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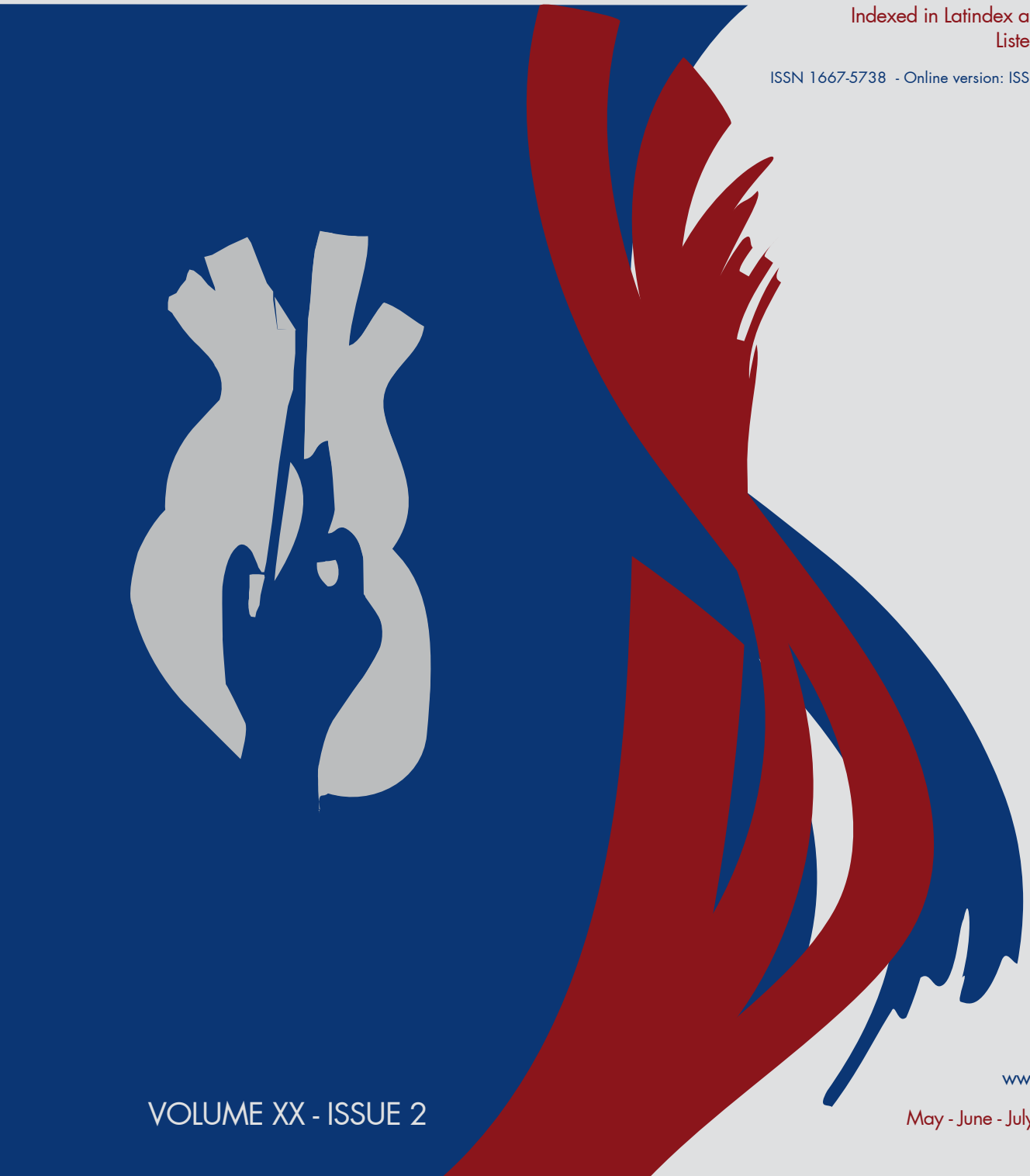

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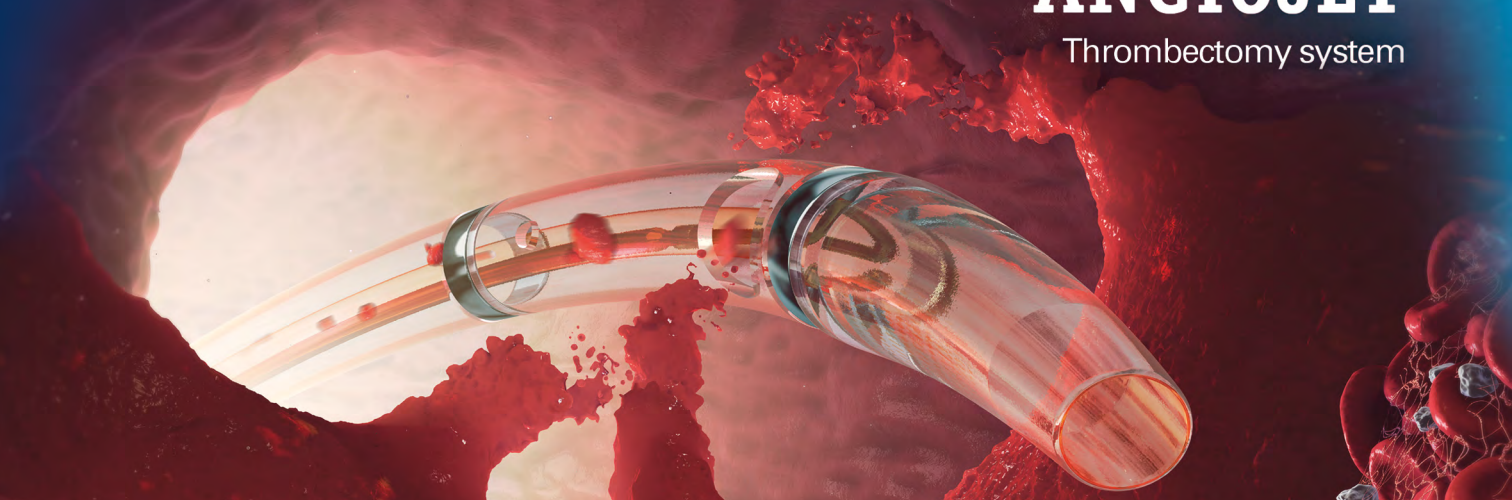

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SUMMARY

SCIENTIFIC LETTER

BRIEF EXPERIENCE IN AORTIC ROOT OCCLUSION ON A VALVED TUBE IN AORTIC ROOT ANEURYSM

ABSTRACT

Since 1968, when Bentall and De Bono introduced a novel technique to treat aortic root disease —be it as a result of dissection or aneurysm— surgical mortality improved so much that it became possible to establish this technique as the gold standard for surgical treatment of aortic root disease. Several modifications have been made of the original technique until the present surgery with remodeling or conservation of the aortic valve was developed. In this paper we present our experience with a slight variation of the Bentall technique applied in four patients with aortic root aneurysm that has allowed a reduction of the surgical time and bleeding, fast recovery and easy reproducibility.

Keywords: *Aneurysm, Bentall, dissection, aortic root*

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INTRODUCTION

In 1968, Bentall and De Bono reported the technique that would become the standard for the treatment of combined ascending aorta and aortic valve disease[1], marking a before and after in the post-surgical evolution of these patients. Later, in 1981, Kouchoukos et al. modified the anastomosis of the coronary ostia to the Dacron tube with the button technique[2,3], providing greater mobility and more tension on the ostial anastomosis with reduction of bleeding and preventing coronary twisting. In 1986, Cabrol published another modification to reduce bleeding resulting from tension of the coronary anastomosis with the interposition of a fine 8 mm Dacron tube between both ostia, and in turn, the latter anastomosed to a valved tube[4,5].

In 1999, Doty DB et al. reported the implant of the FreeStyle bioprosthesis, both in subcoronary position as well as with inclusion in the aortic root with good results[6]. In 1992, David TE et al. published their experience in aortic root remodeling with promising results[7].

In 1993 Copeland created the miniskirt technique: after the tandem suture in an intra-annular U, a continuous suture of the aortic wall remnant is performed 1 cm above the prosthesis skirt in the valved tube with the aim of reducing bleeding of the proximal anastomosis[8]. By 1995, Khana et al. reported that a tobacco-pouch suture, reinforced with Teflon patches through the aortic wall, above the proximal suture line may prevent bleeding[9]. Later, in 2010, Mohite *et al.*[10] reported their experience with the use of everted mattress sutures, interrupted in the proximal anastomosis, passing them through the tube suture sleeve with a valve, and then through an autologous pericardial strip. Chen et al. used a prosthesis that was modified with a Dacron miniskirt joined to the suture sleeve, which was sutured to the remaining proximal aortic tissue, thus creating a perianostomotic space that was later filled with fibrin glue[11]. Finally, in 2012, Alessandro Della Corte performed an intra-annular imbricated U suture in proximal anastomosis, obtaining a marked bleeding reduction and good surgical results[12].

TECHNIQUE

The technique consists in performing a transversal aortotomy at the level of the sinotubular junction. We fix the comissures with multifilament 2.0, resect the veils, decalcify if required, place the braided multifilament suture on Teflon with an intra-annular technique (Figure 1), pass these sutures through the Dacron tube prosthesis skirt and knot one by one. We fill the prosthesis with saline solution plus a Valsalva manouver, stop venting, and then mark the coronary ostium site with demographic pencil. We create an ovoid opening with the cautery device in the Dacron tube on the mark, resect a margin of at least 5 mm outside the left ostium and suture with polypropylene 6.0 from inside the tube with a 0.5 cm margin of coronary ostium towards the aortic wall and Dacron tube with a three-loop parachute technique. Then we proceed with a continuous suture until completing the circumference. We recommend to start and finish at 3:00 o´clock position and move forward clockwise as the anastomosis accommodates.

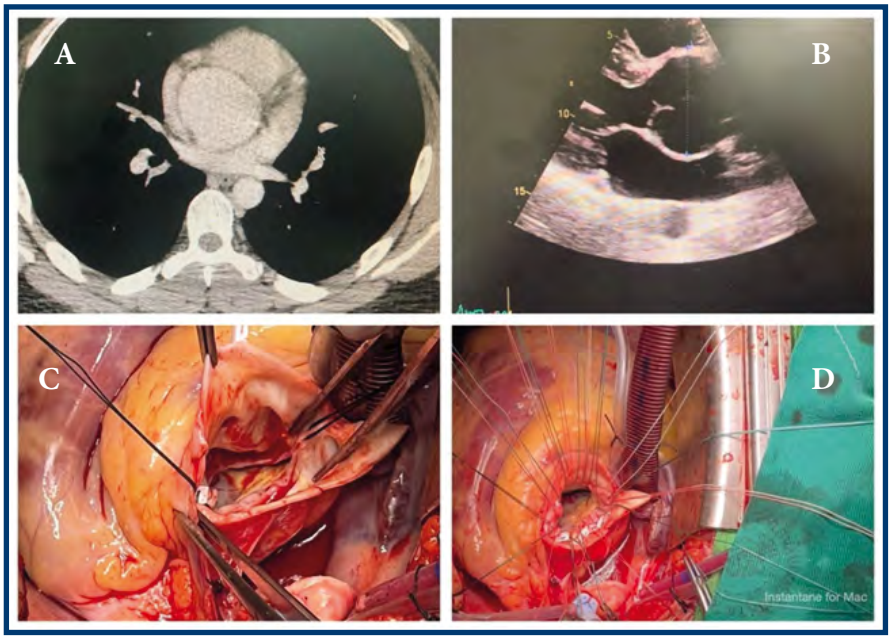

FIGURE 1. A. Chest CT showing aneurysm of the aortic root. **B.** Echocardiography showing bicuspid valve with aortic-root dilation. **C.** Transverse aortotomy in a sinotubular junction. **D.** Intra-annular valved tube implant.

It is not necessary to reinforce the ostium wall (starting from inside and taking aortic wall reinforces the suture against the Dacron tube). We inspect the ostium integrity and make sure that it does not bend when released. We proceed to fill the Dacron tube and mark with demographic pencil the site where the right coronary ostium will lie. We perform the prosthesis foramen with the cautery device in an ovoid shape with a similar technique as that of the left ostium. We cut the valved tube to the height of the distal anastomosis, first performing a continuous raphy of the remaining aortic wall with polypropylene 5.0 in the sinotubular junction against the Dacron tube contour. We use biological glue in this raphy (not indispensable) and perform the distal anastomosis with polypropylene 4.0 lying on Teflon, Dacron or pericardium with a sandwich technique with Dacron or felt (Figure 2). In Figure 3 we sketch the surgical steps.

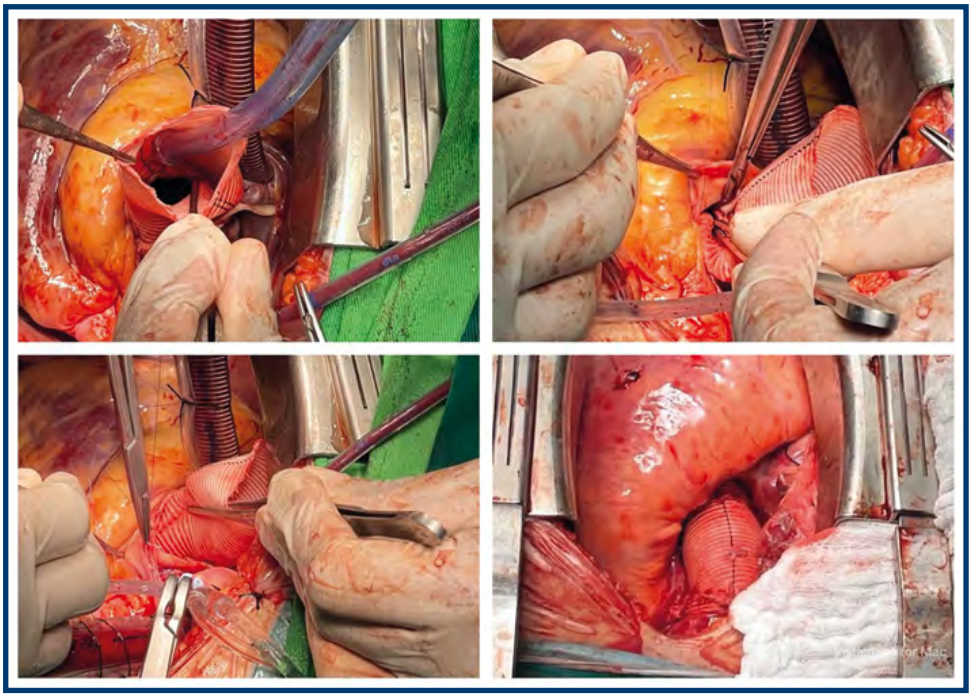

FIGURE 2. A. Intra-aortic root mechanic valved tube. **B.** Endoaortic raphy of the right ostium. **C.** Continuous raphy of the supracoronary crown against Dacron tube. **D.** Anastomosis performed, mínimum bleeding.

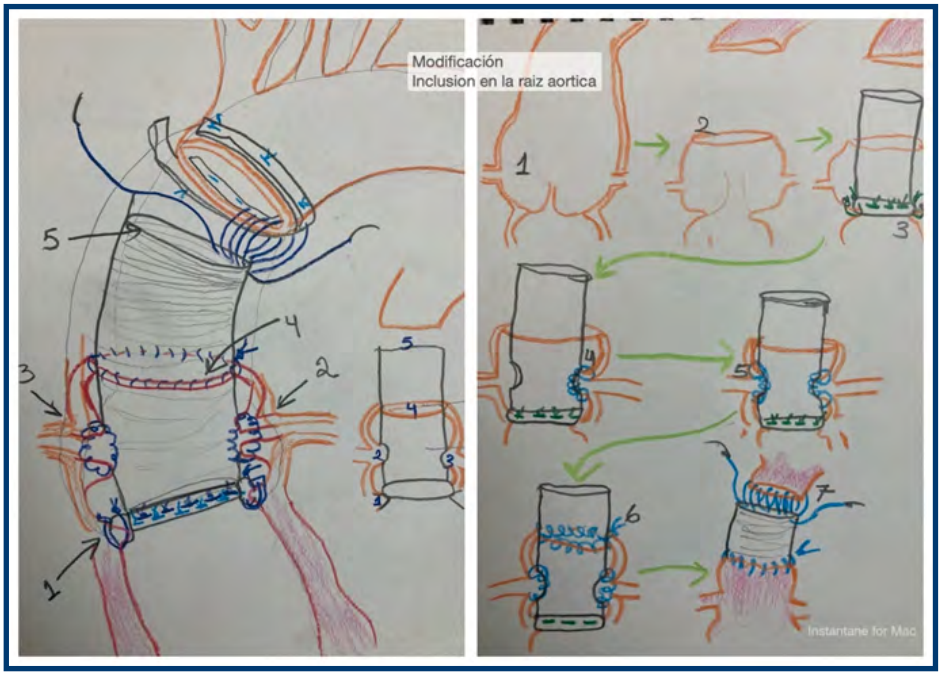

FIGURE 3. A. Drawing of the applied technique. **B.** Modification steps of the Bentall technique.

CASES

Mean age: 48 years; one woman and three men. Mean extracorporeal circulation time: 112 minutes; average clamping time: 95 minutes; 24-hour bleeding in three patients, the mean was 658 ml. One of the four patients bled 1420 ml in the context of coagulopathy that soon reverted. Three of the four patients remained less than 48 hours in intensive care units, one of them prolonged the stay to four days and the mediastinal drainage tubes were removed on day three. No deaths were reported.

DISCUSSION

Our initial experience has been very encouraging. Results have been very good, both in terms of shorter aortic clamping, extracorporeal circulation and total surgery time as well as less post-surgical bleeding and fast recovery. We present for your consideration this short experience of a minimum modification of the original technique that, in our understanding, might benefit a significant group of patients.

Conflicts of interest

The authors have no disclosures to declare.

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SCIENTIFIC LETTER

TREATMENT OF BRACHIAL ARTERIAL PSEUDOANEURYSM AND THE IMPORTANCE OF EARLY DIAGNOSIS WITH DOPPLER ULTRASONOGRAPHY

ABSTRACT

With the increased use of endovascular procedures, a rise in the number of cases of pseudoaneurysms has been seen. They have a low incidence, being its etiology traumatic or iatrogenic. Potential complications are edema, pain, hemorrhage and ischemia of the affected limb, which can even lead to loss of the fingers.

We report a clinical case of a patient with brachial artery pseudoaneurysm after coronary angioplasty, which was resolved with Doppler ultrasound- guided puncture with thrombin injection.

Keywords: *pseudoaneurysm, brachial artery, thrombin injection.*

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INTRODUCTION

Pseudoaneurysms or false arterial aneurisms are defined as cavities in which a rupture of the vascular wall permits blood extravasation, which leads to pulsatile hematoma[1]. Said hematoma is surrounded by a pseudo-sac formed by adjoining tissues, which means that this pseudo-sac is not formed by elements of the vascular wall. Its etiology can be infectious, traumatic[1] or iatrogenic. The latter has seen an increase given the advances in interventional medicine with increased use of diagnostic and therapeutic methods.

An incidence of post-puncture complications has been described, ranging from 0.2 to 7%[2], whereas other studies report up to 9%. Pseudoaneurysm accounts for 1.5% of post-angiography complications and up to 6% of post therapeutic procedures complications[3].

It is well known that brachial artery pseudoaneurysms have a low incidence, although it has increased in recent years as a result of the greater use of upper limbs in endovascular procedures. Given their potential complications, i.e. hemorrhage, edema, pain, limb ischemia, pseudoaneurysms must be treated promptly.

We report a clinical case of brachial artery pseudoaneurysm diagnosed by doppler ultrasound and treated with ultrasound-guided thrombin injection. The study allowed for early diagnosis and satisfactory treatment, reducing morbidity as it is a method that does not require the use of nephrotoxic contrast agents or radiation, allowing for real time evaluation and reducing hospitalization time and related costs.

CASE REPORT

Male, 69 year-old patient, with a history of coronary angioplasty of 7 days of evolution. The approach pathway was the brachial artery of the right upper limb. Ecodoppler was performed, diagnosing brachial artery pseudoaneurysm (Figure 1). It was decided to attempt to compress it on two occasions, not obtaining the expected result.

The ecodoppler revealed a patent brachial artery, with preserved flow pattern and the presence of a 15.8 mm diameter pseudoaneurysm with the typical ying-yang pattern, patent 2.4 mm diameter and 11 mm long neck, with a high-speed and resistance flow pattern.

Thrombin was injected in the bottom of the sac with the aim of thrombosing, not reaching the neck in order to avoid migration of the product as it might cause arterial thrombosis. Being this a real-time procedure, once thrombosis in the sac was observed it was decided not to continue injecting thrombin although the neck remained patent, since as there is no cavity to receive the blood, the neck would thrombose. In order to prove that this was the case, the patient was seen at 24 hours for ecodoppler control (Figure 2). Neck and pseudoaneurysm sac thrombosis was observed. Even so, the patient was seen for a second control with ecodoppler 7 days after the procedure, evidencing complete exclusion of the pseudoaneurysm.

COMMENTS

Brachial artery pseudoaneurysms are infrequent but, given their potential complications, they are considered a vascular emergency.

Treatments range from a watch and wait approach, manual compression, endovascular procedures to conventional surgery. Endovascular procedures with stent placement use nephrotoxic iodine agents that also imply a high cost, whereas conventional surgery requires anesthesia and hospitalization.

Thrombin injection has proven to be effective and does not require iodine contrast agents or anesthetics, does not expose the patient to radiation, can be administered in an outpatient procedure with few hours of stay in the medical center and allows for arterial hemodynamic control of the treated limb. This method also makes it possible to prove effectiveness of the procedure and arterial patency in real time and, finally, it also reduces treatment costs[3].

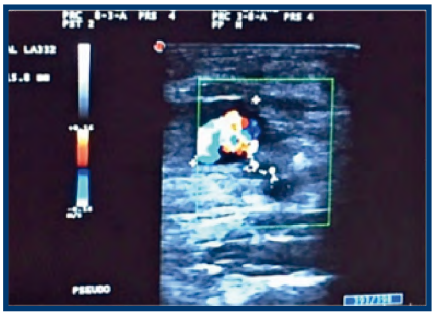

FIGURE 1. Pseudoaneurysm. Measurement of the cavity, neck diameter and length and jet speed.

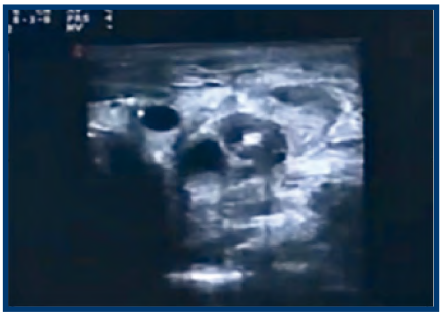

FIGURE 2. Obliteration of the sac, control 24 hours after the procedure.

Vascular ecodoppler is a fundamental diagnostic tool (94% to 97% sensitivity)[4]. It permits evaluation of the lesion features (number of cavities, dimension, presence of thrombi, internal septa), the relation with neighboring structures, study of the arterial tree (walls and flows) and the presence of thrombi in vascular structures. With this method it is possible to establish differential diagnosis, namely: true aneurysm, hematoma, arteriovenous fistula, lipoma, neoplasia or abscesses.

On the other hand, it is a low cost, reproducible method that can be performed on the bed side, not using radiation or nephrotoxic contrast media. It has been proven that ultrasound-guided percutaneous thrombin injection is safe and efficacious[5,6].

It must be noted that when an endovascular procedure is required, it is necessary to consider that there are predisposing factors for the development of an aneurysm, including anticoagulation, age older than 60, use of larger diameter catheters, obesity, non-effective compression in the puncture site or technical errors during the procedure.

We conclude that ecodoppler is a fundamental tool in the diagnosis and treatment of vascular procedures.

Conflicts of interest
The authors have no disclosures to declare.

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OPINION ARTICLE

CONFLICTS OF INTEREST AMONG TRANSCATHETER MITRAL VALVE REPAIR

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We have lost valuable ideas and concepts to get rid of what we just don't want. Our understanding of transcatheter edge-to-edge repair (TEER) to treat the mitral valve (MV)—of which MitraClip is the most common device used in the routine medical practice (MitraClip therapy MitraClip™; transcatheter mitral valve repair (TMVR); Abbott, 3200 Lakeside Dr, Santa Clara, CA, United States)—comes from not very reliable systems of prediction that, on many occasions, are not compatible with reality. Conflicts of interest have appeared between members of the Mitral Valve Academy Research (MVARC) and a few trials conducted to analyze TEER outcomes in mitral regurgitation (MR). This adds to the potential irregularities that have come up as we keep investigating the disparity of data available from large randomized clinical trials up to this date. More specifically, the conflicts of interest among MVARC, COAPT, and MitraClip (Abbott) is disturbing, and should be cleared out as soon as possible.

Surgical mitral valve repair as a reference framework for transcatheter therapies to treat mitral regurgitation

The comparison point for state-of-the-art technologies used for MV repair is surgical repair like the treatment of choice of mitral regurgitation. By applying specific parameters on MV repair in degenerative disease, McCarthy *et al.* demonstrated that the 10-year reintervention-free rate was 99.7%, the lack of recurrent MR ≥ 3+ was 98.4%, and 84.4% for grade 2+ MI.[(1)]

Using quadrangular resection, native annulus plication, and the use of annuloplasty ring in patients with degenerative disease of the MV, Lapenna *et al.* reported a reintervention rate of 4.3% ± 1.7% [95% confidence interval (95%CI) 1.7% to 8.8%], and a rate of MR 3+ of 8.8% ± 2.8% (95%CI, 4,3% a 15,5%). Regarding MR grade 2+, the rate was only 10% at 18-year follow-up.[(2)] De Bonis *et al.* used a maximum 17.6-year follow-up in patients with degenerative disease of MV after MV repair due to regurgitation using Alfieri's "edge-to-edge" technique and annuloplasty ring, and reported an reintervention-free rate of 89.6 ± 2.51%, with MR ≥3+ in 13.6% of the patients.[(3)]

Working on patients with anterior valve prolapse due to degenerative disease and using Alfieri's "edge-to-edge" technique combined with the use of mitral annuloplasty, De Bonis *et al.* reported a reintervention-free rate of 89.6% ± 2.74%, and a rate of MR ≥3+ of 12.5% at a maximum follow-up of 21 years. [(4)] In cases with degenerative disease, David et al. demonstrated that after MV repair, the recurrence-free ratio for MR ≥3+ and ≥ 2+ was 90.7% and 69.2%, respectively. The rate of reintervention was 5.9%. All these data come from a 20-year follow-up.[(5)] Regarding the durability of the MV surgical repair due to degenerative etiology, the reintervention-free rate at 15 and 20 years was 84% and 80%, respectively. The reintervention-free rate was 72% and 89% for the anterior valve prolapse and posterior valve, respectively, at 15-year follow-up.[(6)]

After this analysis, we should understand that surgical repair of MV due to degenerative disease is associated with very low rates of reintervention and recurrence of MR ≥ 2+ at almost 2-decade follow-up. Therefore, these results provide solid evidence in favor of surgical repair as the treatment of

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choice. These values should come back as remain the reference foundation on which to base any comparisons between surgery and emergent technologies with catheter-based techniques such as TEER.

Alfieri's "edge-to-edge" technique supporting the TEER therapy

Before repairing the MV in the adult population, the use of a mitral annuloplasty annulus is a prerequisite. Carpentier described it phenomenally in the so-called "French Correction"[7,8]. As a matter of fact, the lack of an annuloplasty annulus is the strongest predictor of failure after the MV repair in the long run.[5,9] This rule is universal and, therefore, applicable to all MV repair in the adult population. Alfieri's "edge-to-edge" technique that is based on the TEER principle is not an exception to this rule.[2-4,10-14]

These days, when a comparison is drawn between TEER therapy and surgical repair important details appear we should address here. The first detail is that despite the excellent results reported with Alfieri's "edge-to-edge" technique for mitral repair,[2-4,10-14] such technique was never the first-line therapy in the therapeutic armamentarium to repair MV regurgitation in the surgical community.

As a matter of fact, even in the experience published by the Milan working group (Italy), the great difference seen between the total number of MV repairs and the number relative to Alfieri's "edge-to-edge" technique is obvious.[14]

The TEER therapy as an incomplete and only partially effective technique

The most significant difference between the surgical and the percutaneous technique is the lack of an annuloplasty prosthetic ring in the TEER catheter-based percutaneous technique. Therefore, this factor makes the TEER percutaneous procedure be partially effective. Therefore, we should mention that the TEER procedure as such is an incomplete procedure. However, this is a problem that has not been properly discussed by the interventional cardiology community. Consequently, we should define the potential complications that stem from such limitations especially their long-term impact.

An undisputed fact overlooked by interventional cardiology is that the rules that regulate MV repairs do not simply change just by changing the approach whether it may be surgical or percutaneous. In its condition of a ringless therapy, MitraClip is subject to repair failures due to several mechanisms. At this point a cascade of errors can be found in the clinical trials and descriptions regarding the use of MitraClip.

Incorrect and ambiguous definition of failed or successful TEER according to the Mitral Valve Academic Research Consortium

One of the greatest inconsistencies is the very definition of success or failure depending on the degree of residual MR after the procedure. Such is the case of the definition of the endpoints of success established by the Mitral Valve Academic Research Consortium. Such document includes every criterion and its values to determine when a successful outcome has been achieved after TEER therapy. Regarding residual MR after TEER, this document describes "…a reduction of MR down to optimal or acceptable levels without significant mitral stenosis (with transmitral gradient <5 mm Hg), and mild non-major paravalvular MR (1+)." However, the document ambiguously mentions in the footnote of a figure that "the reduction of MR will be considered acceptable when the MR after the procedure has been reduced in, at least, 1 functional class or degree since the beginning and does not exceed the moderate category (2+) regarding severity." [15] This definition is totally unacceptable for the surgical or percutaneous approach used to treat MR.

It is surprising to see how easy these concepts have universally been accepted by cardiology groups worldwide without this type of deviation ever being discussed.

Impact of residual or recurrent mitral regurgitation grade 2+ after surgical mitral valve repair

The impact residual MR has after the procedure has been largely studied by different surgical groups. The presence of residual or recurrent grade 2+ MR after the MR surgical repair negatively impacts the patient's long-term survival. De Bonis *et al.* found as predictors of severe MR recurrence the presence of residual MR >1+ the moment of hospital discharge [hazard ratio (HR), 7,4; 95%CI, 2.5 to 21.2; P = .0001).[3] In a differente study, De Bonis et al. demonstrated that the only predictor of recurrence for MR ≥3+ was the presence of residual MR >1+ at hospital discharge (HR, 5.7; 95%CI, 1.6 to 20.6; P = .007).[4] Suri *et al.* demonstrated that the presence of residual MR >1+ at the operating room had an OR of 3.99 (1.79 to 7.65), and P = .002 in the univariate analysis, and an OR of 4.23 (1.86 to 8.32), P = .001 in the multivariate analysis.[9] The MR ≥ 2+ reintervention-free rate was closely associated with the degree of residual MR. In the presence of residual MR > 1+ at the operating room or at 1-year follow-up, the rate of recurrence is nearly 65% at 20 years. Therefore, the presence of MR >1+ after the procedure impacts directly the long-term results of the MR repair.[16]

Impact of residual or recurrent mitral regurgitation 2+ after transcatheter edge-to-edge repair (TEER) o the mitral valve

However. if the results obtained regarding residual or recurrent MR ≥ 2+ after TEER are thoroughly study. we will be able to see that these are totally discouraging. Therefore. in the GRASP-IT registry. Adamo et al. identified recurrent of residual MR ≥ 2+ as the most important predictor of mortality (HR, 2.17. IC 95%: 1.42 a 3.31. P < .001) and for the composite endpoint of all-cause mortality and rehospitalization due to heart failure (HR, 2.20. IC 95%: 1.52 a 3.19. P < .001) at 5-year follow-up.[17] Buzzatti *et al.* found a direct correlation between the presence of residual or recurrent MR grade 2+ after TEER and the appearance of MR gradw 3+, worse survival and quality of life compared to those with residual MR ≤1+ (HR, 6.71; 95%CI, 3.48 a 12.90; P < .001)[18]. Buzzatti [et al.] identified the presence of residual or recurrent MR 2+ after TEER as a stronger predictor for all-cause mortality at 5 year follow-up in the univariate (HR, 2.71; 95%CI, 1.73 a 4.25; P < .001) and multivariate analyses (HR, 4.18; 95%CI, 1.87 a 9.37; P < .001).[19] On this regard. Reichhart et al. demonstrated better results with residual MR ≤ 1+ compared to cases of MR ≥ 2+ (P = .029) after TEER at 1-year follow-up.[20] Similarly, it is rather obvious that the presence of residual o recurrent MR 2+ after TEER has been associated with worse general outcomes. Also, as we have been getting more and more results from the use of TEER both in the number and follow-up time, the negative impact of residual MR ≥ 2+ (including grade 2+) after TEER has become obvious. Therefore, it seems evident that the section dedicated to describing success from the point of view of residual MR within the MVARC document[15] is totally wrong and does not reflect reality at all. Since this could have a tremendous impact on the routine daily practice on thousands of human beings treated with TEER, the document should be reviewed once more and the recommendation downgraded from optimal down to acceptable, both as synonyms of residual MR ≤1+.

The rate of MR 2+ in clinical trials and TEER reports

The lack of emphasis with which MR grade 2+ has been described in the different studies and registries is alarming. On this regard, we will briefly mention the most significant studies and reports published over the last few years on the presence of MR 2+ after TEER therapy to treat MR regurgitation.

We should mention that between one third and half of the patients show recurrent or residual MR ≥ 2+ after TEER. In the EVEREST II trial, 50% of the cases showed MR ≥ 2+ at 5-year follow-up.[21] In the ACCESS-EU trial, 59.4% of the patients had residual or recurrent MR ≥ 2+ after TEER at 1-year follow-up.[22] In the COAPT trial up to 22.8% of the patients had MR ≥ 2+ at 2-year follow-up.[23,24] The MITRA-FR trial reported a rate of residual or recurrent MR ≥2+ at 1-year follow-up of 32%.[25] In the GRASP-IT registry, the rate of residual or recurrent MR ≥ 3+ at 5-year follow-up was 22.4% without reporting on the number of cases with residual o recurrent MR grade 2+.[17] The STS/ACC TVT registry reported a rate of 8,7% for MR ≥ 3.+ However, it did not report the rate for cases with residual or recurrent MR 2+.[26]

Overall, the negative impact that residual or recurrent MR 2+ after TEER has on the patient's survival, quality of life, MR ≥3+ recurrence, and rate of rehospitalization due to heart failure in the mid- and long-term has been downplayed. According to the statistics shown in this document, MR ≥2+ after TEER should be considered a risk factor of poor disease progression in general.

Differences between COAPT and MITRA-FR

After the huge differences seen with totally different results coming from the COAPT and MITRA-FR clinical trials we should take into consideration the association between the industry and the project director. The COAPT was a clinical trial sponsored by the industry (Abbott) with results favoring TEER compared to MitraClip in the management of functional MR in patients with heart failure. At 2-year follow-up, the rate of rehospitalization due to heart failure was 35.8% in the MitraClip group compared to 67.9% in the control group (HR, 0.53; 95%CI, 0.40 to 0.70; P < .0001). The all-cause mortality rate was 29.1% vs 46.1%, respectively (HR, 0.62; IC 95%; 0.46 to 0.82; P < .001).[23] Funding of the MITRA-FR trial was granted by the French National Institute of Health and Medical Research. No statistically significant differences between both treatment modalities were seen, in the all-cause mortality rate (24.3% vs 22.4%; HR, 1.11; 95%CI, 0.69 to 1.77) or in the rehospitalization rate due to heart failure (48.7% vs 47.4%; HR, 1.13; 95%CI, 0.81 to 1.56) at 1-year follow-up.[25] In an extension of this study at 2-year follow-up, no statistically significant differences were seen in these categories either. The all-cause mortality rate and the unscheduled rehospitalization rate due to heart failure were reported in 63.8% of the patients from the TEER group and 67.1% of the patients from the control group (HR, 1.01; 95%CI, 0.77 to 1.34).[27]

Despite the huge efforts done trying to explain and reconcile the totally opposing results of both studies, to this date, it has been virtually impossible

to find a compelling explanation that can be up to the circumstances. Concepts such as proportionate/disproportionate MR[27,28] have resulted in dilemmas that are totally out of the objective reality we are always looking for.[30-35] Also, it has been suggested that the term proportionate/disproportionate MR is not consistent with the physical laws of conservation of both mass and energy. Such inconsistency could only be explained by contradictory and incomplete echocardiographic data like the ones found in the COAPT trial.[34]

Conflicts of interest, MVARC, and COAPT

According to the Organization for Economic Cooperation and Development (OECD), "a conflict of interests is a conflict between the public duties and the private interests of an employee when this employee has personal interests that can interfere with the correct performance of his functions and official responsibilities".[36]

According to these 2 definitions, there is a flagrant conflict of interests since the lead author of the MVARC[15] has the exact same task in the COAPT trial.[23] If we admit that the MVARC defines residual or recurrent MR ≤ 2+ as an "acceptable" result after TEER, and that nearly 23% of the cases of the COAPT trial at 2 years showed MR 2+ (and, therefore, are taken as "acceptable" results), it seems rather obvious that there is a potential conflict of interests in the authorship of both authors. Therefore, there are rather important limitations that need to be responded in a clear-cut way.

Philosophical and ethical implications derived from the conflict of interests

Those involved in the development of technologies like TEER should consider the information available in this sense. They should make reassessments emphasizing the main takeaways we have considered in this study. Some of us question the convenience of taking for granted expansion programs for TEER since the best long-term results based on the current evidence available or data from the surgical field cannot be guaranteed. It is imperative that there is a paradigm and attitudinal change among the professionals involved in this type of technological proposals.

Currently, we have been seeing with an alarming frequency a philosophy based on a desire to reward all investment efforts made by the industry through biased information favorable to study devices such as MitraClip.

Therefore, the association between the industry and the project director is something that should be taken into serious consideration. Unlike the project manager, who does not know what the final outcome will be, the industry needs a device with a guaranteed practical application. On this matter, the project or trial needs funds and, therefore, is vulnerable to pressure from the industry to achieve the results expected by the project manager. Therefore, we see, once again, strong financial reasons and, ultimately, coming from the industry to oppose to an inconvenient outcome that would otherwise be accepted as such. Conflicts of interest among MVARC, COAPT, and MitraClip (Abbott) are a pressing matter that should be dealth with and clarified as soon as possible.

Implications between residual mitral regurgitation 2+ after TEER and bias in the definition of success given by the Mitral Valve Academic Research Consortium

The study main idea is to present and explore the consequences of the real or potential conflict of interests that exist among the TEER technique, the COAPT trial, and the definitions drafted by the Mitral Valve Academy Research Consortium. To this date, this has not been taken into serious consideration. Therefore, this study can serve as a part of the stages that still need to be taken into consideration for a more prudent and realistic analysis of the current state of these technologies in our routine clinical practice. World leaders in this professional setting should come up with convincing responses to our doubts, thus avoiding any outcome distortions, and setting rules and regulations that should govern future investigations conducted in this field.

CONCLUSIONS

Based on what we have developed in this study, the following immediate actions are advised:

1) The rules for mitral valve repair apply to all adult patients equally regardless of the etiology and the access route. A mitral annuloplasty ring is needed as a fundamental part of this repair. To this date, the leaders have not explained clearly how they expect TEER therapy to work properly since it does not include a mitral annuloplasty ring.
2) More clarity regarding the exact degree of residual MR is needed while specifying the degree of MR, including 2+, as part of poor outcomes after TEER.
3) It is absolutely imperative to change the definitions of "success" drafter by the MVARC on the degree of MR, including 2+, as part of failed procedures.
4) Conflict of interest should be avoided. The MVARC lead author cannot be, at the same, time, the lead author of one of the most controversial trials on MitraClip like the COAPT trial. Therefore, the validity of the effectiveness of the device seems

highly questionable regarding residual MR 2+ and its long-term final impact.

The central idea of this study was to express and explore the real or potential consequences of the conflict of interests among the TEER technique, the COAPT trial, and the definitions drafted by the Mitral Valve Academy Research Consortium. To this date, none of this has been taken seriously. Therefore, this study can serve as a part of the stages that still need to be taken into consideration for a more prudent and realistic analysis of the current state of these technologies in our routine clinical practice. World leaders in this professional setting should come up with convincing responses to our doubts, thus avoiding any outcome distortions, and setting rules and regulations that should govern future investigations conducted in this field.

Conflicts of interest

The authors have no disclosures to declare.

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STATEMENT

STATEMENT OF THE ARGENTINE COLLEGE OF CARDIOVASCULAR SURGEONS ON THE 2021 CORONARY REVASCULARIZATION GUIDELINES REPORTED BY THE AMERICAN COLLEGE OF CARDIOLOGY AND THE AMERICAN HEART ASSOCIATION

The recent publication of the 2021 ACC/AHA Guideline for Coronary Artery Revascularization[1] has drawn interest worldwide and called the attention of the surgical community due to the controversies and setbacks expressed, which do not seem reflect the best therapeutic options for patients with stable coronary artery disease (SCAD).

The Argentine College of Cardiovascular Surgeons, and other international scientific societies of cardiac surgery[2-4] have presented their position through their Cardiothoracic Surgery Committee.

The new guidelines express a change in the recommendation from 1 to 2b on coronary artery bypass graft (CABG) over medical therapy alone to improve survival in patients with 3-vessel CAD with preserved left ventricular (LV) function and no left main coronary artery disease (LMCAD). On the other hand, the same degree of recommendation is given to percutaneous coronary intervention (PCI), although it is clarified that "the usefulness of PCI to improve survival is uncertain" (Chapter 7.1 related to revascularization on the survival of patients with stable coronary artery disease [SCAD]).

This change of recommendation is based on the author's interpretation of the results of the ISCHEMIA study[5] that was not designed to compare the results between surgery and the optimal medical treatment (OMT). In this study, patients were randomized to an invasive or conservative strategy group. There was no evidence that an initial invasive strategy—compared to an initial conservative strategy—reduces the risk of ischemic cardiovascular events or the all-cause mortality over a median of 3.2 years[5]. However, it did show that an invasive strategy would seem to reduce the risk of infarction and improve quality of life, although no differences were reported between the groups compared to mortality. Only 26% of the patients with an initial invasive strategy who received revascularization were treated with surgery. Considering that 42% of the patients had diabetes and 71% multivessel disease, it is likely that CABG has been underestimated, leaving the choice between PCI and CABG to local working groups.

The new guidelines show no additional randomized controlled trial (RCT) to support this downgrade in the level of evidence. It is just enough to review the literature to verify that the only treatment that has had an impact on the survival and the incidence rate of myocardial infarction is surgery. From the metanalysis

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published by Yusuf et al. in The Lancet back in 1994 until now, all observational and randomized studies have shown a significant decrease in the mortality rate reported from 5 to 10 years in patients treated with surgery, even more among the highest risk patient subgroups[6].

Although recent studies have shown tremendous improvement in medical therapy[6], better management should include not only the use of cardioprotective drugs, but also risk factor controls, which may decrease the prevalence of refractory angina and the need for subsequent revascularization. This is reflected on the BARI-2D, COURAGE and FREEDOM clinical trials where the rate of patients with a complete medical treatment (tobacco cessation glycohemoglobin, LDL, systolic blood pressure control) was only 23%, 18%, and 8%, respectively[7,8,9].

On the other hand, to assume that revascularization strategy between PCI and CABG is similar or equivalent is wrong. Numerous studies such as the Syntax, the Excel, and the Noble[10,11,12] have already demonstrated the superiority of CABG reducing revascularization and perioperative infarction compared to PCI.

According to different randomized studies comparing PCI vs CABG, the benefits of myocardial revascularization are more evident after 3 years when the mortality, infarction, and need for revascularization curves begin to diverge in favor of surgery.

It is remarkable that the new guidelines do not take into consideration this previously published evidence demonstrating that total arterial revascularization offers excellent survival benefits, reduces the rate of MI, and the recurrence of symptoms at long-term follow-up[13-14].

Another controversial recommendation of the recent 2021 guidelines committee is the use of the radial artery over venous accesses for revascularization purposes. The radial artery has shown greater benefits on patency, fewer adverse cardiac events, and higher survival rates. However, the authors equal radial artery access to the IMA graft (I) and even superior to the BIMA graft (2a). Since this recommendation is supported by small studies only, it would seem not to have been sufficiently substantiated[15]. Furthermore, radial approach for percutaneous procedures has become an IA indication, which stands as another relevant reason to embolden different subspecialties like cardiologists, cardiovascular surgeons, and interventional cardiologists when drafting the guidelines.

The Argentine College of Cardiovascular Surgeons values the effort and work done by the ACC/AHA committee preparing these guidelines. However, following the precepts coming from the heart team and the interdisciplinary joint work done to achieve better outcomes, we consider that the inclusion, approval, and endorsement of this type of recommendations including other international surgical scientific societies like STS, AATS, EACTS, LACES is necessary for a better understanding and agreement on the current evidence available.

Finally, although it is true that the publication of these guidelines is very relevant in our decision-making process, we must take into account their real-world applicability considering the needs and problems of the own environment for a better management of our patients[16].

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CARDIOVASCULAR SURGERY IMAGES

ENDOVASCULAR APPROACH FOR PENETRATING THORACIC AORTA TRAUMA

Thoracic aortic trauma is a devastating injury that can be due to a blunt or penetrating mechanism. Penetrating aortic trauma (PAT) can be due to low- and high-energy objects. PAT can present as cardiac tamponade or massive hemothorax. Lower-energy injuries like stab wounds can produce a small, contained pseudoaneurysm. Back in 1994, Dake et al. described the first successful thoracic endovascular aortic repair (TEVAR) in a series of 13 patients. The mortality rate of the open approach to treat thoracic aorta trauma was 20%, and up to 14.3% of the patients developed paraplegia due to spinal cord ischemia (SCI). The risk of complications such as stroke, extremity ischemia, and SCI still exists with TEVAR but is much lower. There is no recent evidence on the endovascular approach to treat PAT.[1-4] This is the case of a 28-year-old man without cardiovascular risk factors with a left posterior thoracoabdominal high-velocity gunshot wound. The patient remained hemodynamically stability. An early thoracic x-ray was performed that revealed the presence of left hemothorax that was treated with a left chest tube. After being referred to our center, a review of the coronary computed tomography angiography performed on chest, abdomen, and pelvis revealed the presence of PAT with a pseudoaneurysm (grade 3 thoracic aorta trauma) and intraluminal thrombus in the thoracic descending aorta (Figures 1-3) 7 cm above the celiac axis. Although open intervention with left posterolateral thoracotomy with or without cardiopulmonary bypass is a feasible option for some patients with this condition, the procedure is no stranger to complications, and the rates of failure are as high as 28% and 19%, respectively. After careful review of the patient's anatomy and the outcomes of the treatment modalities available, endovascular approach was deemed the better option given the patient's fewer postoperative complications and short intensive care unit (ICU) and hospital stays due to the SARS-CoV-2/COVID-19 pandemic. He was treated with TEVAR with a 22 mm x 117 mm Zenith TX2ZDEG 20-Fr thoracic aortic endograft (Cook Medical, Bloomington, Indiana, United States) via femoral vascular access (Figure 4). The patient did not have any postoperative complications and stayed only 1 day at the ICU for postoperative vital sign monitorization plus another day at the hospital. The patient provided his written informed consent for the publication of the case report and images.

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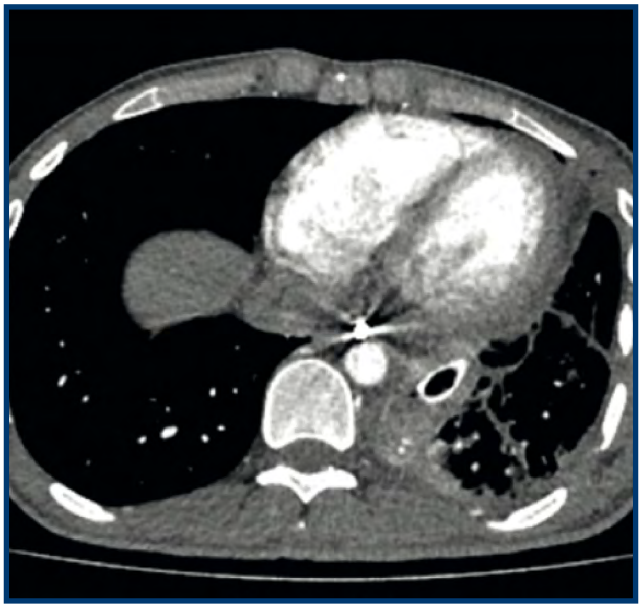
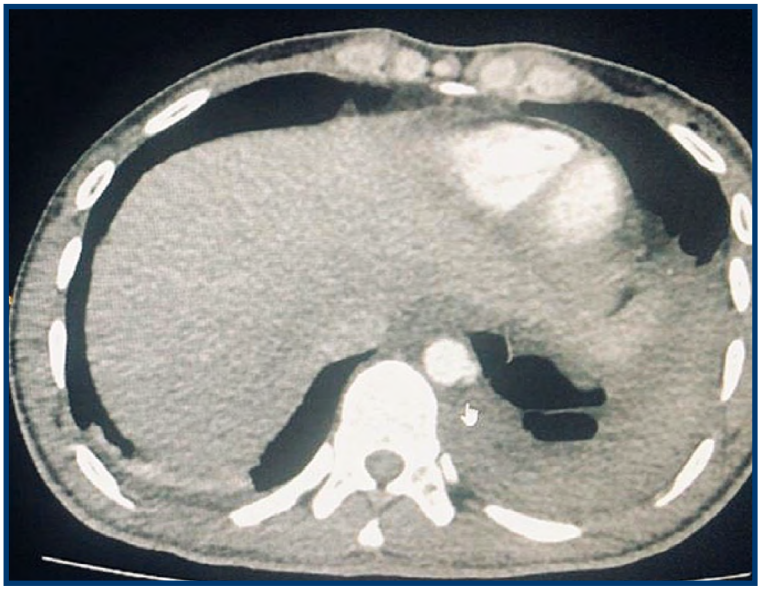


FIGURE 1. Coronary computed tomography angiography showing a high-velocity gunshot wound next to the thoracic aorta.

FIGURE 2. Coronary computed tomography angiography showing the total compromise of the aortic wall due to high-velocity gunshot wound with presence of pseudoaneurysm.



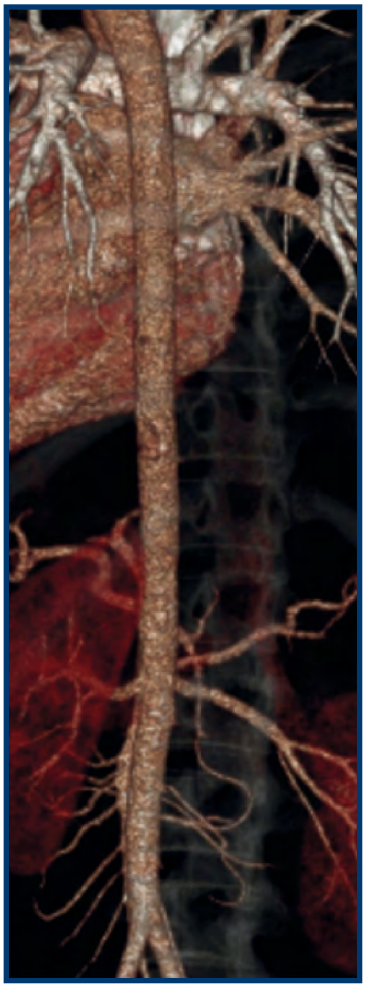


FIGURE 3. 3D thoracic aortic reconstruction showing the loss of aortic wall continuity due to high-velocity gunshot wound.

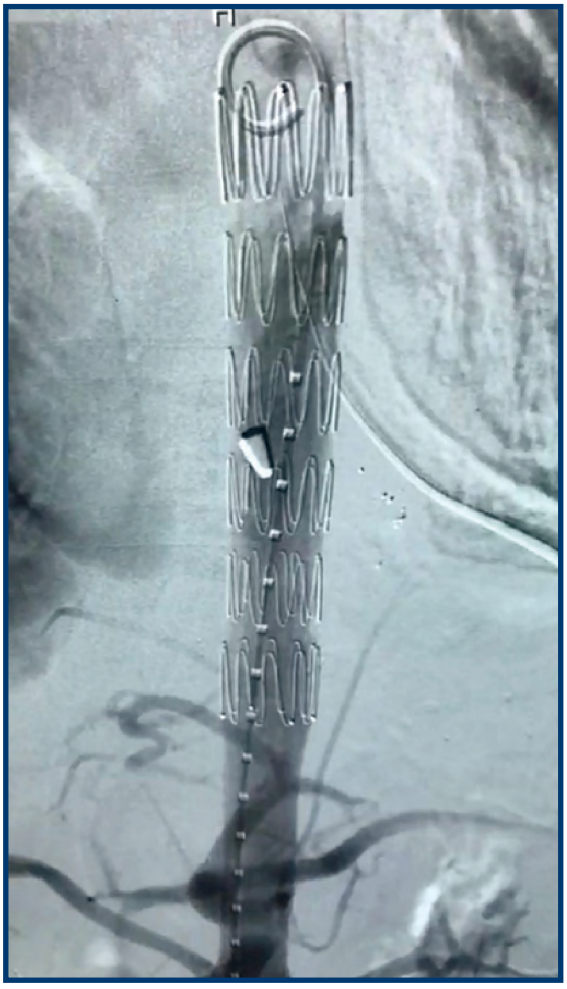


FIGURE 4. Final thoracic aortic angiography after endovascular repair of the aortic injury using the TEVAR technique with endograft covering.

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SELECTED ARTICLES

We hereby present comments on a selection of articles recently published in internationally acclaimed medical journals. We believe these papers deserve special attention due to the quality and importance of the conclusions reached by the studies. Our objective is to keep an open look on new aspects of scientific research or review articles that may, in turn, update aspects of our own medical specialty.

Also, the Editorial Committee will consider suggestions on recent articles that the readers think deserve to be commented in this section (revista@caccv.org.ar).

PROPHYLACTIC ANTIBIOTIC THERAPY FOR INGUINAL INFECTIONS IN VASCULAR SURGERY

AMATO B, COMPAGNA R, DE VIVO S, ROCCA A, CARBONE F, GENTILE M, CIROCCHI R, SQUIZZATO F, SPERTINO A, BATTOCCHIO P. GROIN SURGICAL SITE INFECTION IN VASCULAR SURGERY: SYSTEMIC REVIEW ON PERI-OPERATIVE ANTIBIOTIC PROPHYLAXIS

Antibiotics (Basel). 2022 Feb; 11(2): 134
https://doi.org/10.3390/antibiotics11020134

In spite of recent advances in pre and post-operative care, surgical site infections (SSI) in vascular surgery still remain high. B. Amato, et al., from University of Naples Federico II in Italy, conducted a systematic review of papers published from 1980 to 2020 in OVID, PubMed and EMBASE. All specialties report a 2-4% risk of SSI in "clean" surgeries, but rates are higher in post-traumatic procedures (15-50%) or in populations with risk factors, i.e. high-risk vascular surgery patients (15%-22%). Current guidelines recommend no more than 24 hours of peri-operative intravenous antibiotic therapy in cases of clean vascular surgery, as prolonging treatment has shown no benefits. However, when there are clear signs of infection or risk factors, like the use of synthetic prosthesis, management is still not well defined.

The major incidence of SSI in vascular surgery is observed in the inguinal area, with percentages ranging from 5 to 30%. Some of the factors that increase this risk are diabetes, smoking, female sex, synthetic prostheses, obesity and the use of steroids. Although any bacteria may in theory infect a vascular prosthesis or lead to SSI, the most frequently involved are Gram - Pseudomona aeruginosa and Staphylococcus epidermidis and among Gram + bacteria, S. aureus. A major challenge is posed by biofilms, bacterial complexes characterized by secretion of adhesive matrixes that protect them from external antibiotics and host defenses.

Authors identified 364 publications, 36 of which were deemed apt for meta-analysis upon applying inclusion and exclusion criteria. Meta-analysis results indicate that the pre-operative antibiotic therapy of choice for prevention of SSI in vascular surgery is first or second generation cephalosporins, which are low cost (cefazolin being the most commonly used), whereas vancomycin and clindamycin are reserved for β-lactamic allergies. It is convenient to remember that a history of allergy to these antibiotics is very frequent, but only 10% of cases are a true allergy. For an appropriate treatment strategy in these cases, it is suggested to conduct allergy skin tests. In centers with high prevalence of methicillin-resistant S. aureus, or in patients with high risk of infection (elderly individuals, cancer or dialysis patients), the use of prophylactic vancomycin needs to be considered, and the benefit of its use in combination with cefazolin has been observed. Other authors have found benefits with the administration of a second dose of cefazolin in patients with blood loss higher than 1500 ml or in prolonged surgeries.

In the case of endovascular procedures, there is no general consensus on antibiotic prophylaxis. The usual scheme is the same as for open vascular surgeries (single pre-operative cephazolin dose, replaced by vancomycin in case of allergies to β-lactamics). There is controversy regarding the benefit of peri-operative testing of nasal carriers of methicillin-resistant S. aureus.

Several authors have found very favorable results with collagen implants with gentamicin in the surgical site, although, given the short evidence available, it is considered necessary to conduct multicenter trials in order to validate such observations.

Authors conclude that the prophylactic administration of peri-operative antibiotics with coverage for Gram+ and Gram-, and the possible addition of a second dose in case or blood losses greater than 1500 ml or prolonged surgeries has a significant impact in SSI reduction in vascular surgery.

CAROTID STENTING VS. MEDICAL THERAPY IN ASYMPTOMATIC PATIENTS

KEYHANI S, ET AL. COMPARATIVE EFFECTIVENESS OF CAROTID STENTING TO MEDICAL THERAPY AMONG PATIENTS WITH ASYMPTOMATIC CAROTID STENOSIS.

Stroke 2022;53:1157-1166
https://doi.org/10.1161/STROKEAHA.121.036178

Keyhani S et al. of San Francisco Veterans Affairs Medical Center in the U.S., state that although there are studies that prove the benefits of carotid endarterectomy (CEA) in the prevention of cerebrovascular accidents (CVA) in patients with carotid stenosis, both symptomatic and asymptomatic, there are no clinical trials making a direct comparison of carotid artery stenting (CAS) to medical therapy (MT).

Since the CVA risk in patients with asymptomatic carotid lesion has gone down thanks to advances in MT, the prospective CREST-2 trial comparing MT to surgical approaches is ongoing and the results will be available in 2025. While awaiting for the results, the authors conducted a retrospective study on 219.979 patients >= 65 with carotid lesion that had received an image diagnosis between 2005 and 2009. The cohort of asymptomatic patients excluded patients with CVA or transient ischemic accident during the 6 months prior to the image study, as well as those that had received CAS or CEA during the same period.

The authors initially segregated patients with stenosis >= 65 <50% and later identified 13.371 that had stenosis reports >70% or description of severe, critical or almost occlusive stenosis. Time 0 was considered to be the time of the first study that showed the presence of carotid lesion. The authors selected patients with MT and those that received interventions (CAS or CEA) of similar characteristics.

After applying inclusion criteria, 551 patients were grouped as CAS, 2712 as CEA and 2509 as MT. The lower number of patients with CAS and the greater number of comorbidities (coronariopathy, COPD, use of antiangina medications) prevented the possibility of conducting a comparative study among the three groups, for which reason this trial presents the comparison among those that effectively received CAS within the first year of diagnosis and those that received MT only.

The incidence at 5 years of fatal and non-fatal CVA, as well as non-CVA related deaths was analyzed. The percentage of CVA or death in the CAS group within 30 days was 2.2%. The risk of fatal or non-fatal CVA at 5 years was 10.3% in the CAS group and 6.9% in the MT treatment group; survival at 5 years was 61.7% and 66.9%, respectively. Once statistical adjustments were applied, these differences maintained the lack of significance. All analysis indicate that CAS does not offer a significant advantage over MT in terms of CVA reduction.

Authors acknowledge some limitations of the trial because of its retrospective character, the small number of patients in the CAS group, and for having been conducted in an exclusively male population. Considering these limitations, no differences were found between patients treated with CAS and those that received MT. Further studies are required to confirm these results.

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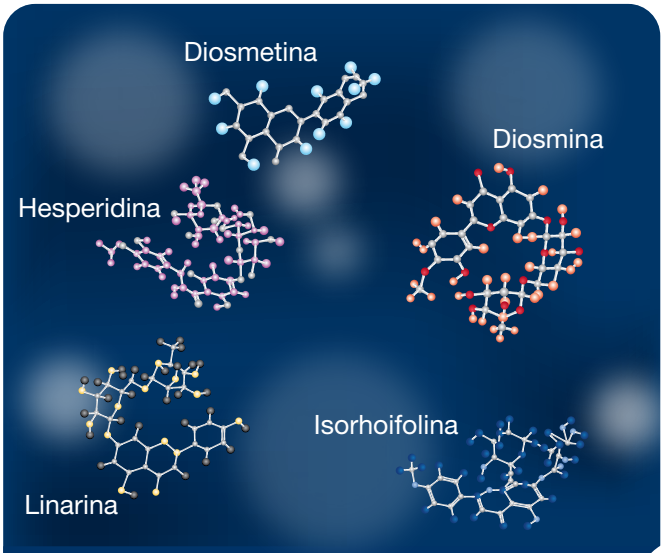

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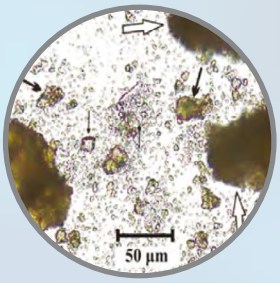

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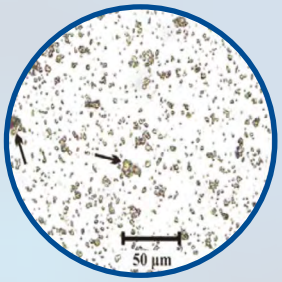

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*Estudio realizado por el Dpto. de Farmacología Clínica y Farmacia Clínica, Universidad Nacional de Farmacia, Jarkov, Ucrania comparando dos productos similares a Daflon en dicho país.

DAFLON 1000 mg comprimidos recubiertos y DAFLON 1000 mg Suspensión Oral
Composición Daflon 1000 mg comprimidos recubiertos: Cada comprimido recubierto de Daflon 1000 mg contiene: Fracción flavonoide purificada y micronizada: 1000 mg (Correspondiendo a: Diosmina 90 %: 900 mg y Flavonoides expresados en hesperidina 10%: 100 mg). **Excipientes**: Carboximetilalmidón sódico, celulosa microcristalina, gelatina, estearato de magnesio, talco. **Recubrimiento:** dióxido de titanio (E 171), glicerol, laurilsulfato de sodio, macrogol 6000, hipromelosa, óxido de hierro amarillo (E 172), óxido de hierro rojo (E 172), estearato de magnesio. **Composición DAFLON 1000 mg Suspensión Oral:** Cada sachet de 10 ml de Daflon 1000 mg contiene: Fracción flavonoide purificada micronizada: 1000 mg (Correspondiendo a: Diosmina 90%: 900 mg y Flavonoides expresados en Hesperidina 10%: 100 mg). **Excipientes:** Malitol en polvo, goma xantan, benzoato de sodio, aromatizante de naranja, ácido cítrico, agua purificada. **Acción terapéutica:** Vasculoprotector. **Indicaciones:** Tratamiento de las manifestaciones de la insuficiencia venosa crónica de los miembros inferiores, funcional y orgánica. Sensación de pesadez, dolor, calambres nocturnos. Tratamiento de los signos funcionales relacionados con la crisis hemorroidal. Contraindicaciones: Hipersensibilidad a las sustancias activas o a alguno de los excipientes. **Advertencias y precauciones de empleo:** La administración de este producto no imposibilita el tratamiento específico de otras enfermedades anales. Si los síntomas no disminuyen rápidamente, debe practicarse un examen proctológico y el tratamiento debe ser revisado. Embarazo: No hay datos o estos son limitados relativos al uso de fracción flavonoide purificada micronizada en mujeres embarazadas. Los estudios realizados en animales no han mostrado toxicidad para la reproducción. Como medida de precaución, es preferible evitar el uso de Daflon durante el embarazo. Lactancia: Se desconoce si el principio activo/los metabolitos se excretan en la leche materna. No se puede excluir el riesgo en recién nacidos/niños. Se debe decidir si es necesario interrumpir la lactancia o interrumpir el tratamiento tras consideran el beneficio de la lactancia para el niño y el beneficio del tratamiento para la madre. **Reacciones adversas:** Trastornos del sistema nervioso: Raras: mareos, dolor de cabeza, malestar. Trastornos gastrointestinales: Frecuentes: diarrea, dispepsia, náuseas, vómitos. Poco frecuentes: colitis. Frecuencia no conocida: dolor abdominal. Trastornos de la piel y del tejido subcutáneos: Raras: erupción cutánea, prurito, urticaria. Frecuencia no conocida: edema aislado de la cara, labios y párpados. Excepcionalmente, edema de Quincke. P**osología y forma de administración:** Posología usual: un comprimido recubierto/ sachet por día preferiblemente por la mañana. Crisis hemorroidal: 3 comprimidos recubiertos/ sachets al día durante los primeros cuatro días y después 2 comprimidos recubiertos/sachets al día durante tres días. La ranura sirve únicamente para fraccionar y facilitar la deglución pero no para dividir en dosis iguales. MAMS Cert Nº 40.987. Daflon 1000 comprimidos: Elaborado en Les Laboratoires Servier Industrie, Gidy, Francia. Daflon 100 mg suspensión oral: Elaborado en 1-3 allée de la Neste - COLOMIERS Francia. Importado por: SERVIER ARGENTINA S.A. Av. Castañares 3222 (C1406IHS) C.A.B.A. - Tel.: 0800-777-SERVIER (7378437) Directora Técnica: Nayla D. Sabbatella - Farmacéutica. Versión: Enero/2020

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