



ARGENTINIAN JOURNAL OF INTERVENTIONAL CARDIOLOGY

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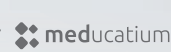
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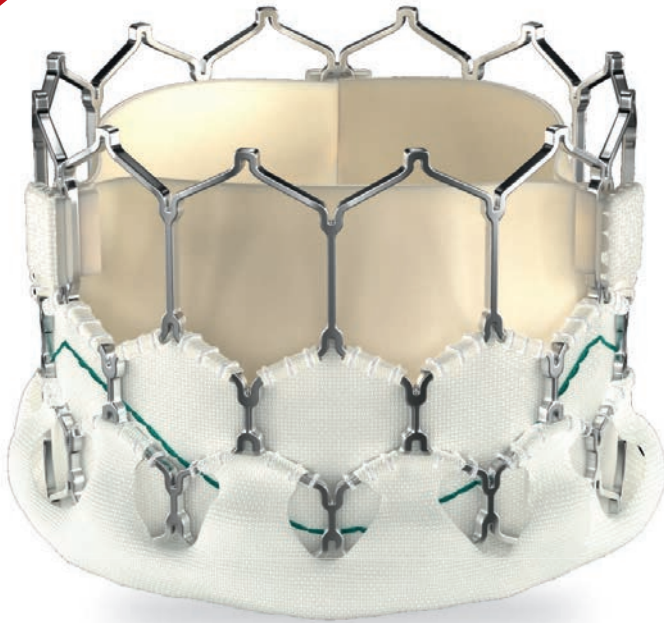
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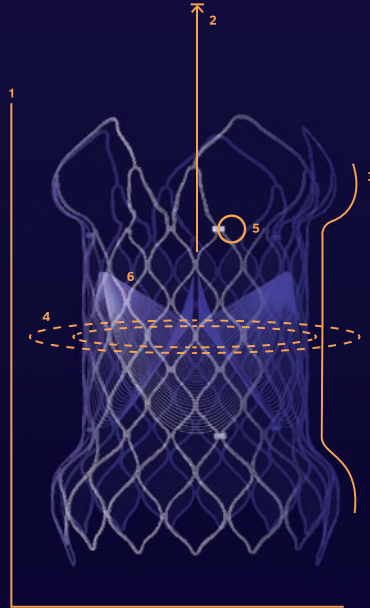
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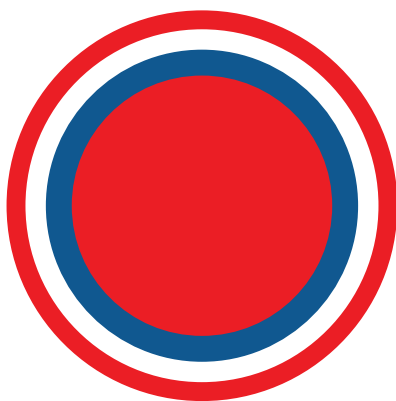
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PERCUTANEOUS FEMORO-FEMORAL BYPASS: A HEMODYNAMIC STRATEGY THAT COULD PREVENT LIMB ISCHEMIA DURING LARGE BORE SHEATHS USE

Fernández Pereira C

Gallardo Galeas et al. publish in this issue¹ a clinical case of complex coronary angioplasty with iVAC2L ventricular assistance in a patient with severely deteriorated ejection fraction. The device allowed for the stabilization of blood pressure and successful revascularization without complications. This report clearly illustrates the value of the iVAC2L as effective pulsatile hemodynamic support in high-risk procedures, while also introducing one of its potential limitations so that we can prevent it: the use of an 18-Fr arterial introducer, which may compromise lower limb perfusion and restrict support duration, which was not necessary in the reported case but could be an eventual requirement.

ORIGINAL ARTICLES / ARTÍCULOS ORIGINALES

PREVALENCE AND FACTORS ASSOCIATED WITH CONTRAST-INDUCED NEPHROPATHY IN PATIENTS WITH ACUTE CORONARY SYNDROME UNDERGOING EMERGENCY CORONARY ANGIOGRAPHY IN A PUBLIC HOSPITAL IN SAN JUAN

Ferreyra DF et al.

Introduction. Contrast-induced nephropathy is defined as renal failure that occurs 48 to 72 hours after the administration of endovenous contrast, without any other cause to justify it, increasing morbidity and mortality. The aim of this study was to determine the prevalence of contrast-induced nephropathy in patients undergoing cardiac catheterization in a setting of acute coronary syndrome, identifying associated risk factors and nephroprotective measures.

Materials and methods. The sample included 101 patients who underwent urgent cardiac catheterization at Hospital Dr. Guillermo Rawson in San Juan province between June 2021 and June 2022. Inclusion criteria were patients of both sexes, aged between 40 and 80 years, whose glomerular filtration rate was assessed at admission, 48 hours after the procedure, and at discharge.

Results. Of the 101 patients with acute coronary syndrome who underwent urgent cardiac catheterization, 82 were men and 19 were women, with a mean age of 58.3 years; 44 patients developed contrast-induced nephropathy, with a predominance of men between 40 and 60 years of age. Of these, 13 underwent nephroprotection. The predominant risk factors were smoking and hypertension.

Conclusions. Contrast-induced nephropathy remains a relevant complication in a setting of acute coronary syndrome and cardiac catheterization. Our findings underscore the importance of recognizing modifiable risk factors and actively promoting nephroprotective

strategies, which are still underused in clinical practice. Prospective studies are required to validate these associations and to define effective interventions to reduce its incidence and consequences.

IN-HOSPITAL OUTCOMES AND FOLLOW-UP OF PATIENTS UNDERGOING ANGIOPLASTY IN HEMODIALYSIS FISTULAS

Leaden Y, Cardone M

Background: An arteriovenous fistula (AVF) is an abnormal connection between a vein and an artery that, in patients with dialysis-dependent renal failure, is created to facilitate renal replacement therapy. Its care and proper functioning are a key factor for the survival of patients with this condition.

We present the in-hospital results and follow-up of patients undergoing fistula angioplasty for hemodialysis.

Materials and methods: This was an observational, retrospective, single-center study. Data collected included demographic variables, risk factors, and the fistula type and location. Procedural details (access type, stent use, success, and complications) were recorded. Immediate outcomes and the incidence of new interventions during follow-up were assessed.

Results: Seventy patients were included. Their mean age was 59 years; 68% were men. There was a high prevalence of hypertension and diabetes (87% and 68%, respectively). The most frequent stenosis site was venous (51%), mainly at the puncture tract, followed by juxta-anastomotic stenosis (30%). Angioplasty was performed ad hoc in most patients (86%). Primary procedural success was 82%, and no complications were recorded during the procedure. Follow-up of up to 36 months was performed and completed in 96% of patients. The need for reintervention was high (55%: 16 repeat angioplasties, 13 new fistulae, and 8 urgent thrombectomies). As regards mortality, there was 1 case. Early dysfunction (<1 year) was associated with a higher reintervention rate (86% vs. 32.5%, $p < 0.00001$; odds ratio [OR] 13.5).

Conclusion: AVF angioplasty is safe and effective, with a high initial success rate. However, the rate of reintervention during follow-up is high, especially in patients with early dysfunction.

CASE REPORTS / CASOS CLÍNICOS

COMPLEX CORONARY ANGIOPLASTY USING THE iVAC2L VENTRICULAR ASSIST DEVICE IN A PATIENT WITH LOW EJECTION FRACTION

Gallardo Galeas P et al.

Percutaneous coronary intervention (PCI) in patients with complex anatomy and severely reduced ejection fraction is a clinical challenge, with a high risk of hemodynamic instability and mortality. Ventricular assist devices are proposed as temporary support during revascularization, although evidence on them is still limited.

A female patient with extensive anterior infarction and a 27% ejection fraction had low cardiac output and required inotropic support. A decision was made to complete revascularization with

pulsatile mechanical ventricular assistance iVAC2L. During the intervention, blood pressure increased from 90/50 mmHg to 150/90 mmHg, allowing for the angioplasty of the circumflex artery with successful implantation of two drug-eluting stents without complications. The use of iVAC2L offers effective and continuous hemodynamic support, improving cardiac output and procedural tolerance. Its advantage lies in its easy implantation, relatively low cost, and compatibility with balloon counterpulsation consoles, without requiring surgical equipment for its removal. The ACC/AHA/SCAI 2025 guidelines support the use of mechanical assist devices in patients with refractory cardiogenic shock or selected high-risk procedures.

Conclusion: The iVAC2L device proved to be a safe, practical, and effective tool for stabilizing this patient with severe ventricular function impairment undergoing complex coronary angioplasty, thus constituting an accessible alternative in settings with limited resources.

BIODAPTIVE STENT IN CORONARY ARTERY DISEASE: AN INNOVATIVE STRATEGY TO RESTORE VASCULAR FUNCTION

Bayón J et al.

An octogenarian patient with a history of arterial hypertension, dyslipidemia, type 2 diabetes mellitus, and chronic kidney disease presented with progressive angina and evidence of ischemia in the inferior and lateral walls. Coronary angiography revealed significant disease in the distal left main coronary artery (LMCA) and the proximal segments of the left anterior descending (LAD) and circumflex (Cx) arteries. Percutaneous coronary intervention of the LMCA–LAD was conducted with intravascular lithotripsy (LithiX Hertz Contact IVL, Elixir Medical Corporation, Milpitas, CA, USA), followed by implantation of two overlapping DynamX™ bioadaptor devices (Elixir Medical Corporation, Milpitas, CA, USA) and subsequent post-dilation with a non-compliant balloon. The circumflex artery was treated with lithotripsy and a drug-coated balloon. The angiographic and intracoronary outcomes were optimal, without complications and with favorable clinical evolution. This case illustrates the feasibility and potential of the combined use of emerging technologies—such as intravascular lithotripsy and bioadaptor devices—in complex calcified lesions in high-risk patients.

TAVI IN A PATIENT WITH SEVERE BICUSPID AORTIC VALVE STENOSIS IN CARDIOGENIC SHOCK: CASE REPORT

Lerner JP et al.

Aortic stenosis (AS) is one of the most prevalent valvular heart diseases, affecting 1.3% of individuals over 65 years of age. To date, the safety and efficacy of transcatheter aortic valve implantation (TAVI) in cardiogenic shock (CS) have remained controversial.

We present the case of a 43-year-old man with severe AS due to a bicuspid aortic valve in cardiogenic shock, successfully treated with balloon-expandable TAVI and a preventive chimney stenting strategy due to a high associated risk of coronary obstruction. The procedure achieved immediate success with no leak or transprosthetic gradient, resulting in immediate improvement in functional class and recovery of left ventricular ejection fraction within 48 hours. This case demonstrates the feasibility of TAVI in severe

re AS with bicuspid aortic valve in a setting of CS when appropriate patient selection, preventive strategies, and individualized procedural planning—including prosthesis choice and customization—are undertaken.

PERCUTANEOUS CLOSURE OF MITRAL PARAVALVULAR LEAK

Weckesser FI et al.

Paravalvular leak (PVL) is a potential complication after cardiac valve replacement that can lead to heart failure, hemolytic anemia, or endocarditis. We present the case of a 69-year-old woman with a history of mechanical mitral and aortic valve replacement who developed a severe mitral PVL diagnosed by echocardiography. Given the high surgical risk, percutaneous anterograde closure was successfully performed using an Amplatzer Vascular Plug III device, with significant improvement in functional class at 6 and 12 months of follow-up. This case highlights the feasibility and safety of percutaneous closure as a therapeutic alternative in selected patients with severe symptomatic PVL, provided there is always a multidisciplinary assessment.

VASCULAR COMPLICATION POST-TAVI WITH SHEATH ENTRAPMENT AND DISTAL EMBOLIZATION: SURGICAL RESOLUTION THROUGH EXTRAPERITONEAL APPROACH. A CASE REPORT

Martínez G, Fernández J

A 69-year-old woman with severe aortic stenosis underwent transfemoral transcatheter aortic valve implantation (TAVI) with a low-profile sheath and favorable sheath-to-femoral artery ratio (SFAR) (0.92). Despite adequate preoperative planning with computed tomography angiography, she experienced a major vascular complication due to entrapment of the femoral introducer, with distal embolization of endothelial fragments. Upon the failure of conventional maneuvers to release the device, a decision was made for extraperitoneal surgery with arterial reconstruction using a vascular prosthesis, followed by successful tibial embolectomy. This case highlights the need for multidisciplinary planning to address uncommon but potentially severe vascular complications following endovascular procedures.

LETTER FROM THE PRESIDENT / CARTA DEL PRESIDENTE

LETTER FROM THE PRESIDENT OF CACI

Fernández JJ

Dear colleagues and friends, in this letter—and in alignment with previous editorial remarks made by our President-elect, Dr. Alfredo Bravo—I would like to reinforce the call for active participation of all our CACI members.

I would like to highlight the existence of our Code of Ethics, voted upon during Assembly and available to all members, which is not mere formality but a call for empathy among colleagues. If we all apply this empathy and put this mutual consideration into practice, labor-related conflicts will decrease to the point of disappearing.

Percutaneous femoro-femoral bypass: a hemodynamic strategy that could prevent limb ischemia during large bore sheaths use

Bypass femorofemoral percutáneo: una estrategia hemodinámica que podría prevenir la isquemia de miembro inferior durante el uso de introductores de gran tamaño

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Gallardo Galeas *et al.* publish in this issue¹ a clinical case of complex coronary angioplasty with iVAC2L ventricular assistance in a patient with severely deteriorated ejection fraction. The device allowed for the stabilization of blood pressure and successful revascularization without complications. This report clearly illustrates the value of the iVAC2L as effective pulsatile hemodynamic support in high-risk procedures, while also introducing one of its potential limitations so that we can prevent it: the use of an 18-Fr arterial introducer, which may compromise lower limb perfusion and restrict support duration, which was not necessary in the reported case but could be an eventual requirement.

The use of percutaneous ventricular assist devices, such as iVAC2L® (PulseCath BV, Amsterdam, Netherlands), has expanded the limits of complex coronary revascularization by providing effective pulsatile hemodynamic support in patients with severe ventricular dysfunction or cardiogenic shock. However, a possible limitation arises from the diameter of the arterial introducer, which entails a potential risk of lower limb ischemia, especially in small-caliber femoral arteries, calcified arteries, or diffuse atherosclerotic disease.

The phenomenon of distal ischemia during possible prolonged use of large-bore introducers can lead to metabolic acidosis, lactate release, and secondary renal failure, particularly when the procedure extends beyond 2–3 hours. This problem is not limited to interventional cardiology: the situation is similar during extensive endovascular procedures, such as aortic repairs with fenestrations or branches, which are usually prolonged procedures.

In light of this limitation, we propose a strategy already in place for other procedures involving percutaneous femoro-femoral bypass, which allows for distal limb perfusion to be maintained during the use of the iVAC2L in cases with presumed risk of ischemia.

The first publication describing percutaneous femoro-femoral bypass as a technique to prevent or treat limb ischemia during long-term procedures using large-caliber femoral introducers dates back to March 2002. This study was first reported by Lin *et al.* in the *Journal of Vascular Surgery*: a minimally invasive endovascular technique was used to create a temporary percutaneous femoro-femoral bypass graft at the patient's bedside to treat acute limb ischemia caused by the placement of an intra-aortic counterpulsation balloon².

This is the technique proposed for cases involving iVAC2L or other large-introducer procedures:

1. The left femoral artery is punctured with a 6-Fr introducer.
2. Using a crossover technique, the right superficial femoral artery is opacified to guide a downward puncture (which may be guided by ultrasound), directing a 5-Fr introducer toward the right popliteal artery.
3. Subsequently, the right common femoral artery is punctured in an ascending direction; the 18-Fr introducer is implanted and the iVAC2L catheter is introduced.
4. Finally, both introducers (the left retrograde one and the right descending, antegrade one) are connected through a closed circuit. The type of connection used is similar to that employed for injector pumps and male-to-male connectors, thus allowing flow from the left femoral artery to the distal right femoral artery, thereby preventing ischemia.
5. Systemic anticoagulation with heparin is maintained, and flow is monitored clinically and angiographically.

This maneuver creates a functional femoro-femoral bypass, which ensures distal oxygenation during assistance and prevents prolonged hypoperfusion.

The proposed strategy—a percutaneous femoro-femoral bypass—could prolong even the duration of iVAC2L support in patients who require it, broadening its applicability beyond complex angioplasty. This bypass could also be used in prolonged endovascular procedures (such as cases of aortic repair with multiple fenestrations or complex reintervention).

This technique offers several advantages: it does not require a surgical team; it maintains distal perfusion during prolonged procedures (>3 h); it is compatible with the use of the iVAC2L and subsequently does not preclude percutaneous closure (for example, PROGLIDE®, Abbott Vascular, Santa Clara, California, United States).

While this strategy is yet to be formally reported, it is inspired by temporary femoro-femoral bypasses used during extracorporeal membrane oxygenation (ECMO) or complex aortic repair.

It should be noted that there is limited but growing evidence supporting the use of percutaneous femoro-femoral bypass (also known as *ex vivo* percutaneous bypass) as a temporary measure to prevent or treat limb ischemia during procedures requiring large-caliber femoral introducers. Case reports and small case series have shown that this technique can restore antegrade flow to the ischemic limb when a large-caliber introducer causes significant arterial obstruction, particularly in a setting of mechanical circulatory support or complex endovascular intervention. These reports describe the successful preservation of limb perfusion through a percutaneous bypass circuit between the contralateral and ipsilateral femoral arteries, allowing for continuous hemodynamic support and minimizing the risk of acute limb ischemia^{3,4}.

However, this approach is not standard treatment and is generally reserved for situations where conventional strategies (such as minimizing introducer size, limiting procedure duration, or using alternative access sites) are insufficient or unfeasible. Available evidence is limited to isolated clinical experiences, and there are no randomized trials or recommendations from major scientific societies that specifically endorse the routine use of percutaneous femoro-femoral bypass for this indication. This technique is considered a rescue or adjunctive option in selected high-risk cases^{3,4}.

Finally, current best practices for large-bore femoral access focus on meticulous preoperative planning, optimal puncture technique, and use of vascular closure devices to minimize vascular complications, as described in recent reviews^{3,5}.

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Prevalence and factors associated with contrast-induced nephropathy in patients with acute coronary syndrome undergoing emergency coronary angiography in a public hospital in San Juan

Prevalencia y factores asociados a nefropatía inducida por contraste en pacientes con síndrome coronario agudo sometidos a cinecoronariografía de urgencia en un hospital público de San Juan

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ABSTRACT

Introduction. Contrast-induced nephropathy is defined as renal failure that occurs 48 to 72 hours after the administration of endovenous contrast, without any other cause to justify it, increasing morbidity and mortality. The aim of this study was to determine the prevalence of contrast-induced nephropathy in patients undergoing cardiac catheterization in a setting of acute coronary syndrome, identifying associated risk factors and nephroprotective measures.

Materials and methods. The sample included 101 patients who underwent urgent cardiac catheterization at Hospital Dr. Guillermo Rawson in San Juan province between June 2021 and June 2022. Inclusion criteria were patients of both sexes, aged between 40 and 80 years, whose glomerular filtration rate was assessed at admission, 48 hours after the procedure, and at discharge.

Results. Of the 101 patients with acute coronary syndrome who underwent urgent cardiac catheterization, 82 were men and 19 were women, with a mean age of 58.3 years; 44 patients developed contrast-induced nephropathy, with a predominance of men between 40 and 60 years of age. Of these, 13 underwent nephroprotection. The predominant risk factors were smoking and hypertension.

Conclusions. Contrast-induced nephropathy remains a relevant complication in a setting of acute coronary syndrome and cardiac catheterization. Our findings underscore the importance of recognizing modifiable risk factors and actively promoting nephroprotective strategies, which are still underused in clinical practice. Prospective studies are required to validate these associations and to define effective interventions to reduce its incidence and consequences.

Key words: glomerular filtration rate, risk factors, nephroprotection, contrast dose.

RESUMEN

Introducción. La nefropatía por contraste se define como el fallo renal que ocurre 48 a 72 horas después de la administración de contraste endovenoso, sin otra causa que lo justifique, aumentando la morbimortalidad. El objetivo de este trabajo fue determinar la prevalencia de nefropatía por contraste en pacientes sometidos a cinecoronariografía en contexto de síndrome coronario agudo, identificando factores de riesgo asociados y la aplicación de medidas de nefroprotección.

Materiales y métodos. La muestra incluyó 101 pacientes sometidos a cinecoronariografía de urgencia en el Hospital "Dr. Guillermo Rawson" de la provincia de San Juan, entre junio de 2021 y junio de 2022. Los criterios de inclusión fueron aquellos pacientes de ambos sexos, entre 40 y 80 años, en quienes se evaluó la tasa de filtrado glomerular al ingreso, 48 horas posteriores al procedimiento y al alta.

Resultados. De los 101 pacientes que presentaron síndrome coronario agudo sometidos a cinecoronariografía de urgencia, 82 pacientes correspondieron a sexo masculino y 19 a sexo femenino, con una edad media de 58,3 años; 44 pacientes intercurrieron con nefropatía por contraste, predominando el grupo masculino entre los 40 a 60 años. De ellos, a 13 se les realizó nefroprotección. Los factores de riesgo predominantes fueron el tabaquismo y la hipertensión arterial.

Conclusiones. La nefropatía inducida por contraste continúa siendo una complicación relevante en el contexto de síndrome coronario agudo y cinecoronariografía. Nuestros hallazgos subrayan la importancia de reconocer factores de riesgo modificables y promover activamente estrategias de nefroprotección, aún poco utilizadas en la práctica clínica. Se requieren estudios prospectivos que permitan validar estas asociaciones y definir intervenciones eficaces para reducir su incidencia y consecuencias.

Palabras clave: tasa de filtrado glomerular, factores de riesgo, nefroprotección, dosis de contraste.

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INTRODUCTION

Contrast-induced nephropathy (CIN) is defined as acute renal failure occurring between 48 and 72 hours after the endovenous administration of iodinated contrast, without any other identifiable cause. It is characterized by an absolute increase in serum creatinine greater than or equal to 0.5 mg/dL, or a relative increase greater than or equal to 25% compared with the patient's baseline value⁴. This complication is associated with an increased

risk of mortality, constituting a predictor of poor prognosis in both the short and long term^{1,8,10}.

It is the third most frequent cause of kidney injury in patients undergoing emergency cardiac catheterization, with an in-hospital mortality risk 2 to 4 times higher than that of patients without it^{1,2,3,11}. In fact, patients who develop this complication have an in-hospital mortality rate of 22%, compared with 1.4% for those who do not⁴.

Risk factors for CIN are divided into those related to the patient (such as a glomerular filtration rate below 60 mL/min/1.73 m², heart failure, anemia, diabetes, hypertension, dyslipidemia, age over 75 years, sustained hypotension, concomitant use of nephrotoxic drugs, and liver disease) and those related to the procedure (all contrast agents have a cytotoxic effect). The risk increases proportionally to the volume of contrast administered: it has been shown that every additional 20 mL above 4 mL/kg doubles the risk of develop-

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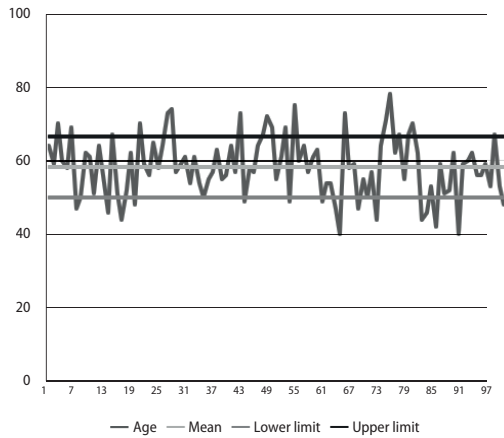


Figure 1. Standard deviation – Age Age group 40–60 years: 61 patients; Age group 61–80 years: 40 patients. Mean age: 58.3 years, with a standard deviation of 8.3

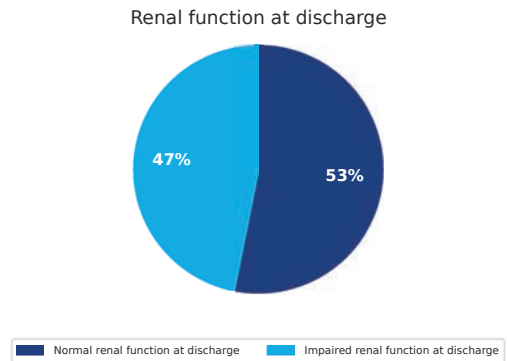


Figure 2. Renal function at discharge. Among the 93 patients with preserved renal function at admission, 44 patients developed renal impairment at discharge (47%), whereas 49 patients maintained preserved renal function (53%).

TABLE 1. Clinical variables according to the presence or absence of contrast-induced nephropathy

Clinical variable	Patients with CIN (n=44)	Patients without CIN (n=49)	p-value (Chi-square)
Age			
Mean±SD (years)	57±9	58±8	
Sex			
Male (%)	11	89	
Female (%)	89	11	
Associated risk factors			
Hypertension (%)	64	61	0,81
Diabetes (%)	25	18	0,436
Dyslipidemia (%)	30	10	0,018
Smoking (%)	89	63	0,004
Obesity (%)	34	31	0,72
Anemia (%)	16	3	0,017
Nephrotoxic drugs (%)	41	9	0
Liver disease (%)	2	1	0,927
Nephroprotection (%)	30%	52%	0,035
Iso-osmolar contrast volume (≥200 mL)	55%	32%	0,572

ping this complication. Therefore, the recommended maximum dose should not exceed 5 mL/kg, with an absolute limit of 300 mL^{3, 8, 9}.

The determination of high-sensitivity troponin has proven useful for diagnosis and prognosis in patients with renal dysfunction, which allows for the adoption of strategies such as the use of non-ionic contrast agents at the lowest possible dose, avoidance of repeat procedures within 72 hours, and prevention of intravascular volume depletion^{1, 5, 6, 7, 12}.

In Argentina, there is limited published information on the prevalence of CIN in the setting of emergency coronary studies, especially in state-funded hospitals in the interior of the country. This lack of local data hinders the development of prevention protocols tailored to our specific healthcare context, which is marked by heterogeneous resources, access to nephroprotection, and patient sociodemographic characteristics. Knowing how big is this problem in our setting makes it possible to bring to the forefront this frequent complication, improve prevention strategies, and provide useful evidence for future renal care policies in interventional cardiology.

The aim of this study was to determine the prevalence of CIN in patients undergoing emergency cardiac catheteri-

zation in an acute setting at Hospital Descentralizado Dr. Guillermo Rawson, assessing renal function at admission, 48 hours after the procedure, and at discharge, along with the dose of contrast used, patient risk factors, and nephroprotection measures applied.

MATERIALS AND METHODS

The study enrolled a total of 101 patients undergoing emergency cardiac catheterization at Hospital Público Descentralizado Dr. Guillermo Rawson (San Juan, Argentina) between June 1, 2021, and June 30, 2022. This was designed as a retrospective, observational, and descriptive study, with the aim of estimating the prevalence of contrast-induced nephropathy (CIN) in patients undergoing emergency catheterization.

Patients were selected using convenience sampling, choosing only those who had the complete clinical data required for the analysis. This strategy sought to ensure homogeneity and completeness of related variables, thereby favoring the internal validity of the study. Cases with incomplete or missing data in key variables were excluded.

The selection process was conducted in two stages: first, by identifying cases through digital medical records and a Mi-

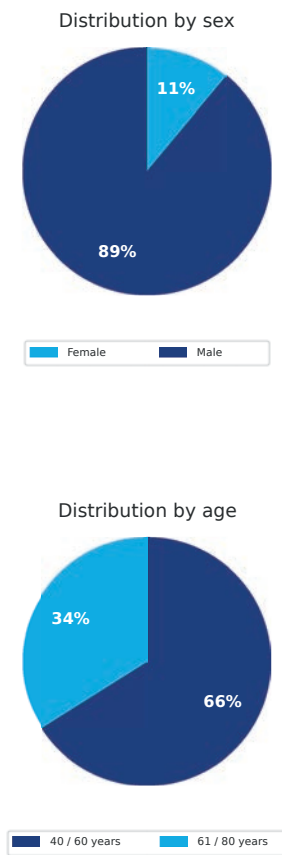


Figure 3. Impaired renal function (by sex and age group). Regarding sex distribution, 11% of patients were women, whereas 89% were men. Regarding age, 31% of patients were within the 61–80-year group, and 66% within the 40–60-year group.

Microsoft Excel database; then, by analyzing the collected data. Sample size calculation was performed using Epi Info 7 software, considering a total population of 172 patients, a margin of error of 5%, and an expected frequency of 50%. Thus, a sample size of 84 patients was estimated for a confidence level of 80% and 154 patients for a confidence level of 99.99%.

Quantitative variables included age, weight, contrast dose administered, and serum creatinine levels. Qualitative variables were sex, hypertension, diabetes mellitus, dyslipidemia, smoking, anemia, pre-existing renal failure, exposure to nephrotoxic drugs, liver disease, type of vascular access (radial or femoral), and application of nephroprotection measures. Patients younger than 40 years or older than 80 years, those without documented renal function, and those without renal function follow-up during hospitalization were excluded from the analysis. Data were extracted from the hospital's MHO and LABLINK medical record systems. A data collection spreadsheet was created in Microsoft Excel (version 2306). It included patient initials, age, sex, risk factors, use of nephrotoxic agents, type of vascular access, weight, serum creatinine levels with their corresponding clearance (at admission, at 48 hours, and at discharge), total administered contrast dose, and use of nephroprotection, which consisted of intravenous hydration with 0.9% sa-

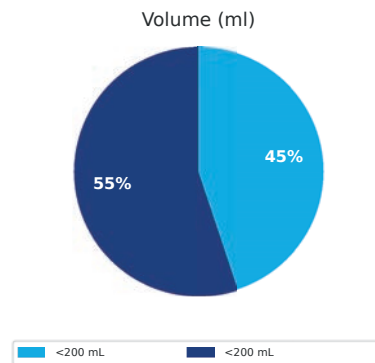


Figure 4. Contrast volume in patients with CIN at discharge. A total of 55% of patients with CIN required ≥ 200 mL of iso-osmolar contrast, whereas 45% required < 200 mL.

line solution, adjusted according to left ventricular ejection fraction. Creatinine clearance was calculated with the Cockcroft–Gault formula, using application Qx Calculate (version 2022), based on sex, age, weight, and serum creatinine. An iso-osmolar contrast medium (Ultrasound 300*) was used.

The procedures were conducted by eight different operators. Variables were analyzed and reported as percentages, using formulas integrated into the Excel database. The study protocol was approved by the Research Ethics Committee of Hospital Dr. Guillermo Rawson. Data confidentiality was ensured pursuant to the Argentine Personal Data Protection Act (number 25,326), and the study followed the ethical principles of the Declaration of Helsinki and the ICH Good Clinical Practice guidelines. As this was a retrospective anonymized study, informed consent was not required.

RESULTS

In this study, researchers analyzed a total population of 172 patients admitted to the Department of Cardiology and the Department of Hemodynamics to undergo cardiac catheterization (CC) in a setting of acute coronary syndrome (ACS) between June 1, 2021, and June 30, 2022. **Table 1** shows the baseline characteristics according to the presence or absence of contrast-induced nephropathy (CIN) after emergency cardiac catheterization.

The sample consisted of 101 patients who presented with ACS and underwent CC, following the inclusion and exclusion criteria mentioned above.

Epidemiology

As regards to epidemiology, 81% of the patients ($n=82$) were men and 19% ($n=19$) were women.

Regarding age, 60% of the patients ($n=61$) were in the 40–60-year age group, and 40% ($n=40$) were between 61 and 80 years of age, with a mean age of 58.3 years and a standard deviation of 8.3 (**Figure 1**).

Renal function

With regard to hospital admission, 92% of the patients ($n=93$) had normal renal function and 8% ($n=8$) had impaired renal function.

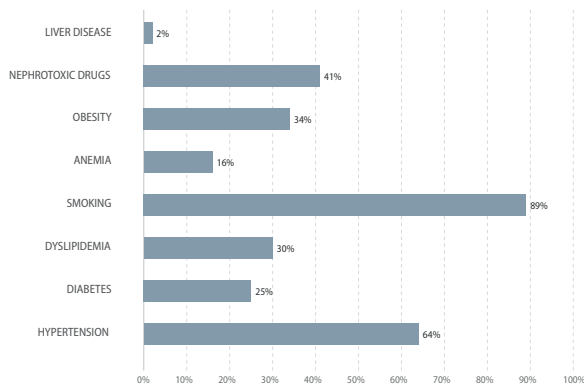


Figure 5. Prevalence of risk factors in patients with CIN. Smoking (89%), hypertension (64%), and exposure to nephrotoxic drugs (41%) were the most common risk factors in the analyzed sample.

Among the 93 patients admitted with preserved renal function, 47% (n=44) developed contrast-induced nephropathy (CIN), whereas 53% (n=49) maintained preserved renal function at discharge (Figure 2).

Of the patients with CIN at discharge, 89% (n=39) were men and 11% (n=5) were women. Regarding age groups, among the 93 patients, 66% (n=29) were between 40 and 60 years of age, while 34% (n=15) were in the 61–80-year age group (Figure 3).

Contrast dose

Considering the administered contrast dose, among the 44 patients who developed contrast-induced nephropathy (CIN) at discharge, 55% (n=24) had been injected with 200 mL or more of iodinated contrast during coronary angiography, whereas 45% (n=20) had received less than 200 mL of it (Figure 4).

Risk factors

The risk factors associated with CIN in the 44 patients were hypertension (64%), diabetes mellitus (25%), dyslipidemia (30%), smoking (89%), anemia (16%), obesity (34%), nephrotoxic drugs (41%), and liver disease (2%) (Figure 5).

Nephroprotection

Finally, among the 44 patients with CIN at discharge, 70% (n=31) did not receive nephroprotection, whereas 30% (n=13) were prescribed hydration according to their ejection fraction as a nephroprotective measure (Figure 6).

DISCUSSION

In general, 92% of the patients had preserved renal function at admission, while 47% showed deteriorating renal function at hospital discharge. It should be noted that only 30% of the patients who developed renal failure received nephroprotection measures, which was attributed to difficulties in administering fluid therapy, mainly due to ventricular dysfunction, reduced ejection fraction, low cardiac output, use of nephrotoxic drugs such as diuretics, ACE inhibitors or ARBs, anticoagulants, and lack of time for nephroprotection before the procedure.

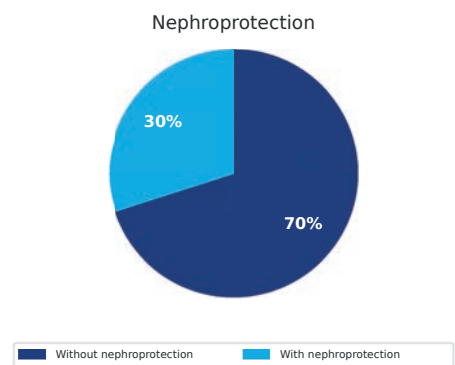


Figure 6. Proportion of patients with contrast-induced nephropathy according to nephroprotection. Seventy percent of subjects did not receive post-procedural preventive measures, whereas 30% received hydration as nephroprotective treatment.

These findings contrast with those reported in previous studies conducted in Argentina and Latin America, where the prevalence of contrast-induced nephropathy (CIN) ranges between 26% and 30%, suggesting a higher incidence in our study group, possibly related to the clinical characteristics of these patients and limitations in the implementation of preventive strategies.

Regarding the demographic profile, CIN predominantly affected men (88%), in agreement with the literature. However, there was a higher prevalence in the 40–61-year age group (63%), as opposed to what has been described in previous studies: a higher incidence in patients older than 75 years. Among modifiable risk factors, smoking (90%) and hypertension (65%) were the most frequent. While hypertension is consistent with previous reports, the incidence of smoking was higher than in earlier studies, in which dyslipidemia was usually more prevalent.

An exploratory multivariate analysis using logistic regression was performed, including variables that were significantly associated with CIN in the univariate analysis (p<0.1). The use of nephrotoxic drugs (odds ratio [OR]: 5.18; 95% confidence interval [95% CI]: 1.61–16.7; p=0.006) and smoking (OR: 2.25; 95% CI: 1.00–5.05; p=0.050) were significantly associated with a higher risk of developing CIN. In contrast, the administration of nephroprotection measures had a significant protective effect (OR: 0.31; 95% CI: 0.13–0.76; p=0.010). Dyslipidemia and anemia also showed a trend toward association, although without reaching statistical significance.

Finally, it should be noted that 51% of the patients who developed CIN received over 200 mL of iodinated contrast during the procedure, in some cases exceeding the maximum recommended dose of 4 mL/kg, but without surpassing 300 mL, the absolute limit suggested by the literature. In all cases, the amount administered was clinically justified by procedural complexity and patient’s condition.

CONCLUSION

In this study regarding cardiac catheterization in acute coronary syndromes, contrast-induced nephropathy (CIN) was a frequent complication, which is associated with worse cli-

nical outcomes. Nearly half of the patients developed renal deterioration despite having preserved renal function at admission. Smoking, anemia, and the use of nephrotoxic drugs were associated with a higher risk, while nephroprotection was insufficiently applied. Preventive strategies and prospective studies are required to confirm these findings.

SUMMARY OF KEY POINTS

- Establish the use of nephroprotection protocols, evaluating which are the most effective (for example, ade-

quate hydration and the administration of nephroprotective agents).

- Implement strategies to reduce the contrast dose used during the procedure while maintaining diagnostic quality.
- Ensure rigorous monitoring of renal function in the days following contrast administration to promptly detect any deterioration.
- Promote ongoing research on contrast-induced nephropathy and the collection of data to identify trends and areas for improvement.

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In-hospital outcomes and follow-up of patients undergoing angioplasty in hemodialysis fistulas

Resultados intrahospitalarios y seguimiento de pacientes sometidos a angioplastia de fístula para hemodiálisis

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ABSTRACT

Background: An arteriovenous fistula (AVF) is an abnormal connection between a vein and an artery that, in patients with dialysis-dependent renal failure, is created to facilitate renal replacement therapy. Its care and proper functioning are a key factor for the survival of patients with this condition.

We present the in-hospital results and follow-up of patients undergoing fistula angioplasty for hemodialysis.

Materials and methods: This was an observational, retrospective, single-center study. Data collected included demographic variables, risk factors, and the fistula type and location. Procedural details (access type, stent use, success, and complications) were recorded. Immediate outcomes and the incidence of new interventions during follow-up were assessed.

Results: Seventy patients were included. Their mean age was 59 years; 68% were men. There was a high prevalence of hypertension and diabetes (87% and 68%, respectively). The most frequent stenosis site was venous (51%), mainly at the puncture tract, followed by juxta-anastomotic stenosis (30%). Angioplasty was performed ad hoc in most patients (86%). Primary procedural success was 82%, and no complications were recorded during the procedure. Follow-up of up to 36 months was performed and completed in 96% of patients. The need for reintervention was high (55%: 16 repeat angioplasties, 13 new fistulae, and 8 urgent thrombectomies). As regards mortality, there was 1 case. Early dysfunction (<1 year) was associated with a higher reintervention rate (86% vs. 32.5%, $p < 0.00001$; odds ratio [OR] 13.5).

Conclusion: AVF angioplasty is safe and effective, with a high initial success rate. However, the rate of reintervention during follow-up is high, especially in patients with early dysfunction.

Key words: angioplasty, arteriovenous fistulas, dysfunction, hemodialysis.

RESUMEN

Antecedentes: Las fístulas arteriovenosas (FAV) son una conexión anormal entre una vena y una arteria que, en pacientes con insuficiencia renal dialítica, se realizan para poder llevar a cabo la terapia de sustitución renal. El cuidado y correcto funcionamiento de estas son un factor primordial para la sobrevida de los pacientes con esta patología.

Presentamos los resultados intrahospitalarios y el seguimiento de pacientes sometidos a angioplastia de fístula para hemodiálisis.

Materiales y métodos: Se trata de un estudio observacional, retrospectivo y unicéntrico. Se recolectaron variables demográficas, factores de riesgo, tipo y localización de la fístula. Detalles del procedimiento (tipo de abordaje, uso de stent, éxito y complicaciones). Se evaluaron los resultados inmediatos y la incidencia de nuevas intervenciones en el seguimiento.

Resultados: Se incluyeron 70 pacientes. Edad media 59 años; 68% hombres. Se observó una alta prevalencia de hipertensión arterial y diabetes (87% y 68%, respectivamente). La zona de estenosis más frecuente fue la estenosis venosa (51%), principalmente en el trayecto de punción, seguida de las yuxtaanastomóticas (30%). Se decidió realizar angioplastia ad hoc en la mayoría de los pacientes (86%). El éxito primario del procedimiento fue 82%, y no se registraron complicaciones durante su desarrollo. Se realizó seguimiento de hasta 36 meses, el cual se completó en el 96% de los pacientes. Se observó una alta necesidad de nueva intervención (55%: 16 nuevas angioplastias, 13 nuevas fístulas y 8 trombectomías de urgencia). Mortalidad: 1 caso. Se observó que la disfunción temprana (<1 año) se asoció a una mayor tasa de reintervención (86% vs. 32,5%, $p < 0,00001$; OR 13,5).

Conclusión: La angioplastia de FAV es segura y efectiva, con una alta tasa de éxito inicial. Sin embargo, existe una alta tasa de reintervenciones en el seguimiento, especialmente en pacientes con disfunción precoz.

Palabras clave: angioplastia, fístulas arteriovenosa, disfunción, hemodiálisis.

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INTRODUCTION

The incidence of patients with chronic kidney disease (CKD) requiring renal replacement therapy by means of hemodialysis has increased over recent decades, due to population aging, improved survival of these patients, and the high prevalence of cardiovascular risk factors. Arteriovenous fistulae (AVF) are the vascular access of choice for hemodialysis, and their proper functioning is essential for patient quality of life and survival. The process ranges from the creation and preservation of vascular access to the treatment of its complications, and it poses a challenge for decision-making because of the com-

plexity of the underlying pathology and the diverse specialties involved (nephrology, vascular surgery, nursing, hemodynamics).

AVF dysfunction is a frequent complication that requires timely diagnosis and treatment. Percutaneous angioplasty is the first-line treatment in these cases. Its success depends on multiple technical and clinical factors, and its long-term effectiveness varies across different series. The aim of this study was to analyze in-hospital outcomes, providing local data on procedural effectiveness and safety. During follow-up, the study also sought to observe long-term evolution, the need for new procedures, the type of reinterventions required, and prognostic factors in patients with CKD and AVF dysfunction undergoing angioplasty.

MATERIALS AND METHODS

This was an observational, retrospective, single-center study. Enrollment included all patients ($n=70$) who consecutively underwent AVF angioplasty between January 2013 and March 2024 at the Department of Hemodynamics and Interventional Cardiology of Clínica San Jorge.

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TABLE 1. Baseline characteristics of patients undergoing arteriovenous fistula angioplasty

Baseline characteristics	Value
Age, mean (SD), years	59 (\pm 11)
Male sex, n (%)	48 (68%)
Hypertension, n (%)	61 (87%)
Diabetes mellitus, n (%)	48 (68%)
Current or past smoking, n (%)	11 (16%)

TABLE 3. Procedural results and follow-up (n=70).

Variable	Value
Ad hoc angioplasty, n (%)	60 (86%)
Use of stents, n (%)	6 (8%)
• Self-expanding	3
• Balloon-expandable	3
Primary technical success, n (%)	60 (86%)
Intraprocedural complications, n (%)	0 (0%)

ge, Ushuaia. Exclusion criteria only featured reinterventions on the same fistula, as they were considered events during follow-up.

Defining fistula dysfunction required the use of clinical and hemodynamic criteria, including decreased pulse, inability to cannulate, venous pressures >200 mmHg, flow <200 mL/min, recirculation $>15\%$, and unexplained reduction in dialysis adequacy.

Stenotic areas were divided into 3 groups: arterial stenoses, which include vascular lesions located in the arterial tree supplying the vascular access; arteriovenous anastomotic or juxta-anastomotic stenoses, located in an area extending from the anastomosis to 5 cm post-anastomosis, and, finally, venous stenoses. This last group was subdivided into puncture tract stenosis, cephalic vein arch stenosis, and central vein stenosis.

All patients were assessed with diagnostic fistulography. Access for this was obtained by puncturing with an 18–20 Abbocath the hemodialysis puncture area; if the patient had no pulse, the afferent artery was punctured. In cases of *ad hoc* angioplasty, if the stenosis was located in the juxta-anastomotic zone, roadmapping-guided retrograde puncture was the alternative of choice. Conversely, if it was located in the puncture tract, cephalic vein arch, or central vein, the Abbocath was exchanged for a 6-Fr introducer.

Significant stenosis was defined as any stenosis $>50\%$ assessed by angiography. In this center, systematic pre- and post-procedural Doppler ultrasound is not used, although its usefulness is acknowledged.

A successful procedure was defined as angiographic resolution of the stenosis, with residual stenosis of less than 30% of the reference segment, restoration of flow, and absence of immediate complications.

Follow-up was performed through medical records and by telephone for up to 36 months. Events assessed included repeat angioplasty, thrombectomy, creation of a new AVF, and death. Statistical analysis was conducted using automated natural language processing tools.

RESULTS

During the study period, 70 AVF angioplasties were performed. Mean patient age was 59 ± 11 years, and 68% of subjects were men. There was a high prevalence of hypertension (87%) and diabetes (68%) (Table 1). Regarding the type of fistula, 39 were brachiocephalic, 21 brachio-basilic, and 10

TABLE 2. Type of fistula and stenosis location

Type of fistula	n (%)
Brachiocephalic	39 (56%)
Brachio-basilic	21 (30%)
Radiocephalic	10 (14%)
Stenosis location	n (%)
Arterial	0
Arteriovenous or juxta-anastomotic anastomosis	21 (30%)
Venous stenosis	43 (51%)
• Puncture pathway	22
• Cephalic vein arch	7
• Central vein	14
Diffuse obstruction in multiple areas	6 (9%)

TABLE 4. Follow-up.

Variable	Value
Patients with complete follow-up, n (%)	67 (96%)
Reintervention, n (%)	38 (55%)
• New angioplasty, n	16
• Thrombectomy, n	8
• New fistula, n	13
Mortality during follow-up, n (%)	1 (1.4%)

radiocephalic. The most frequent obstruction types were venous stenoses (51%), mainly in the puncture tract, followed by juxta-anastomotic stenoses (30%) (Table 2).

Procedural success was 86%. There were no complications during the intervention. All patients had been previously assessed with diagnostic fistulography. In over 80% of cases, the angioplasty was performed *ad hoc*. Deferred angioplasties were mainly due to central vein stenosis or arteriovenous anastomosis.

Stent use was limited to 8.5% of cases (6 patients), 5 of whom had central vein stenosis, while 1 had stenosis along a prosthesis (Table 3). In the remaining patients, semi-compliant balloons without drug elution were used. Drug-coated balloons and cutting balloons were not employed. Successive dilations were performed, increasing balloon diameter until reaching a 1:1 ratio in relation to the non-diseased segment. For juxta-anastomotic lesions, the balloons used were between 2.5 and 5 mm, and for venous stenoses, between 4.0 and 12 mm. Depending on the tightness of the lesion, angioplasty was initiated with a 0.014" coronary system and then exchanged for a 0.035" wire, or it was initiated directly with a 0.035" system.

As an example, we present the clinical case of a 65-year-old man with hypertension, diabetes, and a history of smoking. He had dialysis-dependent CKD with a brachiocephalic fistula created 16 months earlier. The Department of Nephrology reported that he presented with a severe reduction in pulse and thrill, so he was referred for urgent fistulography. Puncture was performed at the level of the humeral artery with an 18 Abbocath. Diagnostic fistulography showed significant juxta-anastomotic stenosis (Image 1). A decision was made to conduct an *ad hoc* fistula angioplasty. An antegrade, roadmapping-guided venous puncture was performed, and a 6-Fr introducer was placed, initially using a 0.014" PT2 wire. The stenotic segment was successfully crossed, and successive dilations were conducted with 2.0×30 mm and 2.5×30 mm balloons up to 16 atm (Image 2). The wire was then exchanged for a 0.035" wire, and dilations were performed with 4.0×40 mm and 5.0×40 mm balloons up to 16 atm (Image 3). Control projections showed improved flow with mild resi-

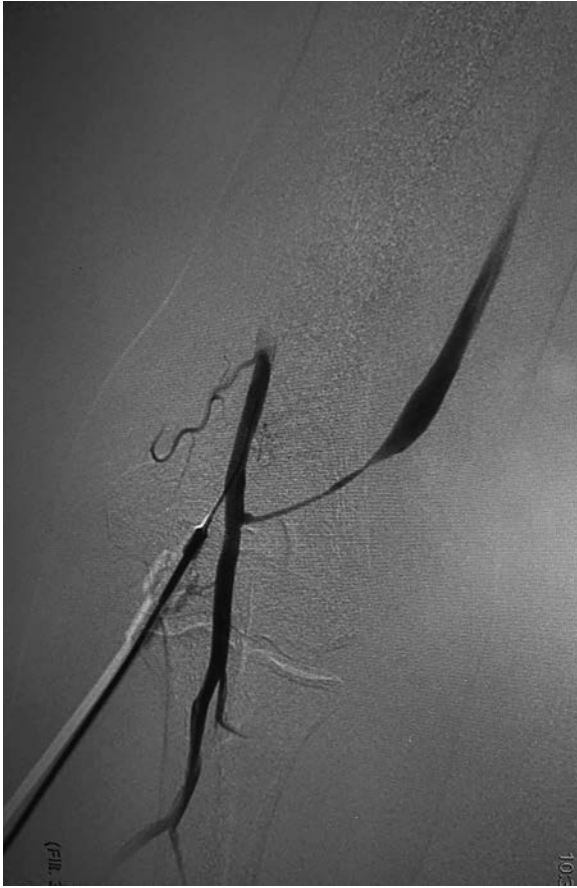


Image 1. Diagnostic fistulography. Severe juxta-anastomotic stenosis.

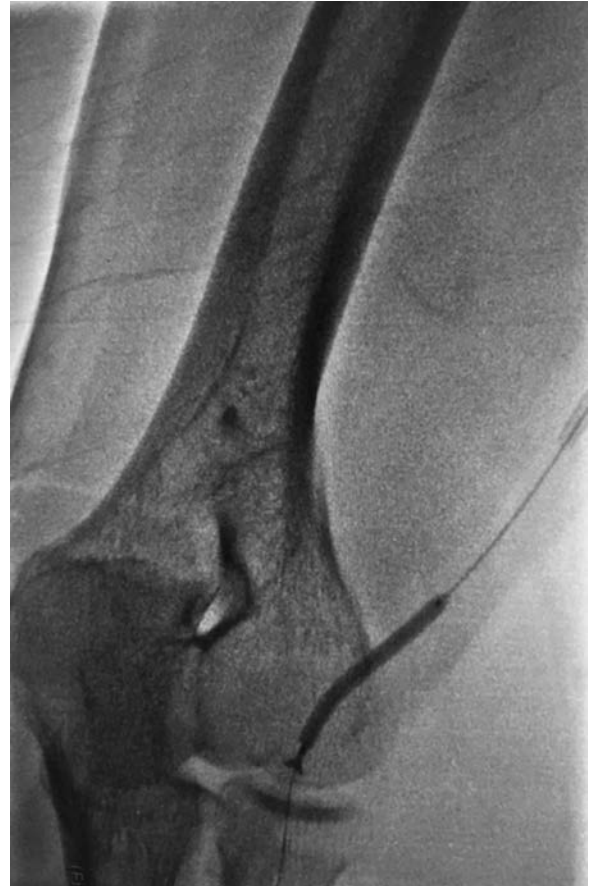


Image 2. Angioplasty using a coronary system.

dual stenosis (**Image 4**). The patient tolerated the procedure well; the introducer was removed, an X stitch was placed at the site, and a semi-compressive dressing was applied. After achieving this result, the procedure was concluded. The study was performed on an outpatient basis, with follow-up at 24 hours at the Department of Nephrology and suture removal at 7 days.

During follow-up (achieved in 96% of patients), 55% of subjects required a new intervention: 16 repeat angioplasties, 8 thrombectomies, and 13 new fistulae. Only one patient died (**Table 4**). In subgroup analysis, dysfunction within the first year was associated with a greater need for reintervention (86% vs. 32.5%, $p < 0.00001$; odds ratio [OR]: 13.5; 95% confidence interval [95% CI]: 3.9-47.0). Another comparison showed that all patients with a failed procedure required a new fistula, compared with 10% of those who had a successful angioplasty.

DISCUSSION

The outcomes of this study confirm that AVF angioplasty is a safe and effective procedure, with a high initial technical success rate (86%) and no intraprocedural complications. These findings are consistent with previous series that describe good immediate results of percutaneous angioplasty in vascular access for hemodialysis^{3-5,8}.

The high rate of reinterventions (55% during follow-up) reflects the progressive nature of vascular disease in this population and is also consistent with the literature, which reports frequent need for new angioplasty or complementary procedures to maintain access functionality^{2-3,7-8}.

Such data underscore that angioplasty, while effective, should be understood as part of a dynamic access maintenance strategy rather than a definitive solution.

The finding that early dysfunction (<1 year) was associated with a higher risk of new intervention (OR: 13.5) allows for the identification of a high-risk subgroup that could benefit from closer surveillance protocols, including systematic clinical assessment, functional monitoring of access, and eventually a more widespread use of Doppler ultrasound, in line with guideline recommendations^{1,6,9}. Additionally, the fact that procedural failure is almost always linked to a need for a new fistula supports the importance of optimizing the technique from the first attempt, preferably in centers with experience and multidisciplinary teams, as suggested by previous studies regarding the effectiveness and safety of procedures performed by specialized teams^{4,7-8}. While pharmacological balloons and specific devices were not routinely used in this series, their role in prolonging the patency of certain stenotic segments is subject of research and could be considered in selected scenarios according to emerging evidence and future recommendations^{3,7-8}.

Finally, these outcomes uphold the need for comprehensive vascular access planning even from pre-dialysis stages, as proposed by the KDOQI guidelines and Spanish guidelines, with the aim of reducing catheter dependence, prolonging the lifespan of AVF, and improving the quality of dialysis therapy^{1,6,9}.

The results of this study are consistent with international literature, showing that AVF angioplasty is a safe procedure, with a high technical success rate and low risk of immediate complications. The high prevalence of reintervention re-



Image 3. Angioplasty with 4.0 and 5.0 balloons.



Image 4. Final result.

flects the complexity of patient monitoring in this setting and the natural progression of vascular disease. The finding that early dysfunction is associated with a higher risk of reintervention allows for the identification of a higher-risk population that could benefit from stricter follow-up. Early nephrology consultation in the pre-dialysis stage is essential, as it allows for the planning of renal replacement therapy, avoiding catheters in central veins, and providing sufficient maturation time for AVFs.

Furthermore, initial technical success seems to have a strong impact on the need for a new fistula, which supports the importance of an effective interventional strategy from the

start. The absence of routine Doppler may have limited the early detection of subclinical restenosis.

CONCLUSIONS

Angioplasty of hemodialysis fistulae proved to be a safe and effective procedure, with a high success rate and low incidence of complications. However, over half of the patients required new interventions during follow-up. Early dysfunction and initial procedure failure were markers of reintervention. Achieving a successful initial outcome can significantly reduce the need for a new fistula.

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Complex coronary angioplasty using the iVAC2L ventricular assist device in a patient with low ejection fraction

Angioplastia coronaria compleja con dispositivo de asistencia ventricular iVAC2L en paciente con deterioro severo de la fracción de eyección

Pedro Gallardo Galeas¹, Jorge Carminatti², Jorge Cuezco³, María Pereyra⁴, María del Milagro Pérez⁵

ABSTRACT

Percutaneous coronary intervention (PCI) in patients with complex anatomy and severely reduced ejection fraction is a clinical challenge, with a high risk of hemodynamic instability and mortality. Ventricular assist devices are proposed as temporary support during revascularization, although evidence on them is still limited.

A female patient with extensive anterior infarction and a 27% ejection fraction had low cardiac output and required inotropic support. A decision was made to complete revascularization with pulsatile mechanical ventricular assistance iVAC2L. During the intervention, blood pressure increased from 90/50 mmHg to 150/90 mmHg, allowing for the angioplasty of the circumflex artery with successful implantation of two drug-eluting stents without complications. The use of iVAC2L offers effective and continuous hemodynamic support, improving cardiac output and procedural tolerance. Its advantage lies in its easy implantation, relatively low cost, and compatibility with balloon counterpulsation consoles, without requiring surgical equipment for its removal. The ACC/AHA/SCAI 2025 guidelines support the use of mechanical assist devices in patients with refractory cardiogenic shock or selected high-risk procedures.

Conclusion: The iVAC2L device proved to be a safe, practical, and effective tool for stabilizing this patient with severe ventricular function impairment undergoing complex coronary angioplasty, thus constituting an accessible alternative in settings with limited resources.

Key words: complex angioplasty, ventricular assist device, left ventricular assist, cardiogenic shock, iVAC2L.

RESUMEN

La angioplastia coronaria percutánea (PCI) en pacientes con anatomía compleja y fracción de eyección severamente reducida representa un desafío clínico, con alto riesgo de inestabilidad hemodinámica y mortalidad. Los dispositivos de asistencia ventricular se proponen como soporte temporal durante la revascularización, aunque su evidencia aún es limitada.

Paciente femenina con infarto anterior extenso y fracción de eyección del 27%, que evolucionó con bajo gasto cardíaco y requerimiento de inotrópicos. Se decidió completar la revascularización con asistencia ventricular mecánica pulsátil iVAC2L. Durante la intervención, la presión arterial aumentó de 90/50 mmHg a 150/90 mmHg, permitiendo realizar la angioplastia sobre la arteria circunfleja con implante exitoso de dos stents farmacológicos sin complicaciones. El uso de iVAC2L ofrece soporte hemodinámico efectivo y continuo, mejorando el gasto cardíaco y la tolerancia al procedimiento. Su ventaja radica en su fácil implantación, bajo costo relativo y compatibilidad con consolas de balón de contrapulsación, sin requerir equipo quirúrgico para su retiro. Las guías ACC/AHA/SCAI 2025 respaldan el empleo de dispositivos mecánicos de asistencia en pacientes con shock cardiogénico refractario o procedimientos de alto riesgo seleccionados.

Conclusión: El dispositivo iVAC2L demostró ser una herramienta segura, práctica y eficaz para estabilizar a este paciente con deterioro severo de la función ventricular sometido a angioplastia coronaria compleja, representando una alternativa accesible en entornos con recursos limitados.

Palabras clave: angioplastia compleja, dispositivo de asistencia ventricular, asistencia ventricular izquierda, shock cardiogénico, iVAC2L.

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INTRODUCTION

Percutaneous coronary revascularization (PCI) in patients with complex anatomy and significant comorbidities is an increasing clinical challenge, especially considering the aging population and the rise of ischemic heart failure. The term “high-risk angioplasty” does not have a single defini-

tion, but it commonly refers to procedures in patients with a combination of the following: complex coronary anatomy (such as left main disease, multivessel disease, severe calcification), left ventricular dysfunction (LVEF <35%), unstable clinical status (including cardiogenic shock), or significant comorbidities (advanced age, chronic kidney disease, etc.).

According to international multicenter registries such as that of the British Cardiovascular Intervention Society (BCIS) and the US National Cardiovascular Data Registry (NCDR), between 10% and 20% of all angioplasties conducted can be considered high risk, although this figure varies depending on applied criteria. In an NCDR CathPCI study that analyzed over 400,000 procedures, approximately 15% of patients met criteria for high clinical or hemodynamic risk¹.

The mortality associated with these procedures is high. In patients with post-AMI cardiogenic shock, in-hospital mortality can exceed 40-50%, and in those with severely reduced LVEF, it can be around 10-15% even without shock². The use of mechanical ventricular assist devices has been explored as a strategy to hemodynamically stabilize patients during an intervention, but evidence is still limited and there is much debate around its benefits.

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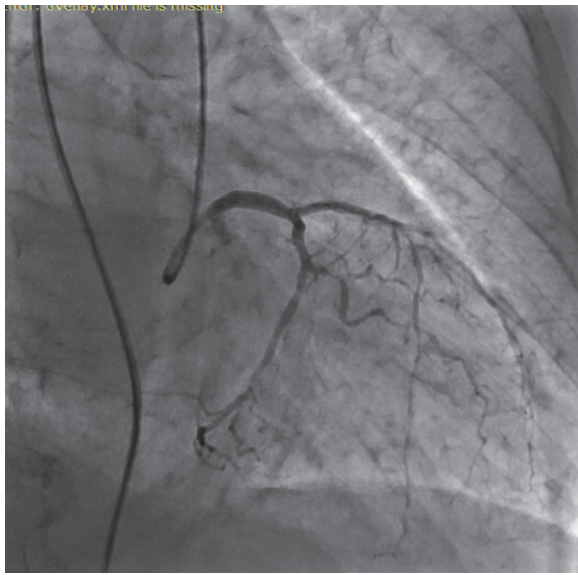


Image 1. Admission cardiac catheterization (CC).

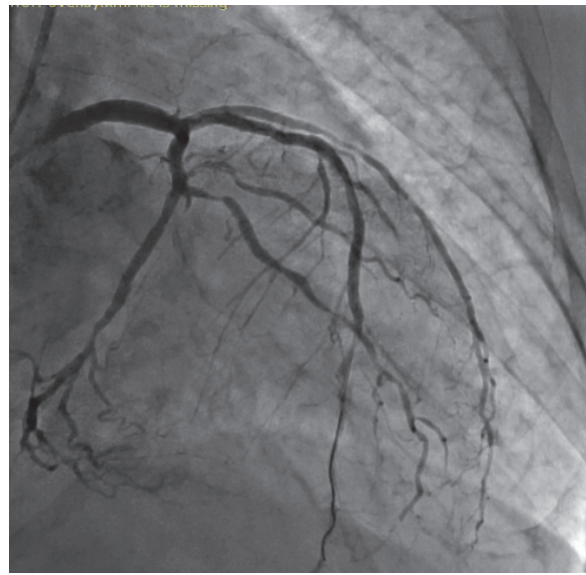


Image 2. CC after LAD PCI.

Regarding data in Argentina, there are not many open registries that specifically document the incidence of high-risk angioplasties. However, according to data from the RENAC (National Registry of Coronary Angioplasties of the Argentine Society of Cardiology), around 8-12% of procedures correspond to patients with LVEF below 40%, and 20% are performed in subjects over 75 years old, two common factors in high-risk profiles³. Nevertheless, the availability of advanced hemodynamic support such as Impella or ECMO is limited in this territory, which has fostered interest in more accessible alternatives like the iVAC2L[®] (PulseCath B.V., Amsterdam, the Netherlands), both for technical, cost, and complexity reasons, which could highlight the actual availability of this method in our country.

CLINICAL CASE

A female patient with a history of hypertension initially presents with an episode of oppressive epigastric pain classified as functional class IV, reporting shorter duration pain in prior days. An ECG is performed, revealing sinus rhythm at 100 bpm, a qS pattern with ST-segment elevation of 4 mm in leads V1 to V3, and negative T-waves from V4 to V6, consistent with extensive anterior acute myocardial infarction (AMI). She is clinically classified as Killip-Kimball II upon admission (blood pressure [BP] 110/80 mmHg, heart rate [HR] 110 bpm).

She is transferred as an emergency to the Department of Hemodynamics, where she undergoes coronary angiography. Findings include a thin caliber left anterior descending artery (LAD) with subtotal obstruction in the proximal and mid segments, with probable intraluminal thrombus. The circumflex artery is dominant with severe lesions in the lateral and posterior ventricular branches. The right coronary artery is hypoplastic. Primary PCI is performed on the LAD, requiring inotropic support during the procedure. Balloon predilation is followed by the successful implantation of two drug-eluting stents: first, a distal stent measuring 2.5×24 mm and, second, a proximal stent measuring 2.75×28 mm. Final flow is classified as TIMI III.

Admission laboratory tests showed leukocytosis (white blood cell count [WBC]: 18,000; 80% neutrophils), creatine phosphokinase (CPK) 800, creatine kinase-MB (CK-MB) 71, troponin 7.8, lactate dehydrogenase (LDH) 414. Renal function was preserved.

Color Doppler transthoracic echocardiogram showed a 27% left ventricular ejection fraction (LVEF), with severe anteroseptal and apical hypokinesia, mild mitral regurgitation, mild aortic regurgitation, and moderate tricuspid regurgitation, with an estimated pulmonary systolic pressure of 87 mmHg, compatible with severe pulmonary hypertension. The left atrium was normal in size, and the right-sided chambers showed no dilation or systolic dysfunction.

The patient progressed well from a coronary standpoint, but she developed low cardiac output in the Coronary Care Unit (CCU), requiring inotropic support (dopamine + dobutamine) and diuretics. For this reason, a decision was made to conduct complete revascularization as soon as possible. Taking into account this clinical scenario and the patient's high clinical risk, operators decided to use ventricular assist devices during angioplasty.

Mechanical circulatory support (MCS) can be pulsatile—such as in the case of the IABP—, which is widely available but has limited clinical benefit, or continuous, which are more effective—especially the Impella—but with considerably higher cost. The iVAC2L MCS device is pulsatile and uses the same console as the IABP, which facilitates implementation⁴.

The patient was admitted to the cath lab, where subtotal obstructions were found in the posteroventricular branch, associated with subtotal obstruction of a large lateral ventricular branch. An 18-Fr arterial introducer sheath was placed through left femoral access, after which the assist device was advanced into the left ventricle and aorta; the device was programmed from the console and ventricular assistance was initiated. The patient began PCI with a BP of 90/50 mmHg. After starting the assistance, BP increased to 150/90 mmHg. The circumflex artery was predilated with a balloon and the first drug-eluting stent (2.5×16 mm) was successfully implanted in the branch. Finally, a second drug-eluting stent (2.75×12 mm) was implanted without complications.



Image 3. PCI with iVAC2L device.

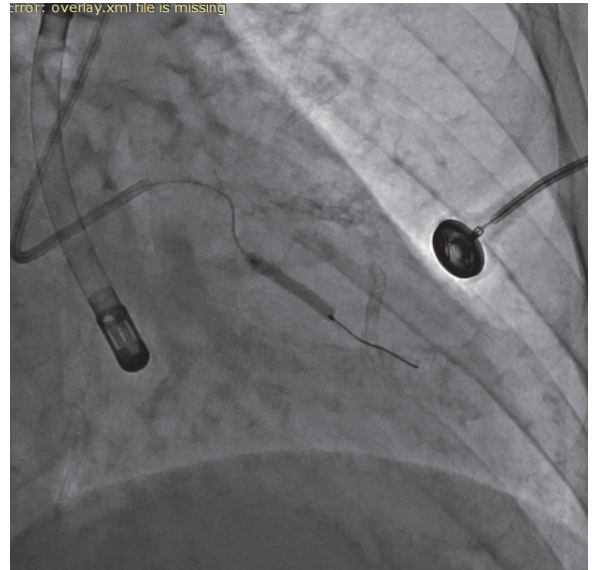


Image 4. PCI to the circumflex artery

DISCUSSION

In this patient, the clinical scenario was complex due to a poor hemodynamic evolution, depressed ejection fraction, complex coronary anatomy, and a need for complete revascularization in order to improve patient hemodynamics. For these reasons, based on the literature review and expert consensus, the use of ventricular assist devices during the intervention emerged as a possible strategy, with the aim of providing better support and improving patient tolerance to this procedure, which is often complex and prolonged, and also associated with high mortality rates⁴⁻⁷.

The main theoretical foundations supporting this therapeutic decision are based on the management guidelines for patients with acute coronary syndromes with cardiogenic shock and multivessel disease, as described in the 2025 ACC/AHA/ACEP/NAEMSP/SCAI guidelines, which recommend the treatment of non-culprit vessels in cases of persistent shock, and also consider as reasonable the use of mechanical circulatory support devices in selected patients with refractory cardiogenic shock in a setting of an acute coronary syndrome (Class IIa recommendation, Level of Evidence B-R)⁸.

These were the reasons for selecting, among the available options, the iVAC2L system, as it is one of the most efficient devices, substantially increasing cardiac output during the procedure—even though this is not routinely quantified—and helping maintain stable systolic blood pressure with reduced need for inotropic agents^{4-5,7}.

This device is one of the easiest to use and its placement is fast: unlike arterial/venous or biventricular systems, it only requires the introduction of a catheter into the left ventricle, with support dependent on the intra-aortic balloon pump console, which is simple to operate⁶⁻⁷.

It provides a satisfactory level of circulatory support that allows the operator to perform revascularization with greater stability and safety. In addition, it can be implanted and removed directly in the cath lab without the need for vascular surgery, since the access site can be easily closed with

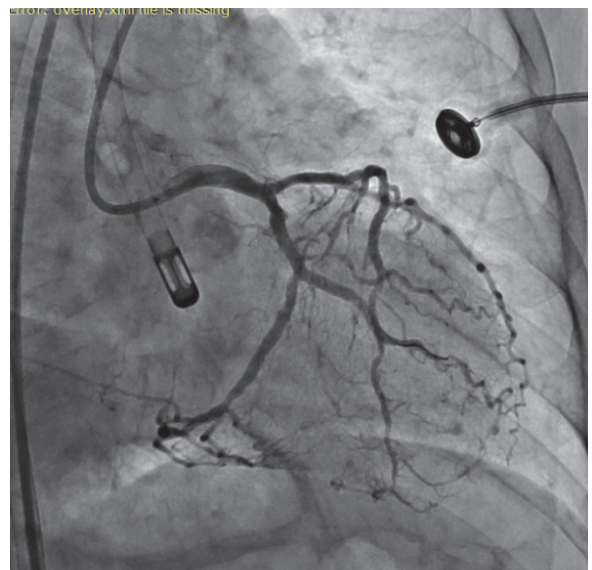


Image 5. Final post-PCI outcome.

a percutaneous device such as PROGLIDE® (Abbott Vascular, Santa Clara, CA, USA)⁶⁻⁷.

Another relevant aspect is the low incidence of device-related complications, particularly hemorrhagic or major complications, compared to other systems such as ECMO or Impella^{4-5,7}.

Finally, the lower economic cost of the iVAC2L compared to other mechanical assist devices reinforces its potential applicability in resource-limited centers⁶.

CONCLUSION

In this complex PCI, pulsatile left ventricular assist device iVAC2L proved to be a highly useful support method for our fragile patient, with accessible implantation, no complex management required, and no need for a vascular surgery team for device removal.

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Bioadaptive stent in coronary artery disease: an innovative strategy to restore vascular function

Bioadaptador en enfermedad coronaria: una estrategia innovadora para restaurar la función vascular

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ABSTRACT

An octogenarian patient with a history of arterial hypertension, dyslipidemia, type 2 diabetes mellitus, and chronic kidney disease presented with progressive angina and evidence of ischemia in the inferior and lateral walls. Coronary angiography revealed significant disease in the distal left main coronary artery (LMCA) and the proximal segments of the left anterior descending (LAD) and circumflex (Cx) arteries. Percutaneous coronary intervention of the LMCA–LAD was conducted with intravascular lithotripsy (LithiX Hertz Contact IVL, Elixir Medical Corporation, Milpitas, CA, USA), followed by implantation of two overlapping DynamX™ bioadaptor devices (Elixir Medical Corporation, Milpitas, CA, USA) and subsequent post-dilatation with a non-compliant balloon. The circumflex artery was treated with lithotripsy and a drug-coated balloon. The angiographic and intracoronary outcomes were optimal, without complications and with favorable clinical evolution. This case illustrates the feasibility and potential of the combined use of emerging technologies—such as intravascular lithotripsy and bioadaptor devices—in complex calcified lesions in high-risk patients.

Key words: coronary artery disease; intravascular lithotripsy; bioadaptor; DynamX; left main disease.

RESUMEN

Se presenta el caso de un paciente octogenario con antecedentes de hipertensión arterial, dislipidemia, diabetes tipo 2 y enfermedad renal crónica, con angina progresiva y evidencia de isquemia en cara inferior y lateral. La angiografía coronaria reveló enfermedad significativa del tronco coronario izquierdo (TCI) distal y de los segmentos proximales de la descendente anterior (DA) y circunfleja (CX). Se realizó angioplastia del TCI-DA con litotricia intravascular (LithiX Hertz Contact IVL, Elixir Medical Corporation, Milpitas, CA, USA) y posterior implante de dos dispositivos bioadaptadores DynamX™ (Elixir Medical Corporation, Milpitas, CA, USA) solapados, seguidos de postdilatación con balón no complaciente. La arteria circunfleja fue tratada con balón de litotricia y balón farmacológico. El resultado angiográfico e intracoronario fue óptimo, sin complicaciones y con evolución clínica favorable. Este caso ilustra la factibilidad y el potencial del uso combinado de tecnologías emergentes—litotricia intravascular y bioadaptador—en lesiones calcificadas complejas en pacientes de alto riesgo.

Palabras clave: enfermedad coronaria, litotricia intravascular, bioadaptador, DynamX, tronco coronario izquierdo.

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INTRODUCTION

The percutaneous treatment of complex coronary artery disease in elderly patients with significant comorbidities is still a therapeutic challenge. In calcified lesions, adequate plaque preparation is essential in order to achieve optimal expansion of the implanted device and to reduce late adverse events.

Intravascular lithotripsy (IVL) has emerged as an effective and safe tool for modifying coronary calcium through shock waves, facilitating stent or bioadaptor expansion with minimal damages to healthy tissue.

In parallel, bioadaptors constitute a new generation of devices designed to combine the advantages of drug-eluting stents with the restoration of vascular physiology after bioresorbable polymer resorption, allowing for the recovery of target vessel pulsatility and vasomotion.

In this context, we describe the case of a patient treated with the DynamX™ Bioadaptor system (Figure 1) after lesion pre-

paration with LithiX lithotripsy, an innovative approach to distal left main bifurcation disease.

CLINICAL CASE

An 82-year-old male patient with a history of hypertension, dyslipidemia, type 2 diabetes mellitus, and stage 3a chronic kidney disease went to the Emergency Department with recent-onset progressive angina. An electrocardiogram showed ST-segment depression in inferior and lateral leads, and troponin T levels rose to 677 ng/L. Echocardiography revealed preserved systolic function of the left ventricle with no segmental wall-motion abnormalities.

Coronary angiography showed significant distal left main coronary artery (LMCA) disease and critical lesions in the proximal segments of the LAD and circumflex (Cx) arteries (Figure 2a–b). A decision was made to conduct percutaneous coronary intervention of the LMCA and LAD using a LithiX Hertz Contact IVL lithotripsy balloon (3.0 × 14 mm), followed by implantation of two overlapping DynamX™ bioadaptor devices (3.5 × 23 mm and 4.0 × 23 mm) between the proximal LAD and the distal LMCA. Subsequent post-dilatation was performed with a non-compliant balloon (4 × 16 mm).

The proximal Cx artery was treated with lithotripsy (2.5 × 14 mm) and a drug-coated balloon (2.5 × 15 mm). The angiographic result was optimal, with TIMI III flow and adequate device expansion confirmed by intracoro-

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Figure 1. The Elixir DynamX coronary bioadaptor stent technology uses a bioresorbable polymer that dissolves after three months, disconnecting the links between multiple stent segments and allowing the device to articulate and adapt to the vessel and its motion.

nary imaging (optical coherence tomography, OCT) (Figure 2c–d).

The patient had a favorable clinical course, remaining asymptomatic and hemodynamically stable, and was discharged early under dual antiplatelet therapy for 12 months.

DISCUSSION

This clinical case describes a complex intervention in an octogenarian patient with multiple comorbidities and multi-vessel coronary artery disease, highlighting the combined use of two innovative technologies: the LithiX intravascular lithotripsy system and the DynamX™ bioadaptor.

The selection of the LithiX system was key for the treatment of calcified lesions, particularly in the proximal LAD segment. Unlike conventional lithotripsy balloons, LithiX uses metallic hemispheres integrated within a semi-compliant balloon that, when inflated at low pressure, generate contact stress points that effectively fracture calcium with minimal damage to healthy vascular tissue¹. The PINNACLE I study supports its efficacy, demonstrating a clinical success rate of 98.3%, an angiographic success rate of 100%, and extensive deep calcium fractures confirmed by OCT in over 90% of cases, along with optimal stent expansion².

The DynamX™ bioadaptor consists of three cobalt–chromium helical strands connected by unlockable elements coated with a bioresorbable polymer. This structure allows the strands to separate after polymer resorption at approximately six months, while maintaining dynamic support of the treated vessel. The design aims to combine the acute performance of drug-eluting stents with the additional advantage of enabling restoration of vascular compliance and natural cyclic vessel motion³.

BIOADAPTOR-RCT is the first randomized clinical trial comparing a sirolimus-eluting bioadaptor (DynamX™) with a contemporary zotarolimus-eluting stent (Resolute Onyx™) in patients with *de novo* coronary lesions. This multicenter study, which included 445 patients, demonstrated non-inferiority in 12-month target lesion failure (TLF) (1.8% vs. 2.8%; $p < 0.001$), as well as superiority in imaging endpoints, including lower in-stent late lumen loss (0.09 mm vs. 0.25

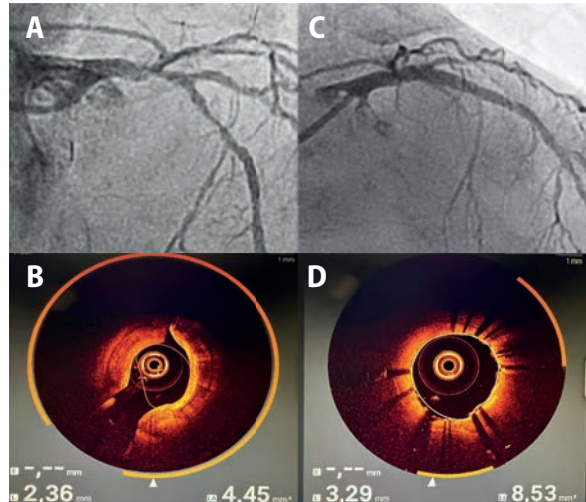


Figure 2. Coronary angiography images showing significant lesions in the distal LMCA and proximal LAD before PCI (2a) and after PCI (2d). OCT images at the proximal LAD before (2b) and after implantation of the DynamX™ bioadaptor (2d).

mm; $p = 0.038$) and greater cyclic vessel pulsatility (7.5% vs. 2.7%; $p < 0.001$), supporting functional treated vessel restoration³.

The INFINITY-SWEDEHEART trial, a large registry-based randomized clinical trial including 2399 patients with chronic or acute coronary syndromes, showed that the DynamX bioadaptor was non-inferior to contemporary zotarolimus-eluting stents for 12-month target lesion failure (TLF), with event rates of 2.4% vs. 2.8%. Notably, in the prespecified 6- to 12-month landmark analysis, the bioadaptor showed lower rates of TLF (0.3% vs. 1.7%; hazard ratio [HR]: 0.19; 95% confidence interval [CI]: 0.06–0.65) and target vessel failure (0.8% vs. 2.5%; HR: 0.35; 95% CI: 0.16–0.79), suggesting a potential benefit in reducing late device-related events. Device thrombosis rates were low and similar across groups⁴.

Imaging studies have confirmed the ability of the bioadaptor to preserve lumen area while allowing for positive vessel remodeling and cyclic pulsatility restoration at 12 months, further supporting the mechanistic rationale of device design⁵.

In summary, the DynamX bioadaptor has shown non-inferior safety and efficacy compared with contemporary DES at 1–2 years, with signals of reduced late adverse events and vascular physiology restoration. Ongoing long-term follow-up will clarify its impact on clinical outcomes beyond two years^{3–5}.

In our patient, the selection of both technologies was justified by the anatomical complexity of the lesion and the clinical context (advanced age and chronic kidney disease), with the aim of maximizing procedural effectiveness and reducing long-term adverse event risk. The intervention was successful, with low contrast volume, no immediate complications, and favorable angiographic and intracoronary imaging results, reflecting both the technical feasibility and the acute safety profile of the devices used.

CONCLUSION

The combination of intravascular lithotripsy and bioadaptor stenting is an innovative and safe therapeutic alternati-

ve for the treatment of complex calcified coronary lesions. Our case demonstrates the technical feasibility, safety profile, and potential physiological benefits of the DynamX™ bio-

adaptor in the pursuit of functional coronary vessel restoration following percutaneous intervention.

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TAVI in a patient with severe bicuspid aortic valve stenosis in cardiogenic shock: case report

TAVI en paciente con estenosis aórtica severa de válvula bicúspide en *shock* cardiogénico: reporte de caso

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ABSTRACT

Aortic stenosis (AS) is one of the most prevalent valvular heart diseases, affecting 1.3% of individuals over 65 years of age. To date, the safety and efficacy of transcatheter aortic valve implantation (TAVI) in cardiogenic shock (CS) have remained controversial.

We present the case of a 43-year-old man with severe AS due to a bicuspid aortic valve in cardiogenic shock, successfully treated with balloon-expandable TAVI and a preventive chimney stenting strategy due to a high associated risk of coronary obstruction. The procedure achieved immediate success with no leak or transprosthetic gradient, resulting in immediate improvement in functional class and recovery of left ventricular ejection fraction within 48 hours. This case demonstrates the feasibility of TAVI in severe AS with bicuspid aortic valve in a setting of CS when appropriate patient selection, preventive strategies, and individualized procedural planning—including prosthesis choice and customization—are undertaken.

Key words: aortic stenosis, cardiogenic shock, bicúspide aortic valve, TAVI, coronary protection.

RESUMEN

La estenosis aórtica (EAO) es una de las enfermedades cardíacas valvulares más prevalentes, que afecta al 1,3% de las personas mayores de 65 años. Hasta la fecha, la eficacia y la seguridad del implante percutáneo de válvula aórtica (TAVI) en el shock cardiogénico (SC) han sido controversiales.

Se presenta el caso de un paciente masculino de 43 años con diagnóstico de EAO severa de válvula bicúspide en shock cardiogénico y su resolución mediante TAVI expandible con balón y estrategia preventiva de chimney stenting por alto riesgo de oclusión coronaria asociado, con resultado inmediato óptimo sin leaks ni gradiente transprotésico, con mejoría inmediata de la clase funcional y recuperación de la fracción de eyección del ventrículo izquierdo a las 48 hs, demostrándose la factibilidad del TAVI en EAO severa de válvula aórtica bicúspide, en contexto de SC mediante la adecuada selección del paciente, la implementación de estrategias preventivas, la individualización del procedimiento, incluida la elección y personalización de la válvula.

Palabras clave: estenosis aórtica, shock cardiogénico, válvula aórtica bicúspide, TAVI, protección coronaria.

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INTRODUCTION

Aortic stenosis (AS) is one of the most prevalent valvular heart diseases, affecting 1.3% of individuals over 65 years of age. About 0.7% present moderate-to-severe disease¹. Severe degenerative AS is predominantly seen in older adults; therefore, its prevalence is increasing due to population aging. In contrast, bicuspid aortic valve (BAV) is a congenital condition that adds further complexity due to asymmetric calcification and higher risk of coronary obstruction, making multimodality planning and protective strategies critical². Cardiogenic shock (CS) along severe AS carries a poor prognosis. To date, the safety and efficacy of transcatheter aortic valve implantation (TAVI) in CS remain controversial³. Previous studies in patients with AS and CS undergoing successful balloon aortic valvuloplasty (BAV) reported 30-day mortality rates ranging from 33% to 47%, 1-year mortality rates of 70%, and 2-year mortality rates of up to 90%. Therefore, this conservative therapy leads to poor outcomes in these patients. In this context, TAVI has emerged

as a less invasive alternative with superior outcomes compared with BAV and favorable results versus surgery in select patients⁴.

Recently, in 2023, the *European Heart Journal* published results from a large real-world observational study from the United States showing that contemporary balloon-expandable S3 and S3U valves are a safe and effective treatment option for patients with CS. The in-hospital and 30-day mortality rates after TAVI in CS patients were 9.9% and 12.9%, respectively, which are considerably lower than the previously reported 35%–70% mortality rates in patients treated conservatively⁵. In a European multicenter registry including 51 patients with severe aortic valve disease and CS treated with TAVI, the device success rate was 94.1%, with 30-day and 1-year mortality rates of 11.8% and 25.7%, respectively⁶.

We report an urgent TAVI procedure in a patient with bicuspid aortic valve and CS requiring left main coronary artery protection and chimney stenting, with excellent immediate outcomes.

CLINICAL CASE

The patient was a 43-year-old sedentary man. His past medical history included diagnosis of aortic stenosis (AS) during childhood. There was no prior pharmacological treatment. He had been recently diagnosed with *de novo* heart failure 3 months earlier requiring hospitalization. Doppler echocardiography showed a non-dilated left ventricle (LV), left ventricular ejection fraction (LVEF) 58%, double aortic valve lesion, severe AS with

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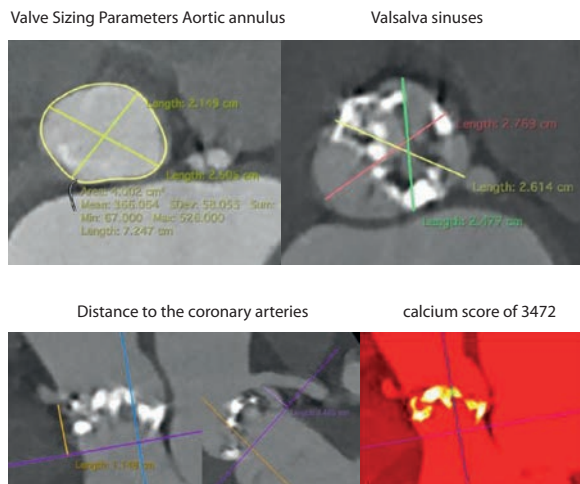


Figure 1. Pre-TAVI CT assessment of bicuspid aortic valve: measurement of the aortic annulus, Valsalva sinuses, distance to the coronary arteries, and calcium burden.

a peak gradient of 137 mmHg and a mean gradient of 92 mmHg, and mild aortic regurgitation. He was initially assessed by the Department of Cardiovascular Surgery, where outpatient preoperative studies were requested in preparation for surgical aortic valve replacement (SAVR). The patient progressively deteriorated over a short period of time, with marked weight loss and worsening functional class (FC, III–IV), prompting readmission to the Coronary Care Unit due to decompensated heart failure in cardiogenic shock, with NT-ProBNP 30,700 ng/L. On physical examination, his general condition seemed to be poor, with evident nutritional impairment and body weight 46.7 kg (body mass index [BMI]: 16.1 kg/m²). Stabilization treatment was initiated with IV diuretics and inotropic support. Admission ECG revealed sinus rhythm, QRS 120 ms, poor R-wave progression in the anterior leads, and left anterior fascicular block. Repeat Doppler echocardiography reported a mildly dilated LV with severe reduction in LVEF (20%) and critical AS, with an aortic valve area of 0.5 cm². The patient remained in cardiogenic shock, requiring inotropic support, with severe LVEF reduction, and marked nutritional compromise (consistent with cardiac cachexia). His STS score predicted mortality of 8.5% (for SAVR) and his EuroSCORE II was 21.2% for mortality. After being assessed by the Heart Team, the patient was deemed high surgical risk with an indication for urgent TAVI.

Computed tomography angiography before TAVI

Findings included bicuspid aortic valve with a calcium score of 3472, leaflet thickening, and significant calcification. There was no atherosclerotic disease in the aorta. However, there was mild dilatation of the ascending aorta in the tubular segment. Two supra-aortic trunks had preserved diameters, with common origin of the brachiocephalic trunk and left common carotid artery. The dimensions for the aortic annulus were 24 mm (coronal) and 20 mm (sagittal), with a 69-mm perimeter. The aortic root (sinus-to-sinus) was 28 mm. The distance from the valve to the left coronary ostium was 7 mm, and 4 mm to the right coronary ostium; 5.7 mm to the left common iliac artery; 6 mm to the right common iliac artery; 5.3 mm to the left external iliac artery;



Figure 2. Preoperative cardiac catheterization. Patent left coronary artery without significant angiographic lesions.

4.6 mm to the right external iliac artery; 5 mm to the left common femoral artery; 5 mm to the right common femoral artery; 4 mm to the left superficial femoral artery, and 4 mm to the right superficial femoral artery.

Procedure. Transcatheter aortic valve implantation (TAVI)

Under neuroleptoanalgesia, vascular access was obtained with 7-Fr introducers via the right and left femoral arteries and the right femoral vein for temporary pacemaker implantation. Right radial access was also achieved. Subsequently, a VL3 6-Fr guiding catheter was positioned in the left coronary artery via the right femoral artery and a 0.014" guidewire with a 4.0×24-mm coronary stent was advanced and parked in the distal left anterior descending artery for coronary protection due to the low takeoff of the left coronary ostium. A 6-Fr pigtail catheter was placed in the aortic root via the right radial access and an AL2-6-Fr catheter, via the left femoral access. The aortic valve was crossed with a straight-tip 0.035" guidewire, with a baseline transaortic gradient of 80 mmHg, and exchanged for a Surpass SF 0.035" guidewire placed at the left ventricular apex. Then, it was exchanged by a 14-Fr introducer in the left femoral artery, and balloon predilation of the aortic valve was performed with a 20×40-mm Mammoth balloon. A 23-mm balloon-expandable MyVal transcatheter aortic valve (Meril Life Sciences, Vapi, India) was then implanted under pacing using a deflectable Navigator delivery catheter, thus eliminating the transaortic gradient. Final post-placement angiography confirmed adequate transcatheter valve positioning with no significant paravalvular leak and sinus rhythm. Upon severe residual stenosis of the left main coronary artery (due to displacement of the native leaflet causing partial ostial obstruction), a 4.0×24 mm sirolimus-eluting BIOMIME stent (Meril Life Sciences, Vapi, India) was successfully deployed at 14 atm with a chimney technique. Control angiography confirmed left coronary artery patency, with no residual stenosis. Percutaneous closure of the left femoral artery was then performed.

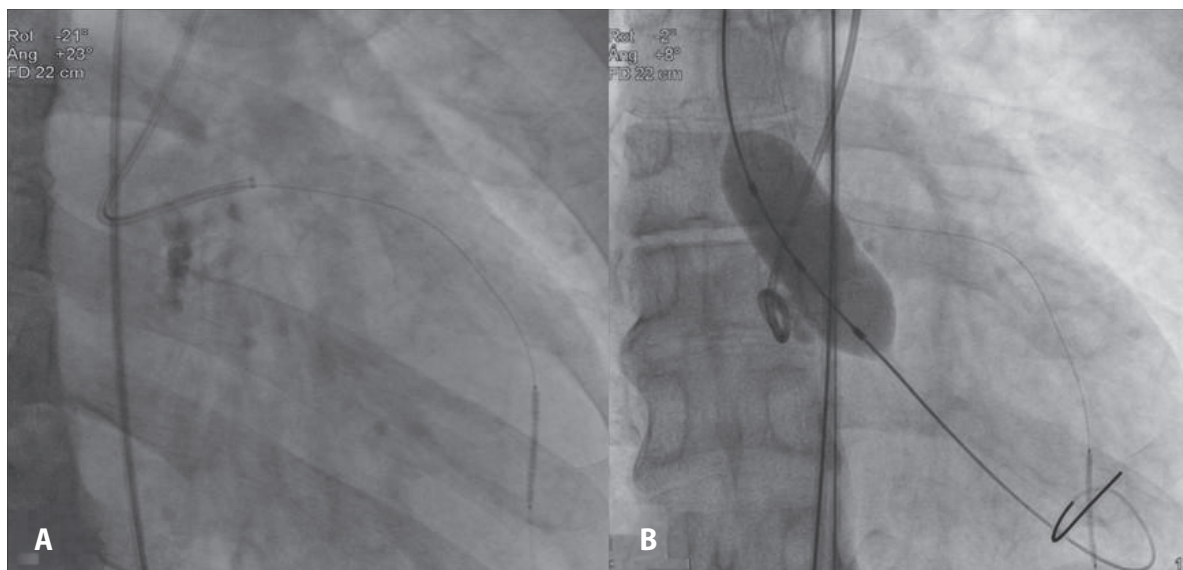


Figure 3. Left main coronary artery protection with guidewire and drug-eluting stent (3A). Balloon predilation of the aortic valve with a 20×40-mm Mammoth balloon (3B).

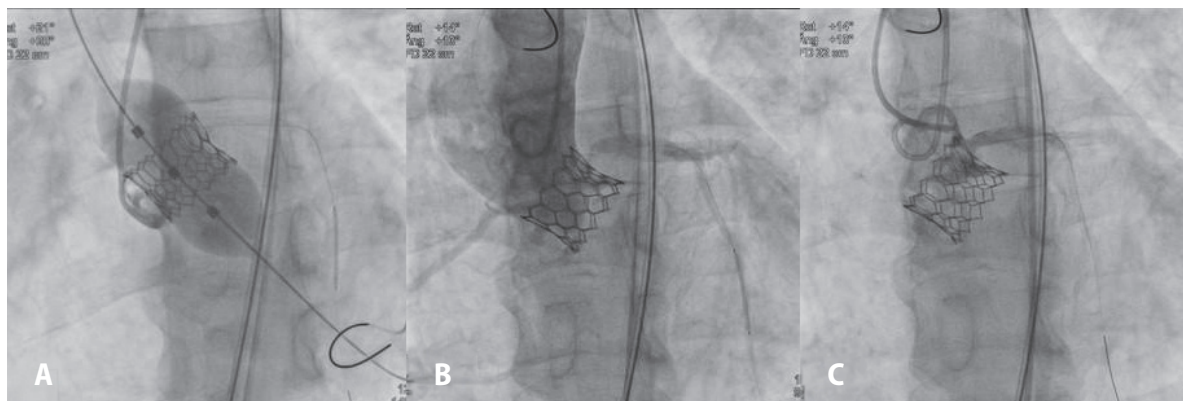


Figure 4. Transcatheter aortic valve implantation of a 23-mm balloon-expandable MyVal device (4A). Severe residual stenosis in the left main coronary artery (4B). Implantation of a sirolimus-eluting stent in the left main coronary artery (4C).

med without complications with a Proglide system (Abbott Cardiovascular, Santa Clara, CA, USA). Control angiography of the left common iliac artery revealed a retrograde dissection at the distal external iliac artery, partially flow-limiting; prolonged balloon angioplasty with a 5.0×40-mm balloon was successfully conducted, thus restoring normal distal flow. Hemostasis of the right femoral and right radial arteries was achieved by local compression. The patient remained hemodynamically stable throughout the procedure without complications and was transferred to the Coronary Care Unit for further monitoring. Hospital discharge occurred 48 hours after the procedure.

Figure 3. Left main coronary artery protection with guidewire and drug-eluting stent (3A). Balloon predilation of the aortic valve with a 20×40-mm Mammoth balloon (3B). At 30-day and 3-month clinical/echocardiographic follow-up, the patient remained in NYHA functional class I with preserved transvalvular gradients, no paravalvular leak, 60% LVEF, and no need for reintervention or adverse events.

DISCUSSION

In patients with severe aortic stenosis (AS), CS can significantly worsen the prognosis and limit therapeutic options.

Mortality associated with TAVI in patients with CS remains significantly higher compared to those without CS. Several studies have reported in-hospital mortality rates in patients with AS and CS undergoing TAVI ranging from 25% to 50%, whereas in patients without CS these rates are considerably lower, usually below 15%⁷. This difference may be attributed to the hemodynamic complexity of CS, which involves severe ventricular dysfunction and systemic compromise, two factors that increase perioperative risk and limit post-procedural recovery⁸.

However, TAVI shows lower early mortality rates than conservative management with simple valvuloplasty, and comparable or superior results to surgery in selected patients, with differences ranging between 10% and 20% in favor of TAVI⁹. This advantage is mainly explained by the lower invasiveness, the avoidance of open-heart surgery, and the shorter recovery time, which is particularly critical for hemodynamically unstable patients.

The use of TAVI in patients with bicuspid aortic valve (BAV) disease and CS remains a clinical challenge, given the peculiar anatomy and the critical hemodynamic status of these patients. Computed tomography determines the risk of coronary occlusion (heights <10–12 mm, small sinuses), justifying preventive strategies such as BASILICA or chim-

ney protection. In our case, the low coronary height and calcified bicuspid morphology prompted active protection and subsequent chimney stenting of the LMCA, with adequate final patency. Given the young patient age, the need for long-term planning (lifetime management), and the odds of requiring ViV (valve-in-valve) reintervention, valve durability and coronary access became central in the decision-making process.

CONCLUSION

In this patient with CS and bicuspid aortic valve, TAVI was a viable lower-risk treatment alternative compared to conventional surgery, allowing for hemodynamic stabilization and faster recovery. Appropriate case selection, CT-based planning, and a multidisciplinary approach were decisive in optimizing the clinical outcome.

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Percutaneous closure of mitral paravalvular leak

Cierre percutáneo de *leak* paravalvular mitral

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ABSTRACT

Paravalvular leak (PVL) is a potential complication after cardiac valve replacement that can lead to heart failure, hemolytic anemia, or endocarditis. We present the case of a 69-year-old woman with a history of mechanical mitral and aortic valve replacement who developed a severe mitral PVL diagnosed by echocardiography. Given the high surgical risk, percutaneous anterograde closure was successfully performed using an Amplatzer Vascular Plug III device, with significant improvement in functional class at 6 and 12 months of follow-up. This case highlights the feasibility and safety of percutaneous closure as a therapeutic alternative in selected patients with severe symptomatic PVL, provided there is always a multidisciplinary assessment.

Key words: paravalvular leak, mitral, percutaneous closure, Amplatzer device, structural intervention.

RESUMEN

El leak paravalvular (LPV) es una complicación que puede aparecer luego del reemplazo valvular cardíaco y generar insuficiencia cardíaca, anemia hemolítica o endocarditis. Presentamos el caso de una mujer de 69 años con antecedentes de reemplazo valvular mitral y aórtico mecánicos, que desarrolló un LPV mitral severo diagnosticado por ecocardiografía. Dado el alto riesgo quirúrgico, se realizó un cierre percutáneo por vía anterógrada con un dispositivo Amplatzer Vascular Plug III, con resultado exitoso y mejoría significativa de la clase funcional a los 6 y 12 meses de seguimiento. Este caso destaca la factibilidad y seguridad del cierre percutáneo como alternativa terapéutica en pacientes seleccionados con LPV grave y sintomático, siempre en el marco de una evaluación multidisciplinaria.

Palabras clave: leak paravalvular, mitral, cierre percutáneo, dispositivo Amplatzer; intervencionismo estructural.

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INTRODUCTION

Paravalvular leak (PVL) is a well-known complication after surgical valve replacement, with an estimated incidence ranging from 2% to 10% depending on valve and prosthesis type. Its clinical presentation may vary from asymptomatic cases to severe heart failure, hemolytic anemia, and endocarditis. Management of PVL depends on regurgitation severity and presence of symptoms. Surgical reintervention has historically been the treatment of choice, but it carries significant risk, particularly in patients with multiple previous sternotomies. In this setting, percutaneous PVL closure has emerged as a minimally invasive alternative, with encouraging results in different clinical series.

In this article, we present the case of a patient with severe mitral PVL successfully treated by percutaneous closure with an Amplatzer Vascular Plug III device, highlighting the feasibility and safety of this strategy.

CLINICAL CASE

We present the clinical case of a 69-year-old woman with New York Heart Association (NYHA) functional class III/IV progressive dyspnea over the past 6 months. Relevant cardiovascular history included mechanical mitral valve replacement 12 months prior to symptom onset and remote mechanical aortic valve replacement. The patient's chronic medication consisted of enalapril 5 mg/12 h, bisoprolol 2.5 mg/

day, acenocoumarol 2 mg/day, and furosemide 40 mg/day. Physical examination revealed signs of heart failure such as bilateral lower-limb edema (3/6) and bibasilar crackles on lung auscultation. Cardiac auscultation revealed a holosystolic murmur at the mitral focus. Transthoracic (TTE) and transesophageal (TEE) Doppler echocardiography showed preserved left ventricular systolic function and severe PVL at the 10 o'clock position, with regularly functioning mitral and aortic prostheses. In view of these findings and the high perioperative risk due to two prior sternotomies, percutaneous anterograde PVL closure was indicated.

Technique

Under general anesthesia, the patient underwent transesophageal echocardiography that showed no visible thrombus in the left atrial appendage. After local anesthesia with 2% lidocaine, venous and arterial femoral access was obtained with 6-Fr introducers (Radiofocus, Terumo Corporation). Using the venous access, a multipurpose catheter was advanced through the brachiocephalic vein and, over a long Amplatz guidewire, exchanged for an 8-Fr Mullins sheath (Cook Medical). A Brockenbrough needle was advanced within the sheath to its distal end. From the brachiocephalic vein, both sheath and needle were carefully advanced and positioned over the fossa ovalis. After confirming positioning by means of TEE, transseptal puncture was performed in the posterosuperior quadrant of the fossa ovalis. Once puncture was achieved, complications such as inadvertent aortic or pericardial entry were ruled out using echographic guidance (saline injection and bubble visualization) and hemodynamic pressure tracings (atrial waveform). The Mullins sheath was then advanced into the left atrium. A 6-Fr Judkins Right 4.0 catheter was inserted through the Mullins sheath and a long hydrophilic guidewire was advanced across the PVL into the left ventricle. A 5-Fr Judkins Right 4.0 catheter was advanced over a 0.035-inch Teflon wire via the arterial access, crossing the valve plane in right anterior

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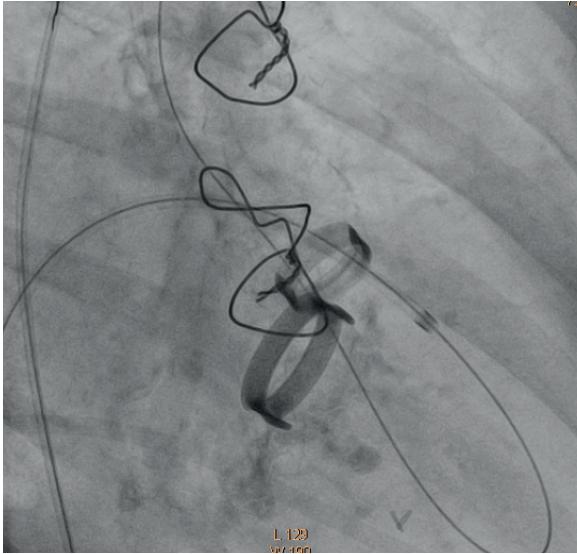


Figure 1. Using a snare, the hydrophilic wire is guided from the left ventricle into the aorta.

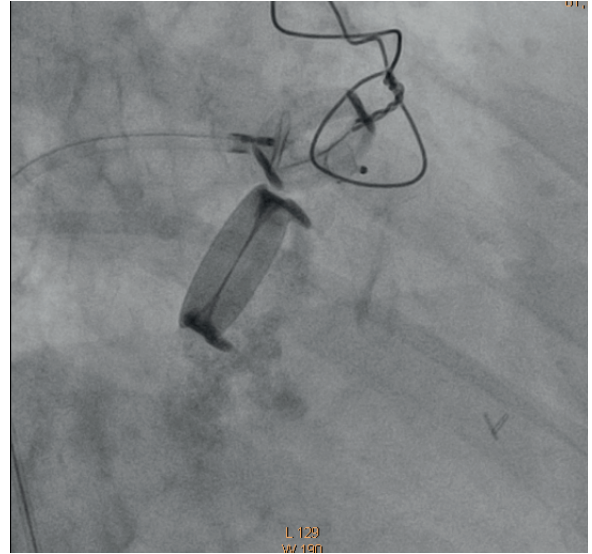


Figure 2. The Amplatzer Vascular Plug III device is deployed over the paravalvular leak.

oblique projection. Once in the left ventricle, a snare was used to capture the hydrophilic wire and redirect it into the aorta, creating an arterio-venous circuit (**Figure 1**). Finally, under simultaneous traction of the hydrophilic wire via the arterial access snare, an Amplatzer Vascular Plug III device (Abbott Cardiovascular, Santa Clara, CA, USA) was advanced to the PVL (**Figure 2**). After confirming correct positioning through multiple angiographic projections and TEE, the device was released—first the disc facing the left ventricle and then the disc facing the left atrium. Successful closure was confirmed with no residual leak on TEE and angiography (**Figure 3**). The patient was transferred to the Coronary Care Unit and discharged 48 hours after the procedure without complications. At the 6- and 12-month follow-up, the patient showed significant improvement in functional class, with no evidence of heart failure.

DISCUSSION

Paravalvular leak (PVL) is a complication that can arise after valve replacement surgery and may lead to heart failure, hemolytic anemia, and endocarditis. Its prevalence varies according to the replaced valve and the type of prosthesis, but it is estimated to occur in approximately 2–10% of patients undergoing valve replacement¹. PVL results from inadequate seal between the prosthetic valve and the surrounding cardiac tissue. This can be attributed to technical factors during surgery, such as improper prosthesis positioning or inadequate suturing, as well as to anatomical factors². PVL diagnosis is usually established through transthoracic and transesophageal Doppler echocardiography, which allow for the assessment of regurgitation severity and its impact on cardiac function. Cardiac magnetic resonance imaging may also be useful in certain cases³. Defining PVL severity based on regurgitant fraction is essential: >30% corresponds to severe leak⁴. Management of PVL depends on regurgitation severity and presence of symptoms. Indications for PVL closure include symptomatic heart failure, significant hemolytic anemia due to paravalvular regurgitation, recurrent or persistent endocarditis involving the prosthetic valve area, and severe paravalvular regurgitation (>30% regur-

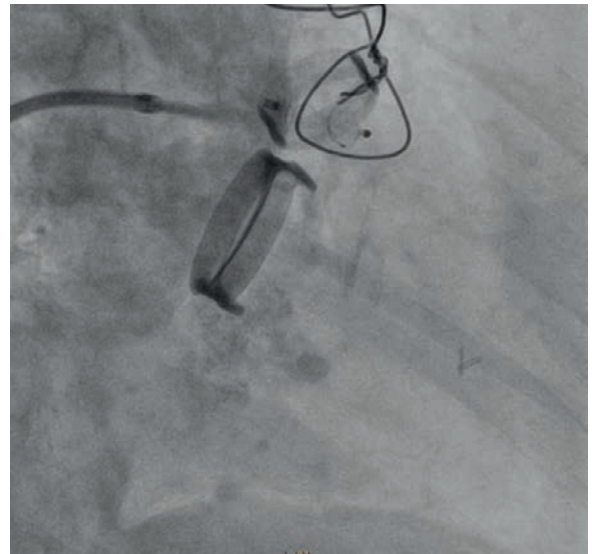


Figure 3. Angiography confirms the absence of mitral paravalvular leak.

gitant fraction)⁵. In asymptomatic patients with mild to moderate PVL, regular clinical and echocardiographic surveillance may be appropriate. However, in symptomatic severe PVL, more aggressive treatment is required. In such cases, percutaneous closure emerges as the main strategy⁵. Percutaneous PVL closure is a minimally invasive technique that involves the deployment of occluder devices to seal the paravalvular defect. Three main percutaneous approaches are currently used: antegrade (from venous to arterial system, as in our case), retrograde (exclusively arterial, primarily used for aortic PVL), and transapical approach. In a case series published by Millán-Ruiz *et al.*, the reported procedural success rate was 86% and the clinical success rate at 42-month follow-up was 89%. The 30-day percutaneous mortality rate was 4.6%, and freedom from cardiac-related death at 18 months reached 91.9%. Conversely, the in-hospital mortality rates for surgical reintervention were 13%, 15%, and 37% for the first, second, and third intervention, respectively, with a 10-year survival of only 30%⁶. Percutaneous PVL closure has therefore shown safety and efficacy in mul-

multiple series, with success rates varying according to anatomical complexity and operator experience⁷.

CONCLUSIONS

PVL is a significant complication after cardiac valve replacement and requires timely diagnosis and manage-

ment. Percutaneous closure offers a viable and effective alternative for patients with symptomatic severe PVL and elevated surgical risk. Device and access route should be chosen within assessment by a multidisciplinary Heart Team. This case further supports the feasibility of the Amplatzer Vascular Plug III as a suitable option in the treatment of PVL.

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Vascular complication post-TAVI with sheath entrapment and distal embolization: surgical resolution through extraperitoneal approach. A case report

Complicación vascular post-TAVI con atrapamiento de introductor y embolización distal: abordaje extraperitoneal quirúrgico. Presentación de un caso clínico

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ABSTRACT

A 69-year-old woman with severe aortic stenosis underwent transfemoral transcatheter aortic valve implantation (TAVI) with a low-profile sheath and favorable sheath-to-femoral artery ratio (SFAR) (0.92). Despite adequate preoperative planning with computed tomography angiography, she experienced a major vascular complication due to entrapment of the femoral introducer, with distal embolization of endothelial fragments. Upon the failure of conventional maneuvers to release the device, a decision was made for extraperitoneal surgery with arterial reconstruction using a vascular prosthesis, followed by successful tibial embolectomy. This case highlights the need for multidisciplinary planning to address uncommon but potentially severe vascular complications following endovascular procedures.

Key words: transcatheter aortic valve replacement, vascular complications, embolectomy, vascular surgery, vascular grafts.

RESUMEN

Se presenta el caso de una mujer de 69 años con estenosis aórtica severa, sometida a TAVI transfemoral con introductor de bajo perfil y SFAR favorable (0,92). Pese a una adecuada planificación preoperatoria con angiografía, desarrolló una complicación vascular mayor por atrapamiento del introductor femoral, con embolización distal de fragmentos endoteliales. Debido al fracaso de las maniobras convencionales para liberar el dispositivo, se realizó abordaje quirúrgico extraperitoneal con reconstrucción arterial mediante prótesis vascular, seguido de embolectomía tibial exitosa. Este caso destaca la necesidad de planificación multidisciplinaria para resolver complicaciones vasculares infrecuentes pero potencialmente graves tras procedimientos endovasculares.

Palabras clave: implante percutáneo de válvula aórtica, complicaciones vasculares, embolectomía, cirugía vascular, prótesis vasculares.

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INTRODUCTION

Vascular complications are among the most relevant adverse events of transcatheter aortic valve implantation (TAVI). They are associated with high in-hospital and short-term morbidity and mortality¹. Despite advancements in preoperative planning with computed tomography angiography and the use of low-profile introducers, these complications are still a considerable clinical challenge². Tools such as the sheath-to-femoral artery ratio (SFAR) and its modified version have proven useful in estimating the risk of major vascular events, but they do not eliminate it completely³. We present the case of a patient with favorable vascular anatomy who experienced an uncommon complication characterized by introducer entrapment and distal embolization, which was resolved through an extraperitoneal surgical approach with favorable outcome.

CLINICAL CASE

A 69-year-old woman with a history of hypertension, dyslipidemia, and overweight (body mass index [BMI] 29; body

surface area: 1.60 m²) was diagnosed in 2018 with severe aortic stenosis. She had a 6-month history of exertional dyspnea, New York Heart Association (NYHA) functional class II. After multidisciplinary evaluation by the Heart Team, a decision was made in favor of TAVI considering the patient's preference and the potential risk of prosthesis-patient mismatch. Regarding risk scores, the Society of Thoracic Surgeons (STS) mortality score was 1.5% and the EuroSCORE II was 1.49%.

Computed tomography angiography (CTA) showed iliofemoral vessels with no severe tortuosity or significant circumferential calcifications, with adequate calibers for the procedure. On the right side, the common iliac artery diameter was 9.0×9.0 mm, the external iliac artery diameter was 6.9×6.1 mm, and the common femoral artery diameter, 6.6×6.5 mm. On the left side, the values were lower: 7.4×7.1 mm for the common iliac artery, 6.1×5.9 mm for the external iliac artery, and 6.0×5.9 mm for the common femoral artery. Right side access was selected, given its better profile. The calculated SFAR was 0.92 (18-Fr introducer/6.5-mm femoral artery), which suggested a low risk of major vascular complications.

Once the right femoral artery was exposed in layers, a 6-Fr introducer was initially advanced. Subsequently, through a series of progressive dilations, the vascular tract was expanded to allow for the insertion of an 18-Fr introducer. Finally, a No. 23 Evolut™ R valve was implanted without complications (**Figure 1**).

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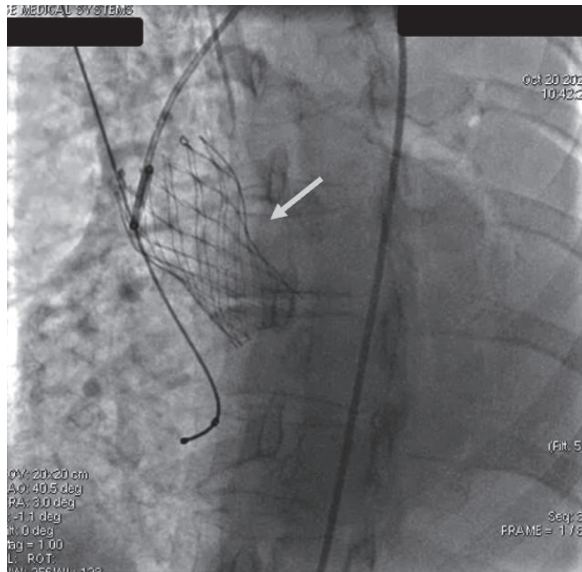


Figure 1. Successful implantation of a No. 23 Evolut™ R valve in the aortic position. Post-procedural angiographic image showing adequate bioprosthesis expansion and positioning (arrow).

Upon procedural completion, an attempt was made to remove the introducer. It failed due to entrapment in the right iliac artery. Control angiography confirmed this finding. Mechanical maneuvers were performed to facilitate extraction, including irrigation with temperature-controlled saline solution to induce vasodilation. However, after multiple unsuccessful attempts at releasing the device, intervention by the cardiovascular surgery team was requested.

An extraperitoneal approach was chosen through an oblique incision in the right iliac fossa, exposing the external iliac artery and the common femoral artery. This allowed for controlled sectioning of both arteries and release of the introducer, which showed endothelial tissue adhered to it (**Figure 2**). A 9-mm Dacron tubular prosthesis was then implanted in the iliofemoral position, with proximal anastomosis at the level of the iliac bifurcation and distal end-to-end anastomosis with the common femoral artery (**Figure 3**).

Upon assessment of right foot perfusion after the surgery, distal coldness and absence of tibial pulse were noted. Control angiography showed occlusion of the tibio-peroneal (tibiofibular) trunk (**Figure 4a**). Embolectomy with a Fogarty catheter was performed in that segment, retrieving fragments of vascular endothelium adhered to the device (**Figure 4b**). Subsequent control angiography confirmed restoration of infrapatellar flow to the foot and tibial pulse (**Figure 4c**).

The patient's clinical course after the procedure was favorable, with no new complications during hospitalization. After close clinical follow-up and satisfactory postoperative evaluations, she was discharged in good general condition.

DISCUSSION

Vascular complications in TAVI—including dissection, perforation, rupture, fistulae, pseudoaneurysms, and distal embolization—remain associated with increased in-hospital and 30-day postprocedural mortality^{1,2}. The ratio between



Figure 2. The 18-Fr introducer catheter extracted after surgical release, with visible endothelial tissue adhered along its surface (arrow).

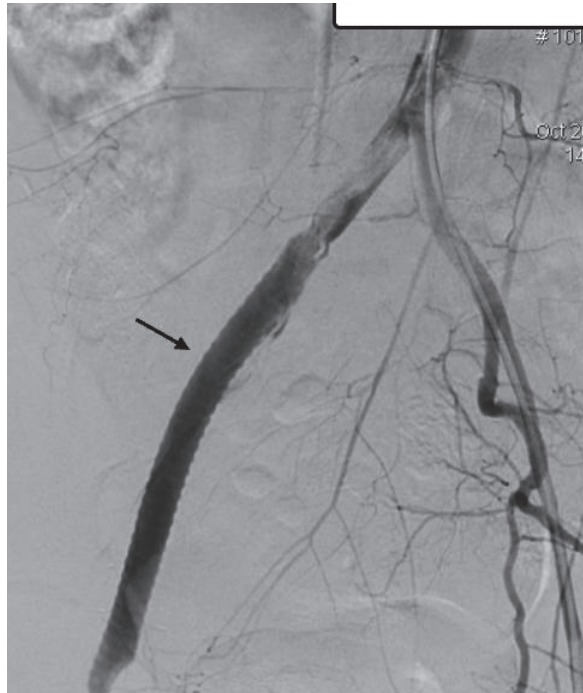


Figure 3. Digital subtraction angiography showing the 9-mm Dacron tubular graft positioned in the iliofemoral artery (arrow), with adequate flow through both anastomoses.

the outer diameter of the introducer and femoral artery diameter, known as “SFAR”, has been used to quantify this risk. SFAR ≥ 1.05 is independently associated with a significant increase in major vascular complications ($p < 0.001$)³. Recently, a modified SFAR (md-SFAR) has been proposed to adjust manufacturer recommendations to real-world clinical practice. In a multicenter study, the md-SFAR proved to be the only independent predictor of major vascular complications after transfemoral TAVI (odds ratio = 3.71; 95% confidence interval: 1.13-12.53; $p = 0.031$)⁴. For example, for the Edwards SAPIEN 3 system, the minimum femoral diameter required for a 14-Fr introducer is 5.0 mm, whereas for the Medtronic Evolut R this threshold is 5.5 mm⁴.

The introduction of low-profile introducers (≤ 18 Fr) has contributed to a dramatic reduction in the incidence of major vascular complications. In a historical cohort, the use of ≤ 18 -Fr introducers was associated with a complication rate of 0.5% compared with 10.5% with ≥ 19 -Fr introducers⁵. Nonetheless, anatomical factors such as circumferential calcification, severe tortuosity, and femoral tract depth remain significant predictors of adverse events⁶.

The SOURCE and TAVI registries have shown a sustained decrease in vascular complications as operator and cen-

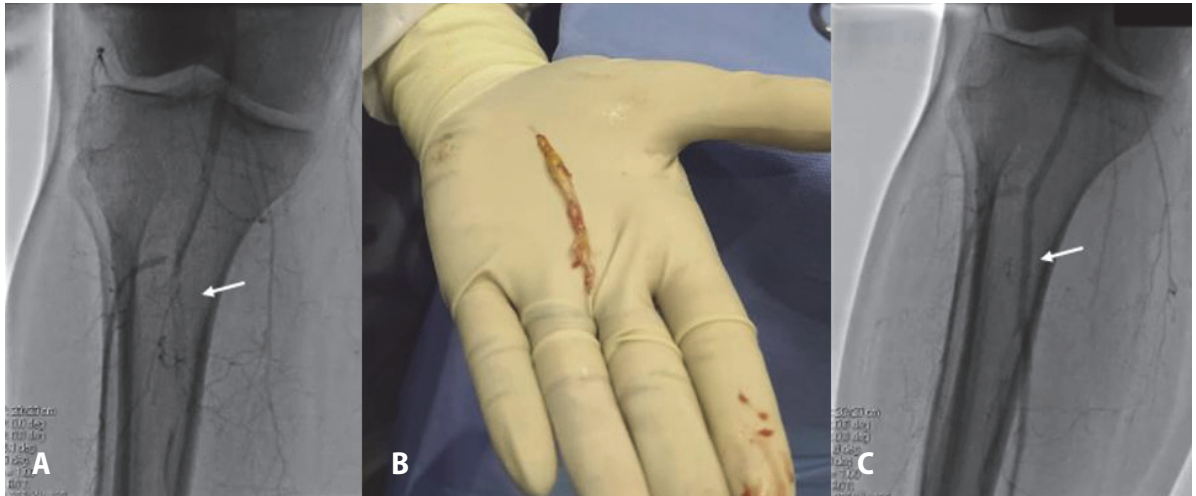


Figure 4. Sequence showing resolution of distal occlusion in the right lower limb. a) Angiography demonstrating tibioperoneal trunk occlusion (arrow). b) Vascular endothelial fragment extracted by Fogarty catheter, held in the operator's palm. c) Post-embolectomy control angiography demonstrating infrapatellar flow restoration (arrow).

ter experience increases, improving selection based on multi-slice computed tomography and percutaneous closure techniques⁷.

In this case, despite comprehensive preoperative assessment—including CT angiography and SFAR calculation—the patient experienced a major vascular complication that required surgical management. This reinforces the importance of using predictive tools such as SFAR in all preoperative planning, preferring low-profile introducers whenever anatomy allows, and maintaining a multidisciplinary team (interventional cardiologists, vascular surgeons, and anesthesiologists) ready for immediate intervention.

CONCLUSIONS

Severe vascular complications related to introducer entrapment during TAVI procedures, while infrequent, can occur even with appropriate preoperative planning and a SFAR within typically safe parameters. This case highlights the usefulness of this index as a guiding tool, but it also demonstrates its limitations in the face of non-quantifiable anatomical factors. It also underscores the importance of having a multidisciplinary team prepared to implement effective surgical strategies, such as the extraperitoneal approach, to resolve these events with good clinical outcomes.

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Letter from the President of CACI

Carta del Presidente del CACI

Revista Argentina de Cardioangiología Intervencionista 2025;16(3):128. <https://doi.org/10.30567/RACI/202503/0128-0128>

Dear colleagues and friends,

In this letter—and in alignment with previous editorial remarks made by our President-elect, Dr. Alfredo Bravo—I would like to reinforce the call for active participation of all our CACI members.

I would like to highlight the existence of our Code of Ethics, voted upon during Assembly and available to all members, which is not mere formality but a call for empathy among colleagues. If we all apply this empathy and put this mutual consideration into practice, labor-related conflicts will decrease to the point of disappearing.

In addition, and in accordance with the previous letter and with the opening of a new cohort in our program, we have begun to work on a new set of regulations for students, establishing requirements both for the training Departments supporting candidates as well as for the applicants themselves.

Regarding the training Departments, they must have a CACI-certified cath lab and provide a registry of procedures performed at the training center, and the Head of Department must be a CACI member with at least five years since certification.

Regarding the applicant, they must hold a medical degree and a specialist degree in Cardiology, Radiology, or Pediatric Cardiology, as well as at least one year of certified practical experience in a Department of Hemodynamics.

Upon fulfillment of these requirements, the applicant will be eligible to sit for the entrance examination—of exclusory nature—for the CACI Interventional Cardiologist Specialization Program, which is currently the only training program with ministerial certification for our specialty.

The intention of this Executive Committee, with support from our Advisory Council, is to further elevate the academic level of the admission process for those pursuing the specialty, prioritizing the medical excellence of future trainees while safeguarding the quality of diagnostic and therapeutic procedures, as well as the radiological biosafety of both patients and professionals in training. Similarly, the number of available positions will be established in accordance with the healthcare needs of our country.

Regarding institutional activities, at this point in the year we have carried out the four institutional CACI sessions detailed below.

- May: *Acute Aortic Syndrome*, at the CACI Auditorium.
- June: *Mitral and Tricuspid Valve Disease*, at the Instituto de Cardiología de Corrientes Auditorium.
- August: *High-Risk Angioplasty*, at the CACI Auditorium.
- September: *Modern Coronary Angioplasty*, at the Cordoba Province Legislative Building Auditorium.

We also held the 10th CACI Conference aimed at medical auditors and healthcare funders, an activity that brings together, year after year, an increasing number of representatives from all union and private medical insurance companies across the country.

Additionally, building refurbishments were carried out at our headquarters, the first since its inauguration in 2008.

We continued with the 14th CACI@SAC “Dr. Liliana Grinfeld” Symposium, held within the framework of the 51st Congress of the Argentine Society of Cardiology.

Another important milestone that should be highlighted is the emergence of new provincial associations. Currently, we have five associations (ACIC, in Cordoba; AEHITE, in Entre Rios; the Salta Interventional Cardiology Civil Association, in Salta; ACIBA, in the Buenos Aires Metropolitan Area; ACISFe, in Santa Fe), while two more are under organization (in San Luis and Misiones), with the aim of finally consolidating our Federation: CACI.

We are now approaching the National CACI Congress; this year, it will take place at the Costa Galana Hotel in Mar del Plata from December 12 to 14. During this meeting, we will also hold the 3rd edition of CACI VALVE on Friday, December 12.

I hope to count on all of you; CACI is built by all of us.

I look forward to seeing you very soon at the CACI MDQ Congress.

Thank you for the support and collaboration of each and every one of you.

Dr. Juan José Fernández
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Publications rules Argentine Journal of Interventional Cardioangiologology

Reglamento de Publicaciones de la *Revista Argentina de Cardioangiología Intervencionista*

La *Revista Argentina de Cardioangiología Intervencionista* (RACI) es una publicación trimestral editada por el Colegio Argentino de Cardioangiólogos Intervencionistas (CACI) con objetivos asentados en la divulgación de material científico y educativo para la especialidad. La distribución nacional es gratuita y está dirigida a cardioangiólogos intervencionistas, cardiólogos clínicos y pediátricos, radiólogos, neurólogos, técnicos en hemodinamia y especialidades afines. La publicación es de tipo impresa y electrónica (www.caci.org.ar).

Los principios editoriales de la revista se basan en las recomendaciones para manuscritos enviados a revistas Biomédicas (*Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals*) redactados por el Comité Internacional de Editores de Revistas Médicas (*International Committee of Medical Journal Editors - ICMJE*) en su más reciente actualización, disponible en www.icmje.org.

A partir del número 2 volumen 9 año 2018, por razones editoriales, los elementos gráficos (figuras, tablas, fotos) se editan a lo sumo en dos colores (azul y negro). Aquellos que los deseen a todo color deberán pagar un costo adicional por el trabajo de 200 US\$.

Los artículos enviados deben ser originales. El Comité Editorial evaluará los trabajos y luego de un primer análisis sobre si el artículo sigue las normas Editoriales de la Revista, el Director y/o Directores Asociados serán los encargados de enviarlos a un arbitraje externo, que será simple ciego, que significa que los autores no conocen el nombre de los revisores y los revisores a su vez no conocen el nombre de otros revisores. Esta política del RACI se hace siguiendo los mismos criterios empleados por el Comité de Revisión y Editorial del *J Am Coll Cardiol* (JACC), que es la revista de cardiología de mayor factor impacto. La decisión final quedará en manos del Comité Editorial de acuerdo con las conclusiones del arbitraje. Asimismo, el Comité Editorial tendrá la facultad de introducir, con el consentimiento de los autores, todos los cambios editoriales exigidos por las normas gramaticales y las necesidades de edición de la revista. Los artículos de Revisión y Editoriales también serán objeto de la misma revisión. Los artículos Editoriales son usualmente pedidos por el Comité Editorial.

Luego de la primera revisión, los trabajos pueden ser aceptados en la forma en que fue inicialmente enviado; Revisiones Menores es cuando si bien el trabajo tiene aportes importantes existen limitaciones menores que deben ser corregidas antes de su eventual publicación; Revisiones Mayores es cuando el trabajo es inaceptable para publicar de acuerdo a como fue presentado. Sin embargo, el Comité Editorial consideraría un posible nuevo envío, también llamado *de novo submission*, si el trabajo es modificado sustancialmente; Rechazo, es cuando los revisores y el Comité Editorial consideran que el trabajo es inapropiado para publicar en la Revista RACI

En casos especiales de consensos de diagnóstico y/o tratamiento realizados en conjunto entre el CACI y sociedades científicas afines, tal consenso, de común acuerdo entre las mismas y con conocimiento del Comité Editorial, podrá ser publicado en forma excepcional por las revistas oficiales de ambas sociedades en forma simultánea.

PRESENTACIÓN GENERAL DEL MANUSCRITO

Todos los autores así como los miembros del Comité Editorial deben declarar conflictos de intereses, en caso de que existan, con las publicaciones.

Cada artículo debe ser presentado con una primera página que debe contener: (a) el título, informativo y conciso; (b) los nombres completos de los autores y de las instituciones en que se desempeñan; (c) un título abreviado para cabeza de página; (d) el número total de palabras del artículo, sin las referencias bibliográficas; (e) el nombre y dirección completa, con fax y dirección electrónica, del autor con quien se deba mantener correspondencia. La segunda página debe incluir el resumen (abstract) en español y en inglés, con 3-6 palabras clave al final de éstos con términos incluidos en la lista del Index Medicus (*Medical Subject Headings - MeSH*). Luego, en la tercera página, se debe desarrollar el contenido del manuscrito (véase Preparación del manuscrito), iniciando una nueva página para cada sección. Todas las páginas deben ir numeradas desde la portada.

El envío del artículo (texto, tablas y figuras) debe realizarse por correo electrónico a revista@caci.org.ar, con una nota firmada por todos los autores (véase modelo página web), con la indicación de la sección a que correspondería el manuscrito y la aseveración de que los contenidos no han sido anteriormente publicados. Una vez recibido el material, el Comité Editorial iniciará el proceso de incorporación que tiene una duración media de cinco semanas.

Quienes figuren como autores deben haber participado en la investigación o en la elaboración del manuscrito y hacerse públicamente responsables de su contenido.

Para cada artículo se permite un máximo de 8 autores, que deben adaptarse a las normas sobre autoría expuestas por la IMCJE. Cada manuscrito recibido es examinado por el Comité Editor y por uno o dos revisores externos. Posteriormente se notificará al autor responsable sobre la aceptación (con o sin correcciones y cambios) o el rechazo del manuscrito. Aprobada la publicación del trabajo, la RACI retiene los derechos de autor para su reproducción total o parcial.

Los autores deberán proveer su código de ORCID a los efectos de consignar sus datos filiatorios.

SECCIONES

Artículos originales (véase Preparación del manuscrito)

Son trabajos científicos o educativos de investigación básica o clínica original. Condiciones: a) texto general, hasta 5.000 palabras, incluidas las referencias; b) resumen, hasta 250 palabras; c) tablas + figuras, hasta 8; e) autores, hasta 10.

Comunicaciones breves

Los trabajos de esta sección cumplen con los lineamientos de Artículos originales, pero no tienen la suficiente cantidad de pacientes como para ser considerados como tales.

Artículos de revisión

Son artículos sobre temas relevantes de la especialidad solicitados por

el Comité Editor a autores de reconocida trayectoria (nacionales o extranjeros). Puede ser escrito por diferentes tipos de médicos (no más de 3 autores). Condiciones: ídem Artículo Original.

Educación básica

Son artículos sobre el manejo racional y protocolizado de diferentes circunstancias que se presentan en la práctica diaria. Son revisados y consensuados previamente con especialistas en el tema, y se culminan con un diagrama de flujo sobre el manejo diagnóstico y terapéutico de la patología. Es solicitado por el Comité Editor. Condiciones: a) texto general, hasta 2.500 palabras excluyendo referencias; b) resumen, hasta 150 palabras; c) tablas + figuras, hasta 6; d) referencias, hasta 20; e) autores, hasta 4.

Caso clínico

Es la descripción de un caso clínico de características inusuales, con su abordaje diagnóstico y terapéutico y su resolución final. Debe acompañarse de una breve discusión bibliográfica. Condiciones: a) texto general, hasta 1.200 palabras; b) resumen, hasta 100 palabras; c) tablas + figuras, hasta 4; d) referencias, hasta 10; e) autores, hasta 5.

¿Cómo traté?

Bajo el título "¿Cómo traté?" los autores presentarán un caso desafiante y la descripción del tratamiento realizado. El título deberá estar incluido al comienzo del texto, por ejemplo "¿Cómo traté un aneurisma en la descendente anterior?". Luego se incluirán los nombres, apellidos, títulos y lugar de trabajo de los autores. Deberá indicarse el autor que recibirá la correspondencia, incluyendo su dirección postal y e-mail. Todos los autores deberán declarar sus conflictos de interés y, en el caso de no tenerlos, indicarlo. Texto, figuras y referencias seguirán los criterios del Caso Clínico

Imágenes en intervencionismo

Se aceptarán para publicar imágenes de casos excepcionales, ilustrativas, y que el Comité Editorial y los revisores externos consideren de sumo interés para su publicación en la revista. Deben ir acompañadas de una leyenda explicativa y un breve resumen de historia clínica. Condiciones: a) texto general, hasta 300 palabras; b) solo 2 figuras originales; c) referencias, hasta 3; d) autores, hasta 5.

Protocolos de investigación

Como artículos especiales la Revista aceptará la publicación de Protocolos de Investigación Clínica, preferentemente multicéntricos y siempre que los mismos no hubiesen reportado antes los resultados parciales o totales del estudio.

Editoriales

Son análisis y/o comentarios de temas relevantes de la especialidad o de la Cardiología General que tuviesen relación con nuestra especialidad. Siempre serán solicitados por el Comité Editor a un experto en el tema. Asimismo, pueden solicitarse comentarios sobre temas no relacionados a un artículo en particular. Condiciones: a) texto general, hasta 2.000 palabras; b) referencias, hasta 40.

Cartas del lector

Es una opinión sobre un artículo publicado en el último número de la revista, el cual requiere un arbitraje realizado por miembros del Comité Editor. Condiciones: a) texto, hasta 250 palabras; b) se podrá publicar una tabla y/o figura; c) referencias, hasta 5. Se aceptarán solo aquellas cartas enviadas dentro del mes de haber salido la versión impresa del número de la revista donde se publicó el artículo original.

PREPARACIÓN DEL MANUSCRITO

El artículo debe estar escrito en castellano, en un procesador de texto Word (Microsoft®) y guardado con extensión *.doc. El tamaño de la pá-

gina debe ser A4 o carta, con doble espacio interlineado, márgenes de 25 mm con texto justificado y con tamaño de letra de 12 puntos tipo Times New Roman o Arial. Las páginas se numerarán en forma consecutiva comenzando con la portada. El manuscrito (artículo original) debe seguir la estructura «IMRD», es decir, Introducción, Material y métodos, Resultados y Discusión (véanse las normas de publicación ICMJE). Además, debe incluir Título, Resumen, Conclusiones, Conflicto de Intereses y Bibliografía. Al final de cada artículo original, antes de las referencias, deberá hacerse como una tabla destacada de los puntos relevantes del trabajo que se llamará Resumen de Puntos Salientes.

En estos 4 o 5 renglones se deberán señalar los problemas y el conocimiento que hay en el tema tratado hasta el momento y además cuáles serían los interrogantes.

En los dos últimos renglones se destaca el aporte y/o los aportes del trabajo más relevantes sobre este tema. Al final de las referencias se escribirán los Agradecimientos y un Apéndice Suplementario cuando correspondiese en estudios aleatorizados o registros multicéntricos que necesiten reportar todos los investigadores incluidos en el estudio.

Como unidad de medida se utilizará el sistema métrico decimal, usando comas para los decimales. Todas las mediciones clínicas, hematológicas y químicas deben expresarse en unidades del sistema métrico y/o UI. Solo se utilizarán las abreviaturas comunes, evitándose su uso en el título y en el resumen. La primera vez que se empleen irán precedidas por el término completo excepto que se trate de unidades de medida estándar.

Las tablas deben presentarse en hojas individuales, numerándose de forma consecutiva utilizando números arábigos (0, 1, 2, etc.) según el orden en que fueron citadas en el texto, con un título breve para cada una de ellas. Todas las abreviaturas de la tabla no estandarizadas deben explicarse. Las notas aclaratorias deben ir al pie de la misma utilizando los siguientes símbolos en esta secuencia: *, †, ‡, §, ¶, **, ††, ‡‡, etc.

Las figuras deben tener formato TIFF, PSD o JPEG e ir, cada una, en un archivo aparte a 300 dpi en formato final. Cada una de ellas tiene que estar numerada de forma correlativa junto a la leyenda explicativa en archivo aparte. El tamaño usual de las fotografías debe ser de 127 x 173 mm. Los títulos y las explicaciones detalladas se colocan en el texto de las leyendas y no en la ilustración misma.

Las referencias bibliográficas se enumerarán de manera consecutiva con números arábigos entre paréntesis. Se incluirán todos los autores cuando sean seis o menos; si fueran más, el tercero será seguido de la expresión «, et al.». Los títulos de las revistas serán abreviados según el estilo empleado en el Index Medicus. Ejemplos:

1. *Registro de Procedimientos Diagnósticos y Terapéuticos efectuados durante el período 2006-2007. Colegio Argentino de Cardioangiología Intervencionistas (CACI). Disponible en <http://www.caci.org.ar/addons/3/158.pdf>. consultado el 01/01/2009. (Página Web.)*
2. *Magid DJ, Wang Y, McNamara RL, et al. Relationship between time of day, day of week, timeliness of reperfusion, and in-hospital mortality for patients with acute ST-segment elevation myocardial infarction. JAMA 2005;294:803-812. (Revistas en inglés.)*
3. *Aros F, Cuñat J, Marrugat J, et al. Tratamiento del infarto agudo de miocardio en España en el año 2000. El estudio PRIAMHO II. Rev Esp Cardiol 2003;62:1165-1173. (Revistas en español.)*