, delayed septal contraction in relation to the free wall of 88 ms and 53 ms, RVP 38 mmHg. It was decided to perform pulmonary artery banding. She was discharged after nine days of the procedure due to improvement (*Figure 1*).

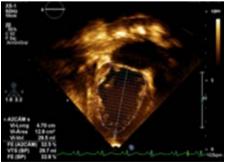
At the age of six years, a new echocardiogram was performed, revealing mild tricuspid regurgitation, mild mitral regurgitation, preserved systolic and diastolic function of the right ventricle, preserved diastolic function of the left ventricle, systolic dysfunction of the left ventricle, and a global strain of -10. The patient continues to be monitored in Cardiology.

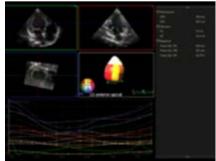
Currently, the patient has weight and height within percentiles, functional class I upon physical examination, with a grade III systolic murmur in the 4th intercostal space left parasternal line, accompanied by splitting of the second heart sound. Electrocardiogram showed a heart rate of 88 beats per minute, sinus rhythm, atrial conduction angle (aP) of 90°, intraventricular conduction angle (aQRS) of -30°, constant PR interval of 120 ms, QRS duration of 80 ms, QTm interval of 440 ms, QTc of 533 ms, sudden transition from V2 to V3, and a predominance of septal forces.

A 1-minute long Lead II strip revealed two QRS complexes, each lasting 140 ms (both with the same morphology), without ST segment elevation, followed by a positive T wave with a compensatory pause (consistent with isolated monomorphic ventricular extrasystoles). Chest X-ray showed levocardia, left apex ICT 0.5, and normal pulmonary flow.

Echocardiogram was reported as follows: right atrial volume 37.2 ml (z=+0.63), telediastolic area of the right atrium 14.7 cm2 (z=+1.28), TAPSE (Tricuspid annular plane systolic excursion) 16.1 mm (Z=-3.63), moderate tricuspid regurgitation, normal mitral valve, E/A ratio of







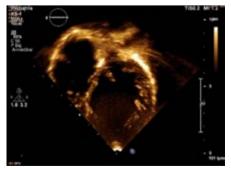


Figure 1: Echocardiogram performed before banding in March 2017: LVEF BP 32.8%; 3D 27.9%.

### April 2021



Figure 2: Postoperative echocardiogram showing improvement in left ventricular function after pulmonary artery banding. LVEF A/L 37.9%.

#### November 2021: LVEF BP 52%; 3D 57%

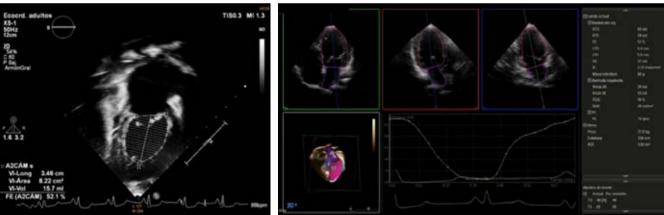


Figure 3: November 2021 Echocardiography with a significant improvement in left ventricular function: Left Ventricular Ejection Fraction (LVEF) increased to 52%.

the mitral valve 1.5, septal E/E' ratio 12.0. Both ventricles exhibited myocardium with a hyper trabeculated appearance, predominantly affecting the left ventricle. Tabulations were present in the apical and mid portions of the free wall of the left ventricle, along with intertrabecular recesses, yielding a non-compacted/compacted (NC/C) ratio of 2.22. The proximal ascending aorta with a diameter of 7.25 mm, generating a gradient of 55 mmHg. Left ventricular mass is 95 grams (Z = 0.45), with a normal left ventricular geometry (GRP 0.45). Right ventricular strain by speckle tracking -21%, Left ventricular longitudinal strain by speckle tracking: 4C - 13.4%, 3C - 27.8%, 2C -16%, Global -19.1%. Aortic insufficiency strain reservoir 34.4%, conduit -21.3%, pump -13.2% (*Figures* 

2 to 4). The study concluded as non-compacted myocardium, operated on the proximal ascending aorta with a gradient of 55 mmHg, moderate tricuspid regurgitation, diastolic dysfunction of the right ventricle, adequate systolic function of the right ventricle, borderline systolic function of the left ventricle.

#### **COMMENT**

The first reported case of a 2-month-old infant with progressive idiopathic dilated cardiomyopathy, who was on the heart transplant list, made a dramatic recovery from terminal heart failure after the placement of a pulmonary artery band by Schranz et al. in 2007.

They describe the surprising mechanism of concentric remodeling with improved left ventricular function in response to chronic pressure load on the right ventricle. This led to a shift in decision-making, focusing on unloading the right ventricle through balloon dilation of the pulmonary band. However, the precise mechanism of left ventricular remodeling still needs further clarification.<sup>2</sup>

In 2013, Schranz et al. presented the first study from one center, in which 12 cases of patients with dilated cardiomyopathy affecting the left ventricle were treated. Clinical functional status improved in all patients. The pressure gradient across the PAB increased from  $28 \pm 7$ to  $43 \pm 15$  mmHg in 20 days. Left ventricular ejection fraction increased from  $14.5\% \pm 5\%$  before PAB to 27%  $\pm$  13% at hospital discharge and to 47%  $\pm$  10% at three to six months. The telediastolic diameter of the left ventricle (z-score) decreased (p > 0.001) from  $46 \pm 6.1 (+7.0 \pm 1.3)$ to 35  $\pm$  15 mm (+3.0  $\pm$  1.3) after three to six months and to 34  $\pm$  15 mm (+1.3  $\pm$  1.14) after a median age of two years (maximum 6.6 years), respectively. Plasma levels of B-type natriuretic peptide decreased from  $3,431 \pm 2,610$ to  $288 \pm 321$  pg/ml at discharge and to  $102 \pm 96$  pg/ml 22 months later. They conclude that in young children with left ventricular dilated cardiomyopathy and preserved right ventricular function, PAB led to an improvement in LV function and mitral valve function through ventricular interaction.1

In 2007, Schranz et al. published a multicenter study, reporting worldwide experience, including three cases from our center.<sup>3</sup> The study describes 15 centers in 11 different cities and presents a flowchart of 70 patients who underwent PAB between 2006 and 2017. Among them, nine patients (mean age  $159 \pm 101$  days) received PAB after complex open-chest procedures, including mitral valve repair (n = 4), mitral valve replacement (n = 1), repair of anomalous left coronary artery arising from the pulmonary artery (n = 1), epicardial pacemaker placement (n = 1), fenestrated atrial septal defect closure (n = 1), and repair of a left-sided partial anomalous pulmonary venous return (n = 1). All patients, except the latter, recovered following a mean intensive care stay of 25  $\pm$  33 days and 54  $\pm$  32 days to discharge. The child with partial anomalous pulmonary venous return died eight months after corrective surgery, as left ventricular dilated cardiomyopathy did not respond to PAB, and heart transplantation listing was declined. The experience with these nine patients supports the use of PAB as a recovery strategy to wean patients with left ventricular dilated cardiomyopathy after open-heart surgery.

Spigel et al. reported the first North American series, comparing their results to those by the German group. They included 14 patients, and ultimately, 4 (29%) experienced cardiac recovery, 8 (57%) were bridged to heart transplantation (6 with ventricular assist device placement), and 2 (14%) died. Although the U.S. and German series



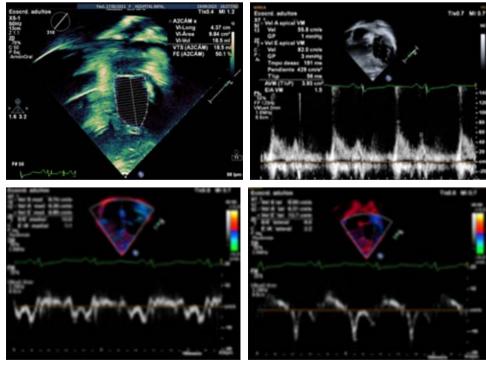


Figure 4:

Latest echocardiographic study in 2023: Left ventricular function is maintained, with a Left Ventricular Ejection Fraction (LVEF) of 50.1%.

demonstrated a high prevalence of achieving the individual patients' goals (either cardiac recovery or transplantation), the mode of success differed (recovery rate: <1/3 in the U.S. and >2/3 in Germany). A lower recovery rate may reflect a sicker preoperative state and, therefore, a more advanced stage of heart failure (preoperative intubation: >2/3 in the U.S. vs. <1/3 in Germany).<sup>4</sup>

In 2020, an Italian group reported their series of four patients. Out of them, three showed favorable outcomes. All underwent elective percutaneous band removal, 18.5 months, 4.8 months, and 10.7 months after PAB, respectively. The ejection fraction increased from  $17.7 \pm 8.5\%$  to  $63.3 \pm 7.6\%$  (p = 0.03), and all were subsequently removed from the transplant list. They concluded that better outcomes seem to be achieved in patients under 12-months old.<sup>4</sup>

In clinical practice, PAB has shown tangible potential to restore left ventricular function in one out of two children affected by end-stage dilated cardiomyopathy. By restoring appropriate left ventricular preload, ellipsoidal shape, and biventricular synchrony, PAB improves myocardial contractility and promotes positive ventricular-ventricular interactions in selected patients. However, several surgical centers remain hesitant to adopt this technique because the precise biological pathways recruited by PAB and the final clinical outcomes are still unknown. To date, only speculative hypotheses derived from ongoing animal experiments on myocardial healing after injury and human data in similar clinical settings, such as morphological retraining of the left ventricle in congenitally corrected transposition of the great arteries, can be proposed. Understanding the cellular and molecular mechanisms of PAB is mandatory to provide an evidence-based explanation supporting this approach. Experimental and specific research is expected to expand the implementation of PAB into the surgical toolkit for pediatric heart failure treatment and refine its effectiveness.<sup>5</sup>

#### **CONCLUSIONS**

As a conclusion, PAB has emerged as a potential therapeutic alternative to mechanical circulatory support or heart transplantation in infants with severe heart failure due to dilated cardiomyopathy.

Further studies are still needed to standardize its indication, although everything indicates that the best results will be achieved in patients under 1-year of age.

In the ultimate treatment of patients with end-stage heart failure and preserved right ventricular function, PAB becomes a viable alternative in the absence of donations in this age group.

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#### CASE REPORT

Vol. 9 No. 3 July-September 2024 doi: 10.35366/116100



# Atypical presentation of late pulmonary vein obstruction, following the repair of total anomalous pulmonary venous connection. Case report

Presentación atípica de obstrucción de venas pulmonares tardía posterior a corrección de conexión anómala total de venas pulmonares. Reporte de caso

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#### **ABSTRACT**

The total anomalous pulmonary venous connection is a congenital heart condition where the pulmonary veins do not connect directly to the left atrium. The clinical presentation of this pathology depends on the degree of obstruction. Without surgical treatment, the likelihood of death can be up to 80%. We report a case of total anomalous pulmonary venous connection obstruction post-correction in a pediatric patient successfully corrected using the sutureless technique.

**Keywords:** anomalous connection, atria, obstruction, post-surgical, pulmonary veins, total anomalous pulmonary venous connection.

otal anomalous pulmonary venous connection (TAPVC) is a congenital cyanotic heart condition in which all four pulmonary veins fail to establish their normal connection with the left atrium, leading to venous drainage into the systemic venous circulation. It occurs in

#### RESUMEN

La conexión anómala total de venas pulmonares es una cardiopatía congénita en el que las venas pulmonares no se conectan directamente a la aurícula izquierda; la clínica de esta patología depende del grado de obstrucción. Sin un tratamiento quirúrgico la probabilidad de muerte es de hasta 80%. Reportamos un caso de obstrucción de conexión anómala total de venas pulmonares post corrección de dicha patología en un paciente pediátrico corregido exitosamente con técnica sutureless.

Palabras clave: conexión anómala, aurículas, obstrucción, postquirúrgica, venas pulmonares, conexión anómala total de venas pulmonares.

approximately 7 to 9 per 100,000 live births and comprises 0.7 to 1.5% of all congenital heart diseases.<sup>2,3</sup>

TAPVC can be classified into four types based on the anatomical location of the connections to the heart.<sup>4</sup> The supracardiac type results from the connection of pulmonary

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veins to the cardinal venous systems, accounting for 45-50% of cases. The cardiac type is identified when pulmonary veins (PV) directly converge into the heart, connecting to the posterior aspect of the coronary sinus or the right atrium (RA), prevalent in 20 to 30% of patients. The infracardiac type represents 13 to 25% of cases. The mixed type accounts for less than 10% of cases and occurs when there is a combination of connections entering at two or more levels of the heart.<sup>5-7</sup>

The clinical presentation depends on the severity of the obstruction and the size of the atrial communication. Patients with severe obstruction exhibit profound cyanosis, pulmonary hypertension, pulmonary edema, respiratory distress, decreased systemic output, and hypotension (which can lead to shock). In the case of patients without venous obstruction, they may be asymptomatic at birth, later developing tachypnea, mild cyanosis, and feeding difficulties; over time, they may experience right ventricular hypertrophy and pulmonary vascular changes leading to right ventricular failure.

Diagnosis is typically achieved through echocardiography, although in some cases, angiography and cardiac catheterization may be necessary when the identification of PV and vertical veins is challenging, as these details are crucial for planning surgical management.<sup>9</sup>

Without surgical intervention, 80% of cases result in mortality within the first year of life, and less than 10% survive to adulthood. <sup>10</sup> Therefore, surgical correction is indicated for all patients, irrespective of the degree of obstruction. The goal of surgery is to establish a direct connection between the pulmonary veins and the left atrium, while preventing pulmonary obstruction. In recent years, the sutureless technique has been employed as a method for the primary correction of TAPVC. <sup>11</sup>

One of the most common postoperative complications is obstruction. Postoperative obstruction is defined as Doppler echocardiographic velocity of 1.2 m/s or higher at the repaired confluence or in an individual PV, or a catheterization gradient from any PV to the pulmonary venous atrium of 4 mmHg or higher.<sup>12,13</sup> It can occur in 5% to 18% of patients.<sup>14</sup> Risk

factors for postoperative obstruction are associated with the presence of obstruction at the diagnosis of TAPVC, increased surgical time, PV hypoplasia, identified PV obstruction in intraoperative transesophageal echocardiography, isolated anomalous PV, mixed type, among others. The use of the sutureless technique has not been reported to influence the risk of postoperative obstruction. <sup>12,13</sup>

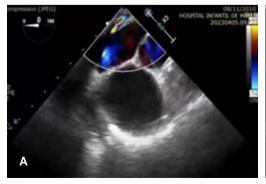
There are numerous surgical and catheter techniques available to address postoperative obstruction. The morphological characteristics of the PV and the severity of the disease should be taken into consideration when choosing the appropriate approach.<sup>14</sup>

#### **CASE DESCRIPTION**

A 12-year-old female with a history of non-obstructed TAPVC to the coronary sinus underwent total correction at nine months of age. At one year of age, an echocardiogram with color flow Doppler (*Figures 1 and 2*) documented obstruction of the right PV with a mean gradient of 13 mmHg. Subsequently, a contrast-enhanced computed tomography angiography (angioTAC) was requested (*Figure 3*), which reported drainage of PV with patent flow. No collector was identified, but three PV were observed, two on the left and one on the right. In the lower left and right PV, a small hypodense band was noted, a finding suggestive of a partial septum at each origin. Reported diameters were as follows: superior right PV of 3.4 mm, superior left PV of 3.2 mm, and inferior left PV of 3.4 mm. The patient showed appropriate evolution and was lost to follow-up.

The patient began with non-cyanotic, non-emetic, and initially non-productive cough. Seventy-six hours before admission, hemoptysis occurred, characterized by bright red blood, progressively increasing until it became exclusively hematic, with a quantity of 5 to 10 ml per episode. The episodes occurred three to seven times a day.

At the time of the echocardiogram, it was observed obstruction in the right PV with a mean gradient of 11 mmHg and a mean gradient of 9 mmHg in the left PV. Pulmonary



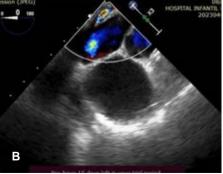


Figure 1:

Echocardiogram showing acceleration of blood arrival due to constriction.



Figure 2: Tomographic study showing complete occlusion of the right pulmonary veins, with no passage of contrast medium. Impairment of the left lung due to obstruction.

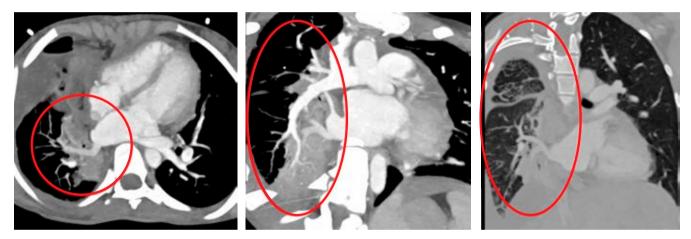


Figure 3: Comparative tomography showing patency of the pulmonary veins at 6 months of follow-up.

arterial hypertension and appropriate biventricular systolic function were noted. A contrast-enhanced computed tomography revealed a significant reduction in the right lung volume, dorsal atelectasis, and a right pleural effusion. A decision was made to perform catheterization, during which a reduction in the caliber of the left PV was found upon arrival at the coronary sinus with an obstructive gradient of 9 mmHg. The proximal portion of the right upper PV was also retrograde, with amputation of both veins upon arrival at the left atrium. The PV cannot be successfully opened, leading to the termination of the procedure.

The patient underwent surgery for the correction of obstructed anomalous PV using a sutureless technique with pericardial flaps. The right PV was found with pinpoint entry into the left atrium (successfully dilated up to Hegar 4), and the PV had an entry from the coronary sinus into the left atrium, both with good caliber. Redilation was performed once again. A transoperative echocardiogram reports adequate flow and

caliber in all four PV. As a complication, right diaphragmatic paralysis occurred, leading to diaphragmatic plication. Healthcare-associated pneumonia was successfully treated with antibiotic therapy. The patient was discharged with appropriate respiratory and cardiac progress, tolerating oral intake, ambulating, and without the need for oxygen supplementation.

#### **COMMENT**

The main complication we face is postoperative obstruction, which is associated with multiple risk factors such as heterotaxy, single ventricle, history of any PV repair procedure, mixed type diagnosis of TAPVC, prolonged cardiopulmonary bypass and aortic cross-clamp time, and preoperative obstruction. <sup>12,13</sup> In the case of obstruction to the coronary sinus, according to Husain et al., <sup>15</sup> it occurs in approximately 9.7% of postoperative cases, the last in terms of frequency. However, in this patient, this type of obstruction

is observed. Postoperative obstruction is clinically associated with pulmonary hypertension, pulmonary vascular disease, hypoxemia, decreased right ventricular function, and an increase in morbidity and mortality.<sup>13</sup>

Moderate obstruction is defined as a Doppler velocity of 2 m/s or higher, a catheterization gradient of 4 mmHg or higher, or clinical respiratory distress requiring urgent surgical intervention. In a study by White et al., it is mentioned that postoperative obstruction is common after six months of TAPVC correction and that late presentation (beyond two years after correction) is rare. In On the other hand, our patient had no follow-up, and nine years later, she exhibited obstruction of the right PV with a mean gradient of 11 mmHg and a maximum velocity of 2.15 m/s, a mean gradient of 9 mmHg in the left PV, and pulmonary arterial hypertension. However, she exhibited no clinical symptoms suggesting respiratory distress or the need for urgent surgical intervention.

The sutureless technique is described as the primary surgical approach for treating patients with pulmonary venous obstruction. Another alternative outlined in the literature is to perform a catheter intervention to correct this obstruction; however, there is a lower rate of potential reintervention in patients undergoing surgical procedures.<sup>15</sup>

#### **CONCLUSIONS**

Intracardiac connection is an uncommon but potentially serious complication that can occur in the postoperative period of cardiac surgery. This connection can become obstructed, leading to symptoms even outside the typical six-month post-surgery period. It's important to recognize that symptom presentation beyond this timeframe may be atypical.

In diagnosing this complication, it's crucial to conduct a thorough evaluation to identify the underlying cause of the patient's symptoms. In this case, the exclusion of the right PV suggests a possible obstruction in that area. The described surgical technique, which restores the permeability of the PV using sutureless techniques, appears to be an effective and reproducible alternative in these cases.

It is essential to address this complication promptly to avoid additional complications and improve the patient's quality of life. Restoring the permeability of the PV through appropriate surgical techniques can yield good results and alleviate the patient's symptoms.

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#### SURGICAL TECHNIQUE

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## Total coronary revascularization via left anterior thoracotomy: a novel approach to achieving comprehensive coronary revascularization

Revascularización coronaria total a través de toracotomía anterior izquierda: un nuevo enfoque para lograr una revascularización coronaria completa

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#### **ABSTRACT**

Coronary artery bypass grafting (CABG) has been the cornerstone for myocardial revascularization. However, rising demand for less invasive procedures, such as percutaneous coronary intervention (PCI), has challenged its dominance. The emergence of total coronary revascularization via left anterior thoracotomy (TCRAT) presents a groundbreaking alternative. TCRAT achieves complete revascularization through a minimally invasive approach, leveraging left anterior thoracotomy, cardiopulmonary bypass, and peripheral cannulation. Its safety and efficacy mark a transformative shift in coronary artery disease management.

**Keywords:** coronary artery bypass grafting, coronary artery disease, minimally invasive cardiac surgery.

#### RESUMEN

La cirugía de bypass de arteria coronaria (CABG) ha sido la piedra angular para la revascularización miocárdica. Sin embargo, la creciente demanda de procedimientos menos invasivos, como la intervención coronaria percutánea (PCI), ha desafiado su dominio. La emergencia de la revascularización coronaria total vía toracotomía anterior izquierda (TCRAT) presenta una alternativa revolucionaria. TCRAT logra una revascularización completa a través de un enfoque mínimamente invasivo, aprovechando la toracotomía anterior izquierda, el bypass cardiopulmonar y la canulación periférica. Su seguridad y eficacia marcan un cambio paradigmático en el manejo de la enfermedad arterial coronaria.

Palabras clave: bypass aortocoronario, enfermedad arterial coronaria, cirugía cardiaca mínimamente invasiva.

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oronary artery bypass grafting surgery (CABG) has been a cornerstone in treating coronary artery disease for over half a century. Despite significant advances in coronary artery disease management, especially in percutaneous interventions and perioperative care, the core techniques of CABG have undergone minimal evolution. Notably, the use of the left internal mammary artery (LIMA) to revascularize the left anterior descending artery (LAD) marks a pivotal advancement in CABG. Despite its unchanged nature, CABG remains the gold standard for myocardial revascularization, particularly for patients with complex coronary artery pathology,<sup>2-6</sup> with a sternotomy approach being the predominant choice globally.<sup>7-9</sup> However, there has been a substantial surge in demand for percutaneous coronary intervention (PCI) and less invasive procedures over the last two decades due to patient attractiveness. 6,10 The preference for PCI over CABG is attributed to perceptions of invasiveness and patients' short- and long-term preferences. 11 Despite evidence favoring CABG, its growth has stagnated, while PCI procedures have tripled and continue to rise. 5,6 Robotic endoscopic CABG and minimally invasive cardiac surgery (MICS) CABG have been introduced to reduce invasiveness, yet their adoption remains limited due to technical complexities and infrastructure requirements.<sup>5,7,9,12-15</sup> Offering complete revascularization through minimally invasive techniques remains challenging despite their effectiveness, highlighting the ongoing need for advancements in surgical approaches. 5,12,16,17

Until 2019, no technique systematically addressed the challenge of complete revascularization while preserving key surgical principles and wide applicability for most patients. Babliak et al. proposed a new operative approach called "total coronary revascularization via left anterior thoracotomy (TCRAT)" in 2019.<sup>18</sup> Based on established

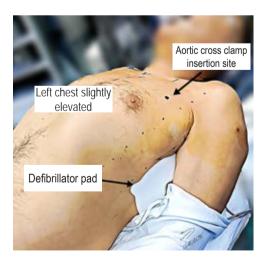


Figure 1: Supine patient, mild elevation of the left chest. Notice the colocation of the defibrillator pad prior to anesthetic induction.

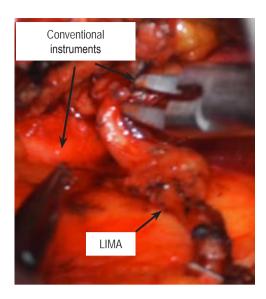


Figure 2: Surgeon's view of the left internal mammary artery; harvesting is accomplished with long conventional instruments.

cardiac surgery concepts and insights from minimally invasive cardiac surgery, this technique utilizes a small left anterior thoracotomy for revascularization in multivessel coronary diseases. TCRAT represents a promising advancement in achieving comprehensive coronary revascularization through minimally invasive means. We describe how we are applying this technique in our center.

#### Preoperative evaluation

Thorough preoperative planning is essential for ensuring the success of surgeries, especially in minimally invasive cardiac surgery. Identifying potential complications ahead of time allows for proactive intervention, minimizing obstacles to the patient's recovery. Specific preoperative conditions such as chronic lung diseases, cerebrovascular diseases, peripheral artery disease, chest wall abnormalities, lung irradiation, and prior cardiac and/or lung surgeries warrant particular attention. Standard preoperative assessments for these cases involve various diagnostic procedures including electrocardiogram, chest X-Ray, complete blood laboratory tests, echocardiogram, and cardiac catheterization, mirroring those performed in cases requiring full sternotomy. However, it is important to note that there may be variations in preoperative investigations for standards CABG. The significance of computed tomography (CT) in the preoperative assessment of minimally invasive procedures cannot be underestimated. 19-21 CT scans provide invaluable insight into the patient's anatomy, facilitating the safe execution of surgeries. Detailed information about the lungs, airway, chest wall, mediastinum, heart, major blood vessels, and peripheral vascular anatomy is obtained through CT scans. Notably, CT findings related to peripheral artery disease are of particular importance, as they can influence the chosen surgical approach, especially in peripheral cannulation (transaxillary or transfemoral), and must be carefully considered during the planning phase.

#### Surgical technique<sup>18,22-24</sup>

Patients are positioned supine with the left chest slightly elevated to optimize exposure of LIMA and the heart (*Figure 1*). The saphenous vein is harvested using a disposable endoscopic retractor and a bipolar radiofrequency vessel sealing system (Vasoview Hemopro, Getinge, Sweden), through a 2.5 cm incision made at the medial surface of the knee.

TCRAT is conducted via a left mini-thoracotomy, which entails a 5 to 8-cm skin incision positioned on the fourth intercostal space, obviating the necessity for rib resection. A small thoracic retractor is introduced through the minithoracotomy, facilitating the identification, clipping, and sectioning of LIMA. Before clipping LIMA, 8,000 units of heparin are administered intravenously. Concurrently, access

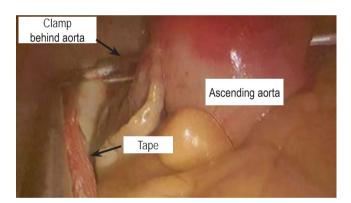


Figure 3: Ascending aorta encircled with tape.

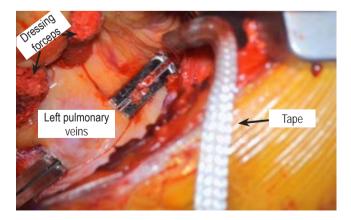


Figure 4: Left pulmonary veins encircled with tape.

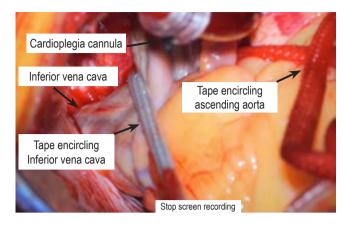


Figure 5: Inferior vena cava encircled with tape.

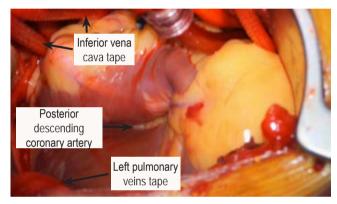


Figure 6: Surgeon's view of the right coronary territory exposure maneuver, notice the feasible access to the inferior surface of the heart.

to the femoral vessels is attained through a 1 cm inguinal incision, and femoral venous and arterial cannulation is accomplished utilizing dedicated cannulae. The placement of these cannulae is always guided by transesophageal echocardiography and in some instances, fluoroscopy. In cases where indicated, access to the axillary artery is achieved through a 2 cm subclavian incision and cannulated using an 8 mm vascular graft.

LIMA harvesting is conducted under direct surgical visualization using long conventional instruments and a specialized internal mammary artery (IMA) retractor (Delacroix-Chevalier, MIDAccess IMA Retractor) (*Figure* 2). Upon completion of LIMA harvesting and cannulation, heparinization is adjusted to 300 units per kilogram, and cardiopulmonary bypass is initiated employing vacuum-assisted drainage.

The pericardium is longitudinally opened from the apex to the ascending aorta and widely to the sides, with careful attention to avoid injury to the phrenic nerve. The ascending aorta is dissected and freed from the pulmonary arteries, encircled with tape (*Figure 3*), and subsequently maneuvered toward the thoracic incision to facilitate the insertion of the cardioplegia cannula. A transthoracic aortic clamp is introduced through the left second intercostal space, between the midclavicular and anterior axillary lines. Under direct vision, the aorta is cross-clamped, and antegrade cardioplegia is administered to achieve cardiac arrest.

Following cardiac arrest, cessation of cardioplegia infusion, and once complete decompression of the heart are achieved, the heart is mobilized with dressing forceps, and left pulmonary veins (*Figure 4*) as well as inferior vena cava (*Figure 5*) are encircled with tapes.

To achieve optimal exposure for coronary artery bypass grafting, specific maneuvers are employed to rotate the heart effectively. These maneuvers are orchestrated to facilitate surgical access to different coronary territories. A detailed description is as follows:

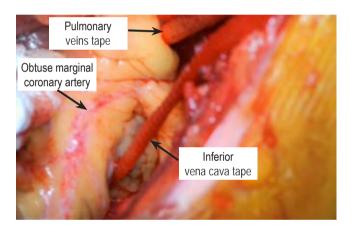


Figure 7: Surgeon's view of circumflex coronary territory exposure maneuver, notice the feasible access of the lateral surface of the heart and exposure of obtuse marginal coronary artery.

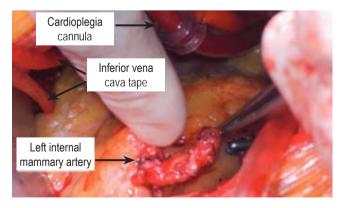


Figure 8: Surgeon's view of the left anterior descending coronary territory exposure maneuver, notice anastomosis being tied without the aid of any special instrument.

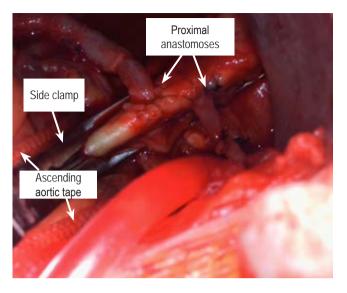


Figure 9: Surgeon's view of proximal anastomosis maneuver using a conventional aortic side clamp.

#### Right coronary territory exposure:

- 1. The left pulmonary vein tape is moved under the heart and towards the inferior vena cava.
- 2. Simultaneously, traction is applied to both the left pulmonary veins and inferior vena cava tapes in a downward direction.
- 3. This maneuver induces a rotation of the heart, enabling the exposure of the posterior descending artery up to the right coronary artery (*Figure 6*).

#### **Circumflex territory exposure:**

- 1. Initially, the inferior vena cava tape is shifted under the heart towards the left pulmonary veins.
- Subsequently, traction is applied simultaneously upwards on both the left pulmonary veins and inferior vena cava tapes.
- 3. This maneuver induces a rotation of the heart, enabling the exposure of the lateral wall for access to the circumflex territory (*Figure 7*).

#### Left anterior descending territory exposure:

- 1. To access the left anterior descending territory, a simpler maneuver is executed.
- 2. Traction is applied downwards on both the left pulmonary veins tape and the inferior vena cava tape (*Figure 8*).

Once the desired anastomosis is completed, traction is discontinued, allowing the heart to return to its original position. Anastomoses are performed using standard coronary instruments and the standard anastomotic technique of running sutures. The average distance from the skin to coronary anastomoses ranges from 6 to 8 cm. Proximal vein anastomoses to the aorta are facilitated using a side clamp while pulling downward on the ascending aorta tape (Figure 9). These meticulous traction and rotation maneuvers ensure adequate and stable exposure of any coronary target, irrespective of ventricular localization; this configuration is outlined in Figure 10 and 11.

#### COMMENT

In Mexico, the field of minimally invasive cardiac surgery has yet to witness complete revascularization through surgical means, with only a handful of previous reports detailing incomplete revascularization procedures. 25-27 However, the introduction of the TCRAT technique marks a significant leap forward. Proposed by Babliak et al. in 2019, 18 this pioneering method integrates insights from minimally invasive cardiac surgery and adheres to established cardiac surgery principles, offering a promising avenue for achieving comprehensive coronary revascularization while minimizing the invasiveness associated with traditional approaches.

The TCRAT technique, characterized by precise maneuvers, ensures adequate and stable exposure of any coronary target identified preoperatively by the heart team for revascularization. Regardless of ventricular localization, this approach enables complete anatomical revascularization with unparalleled dexterity, ensuring optimal graft placement and functional outcomes for every patient.

The advent of TCRAT heralds a new era in the management of coronary artery disease in Mexico, presenting patients with a viable alternative to traditional surgical methods while maintaining the highest standards of safety and efficacy. As the first manuscript documenting such an experience in Mexico, TCRAT not only broadens the horizons of cardiac surgeons but also lays the groundwork for future innovations in minimally invasive cardiac surgery. Furthermore, its reproducible technique ensures that this groundbreaking approach can be embraced and enhanced by any cardiac surgical team, solidifying its status as a transformative milestone in cardiovascular care.

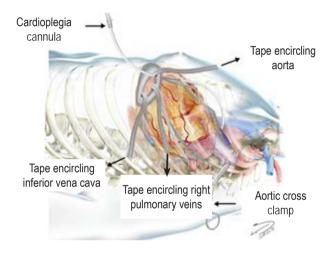


Figure 11: Schematic drawing of tapes that encircle heart structures for maneuvers employed to rotate the heart.

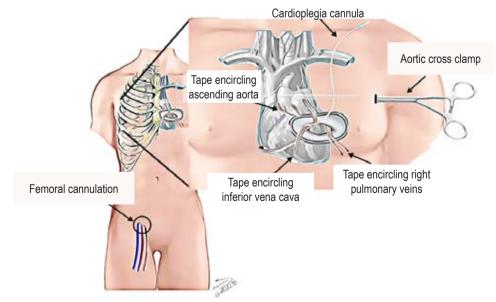


Figure 10:

Schematic drawing of intraoperative setup for total coronary revascularization via left anterior thoracotomy. Notice skin incision through the fourth intercostal space.

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