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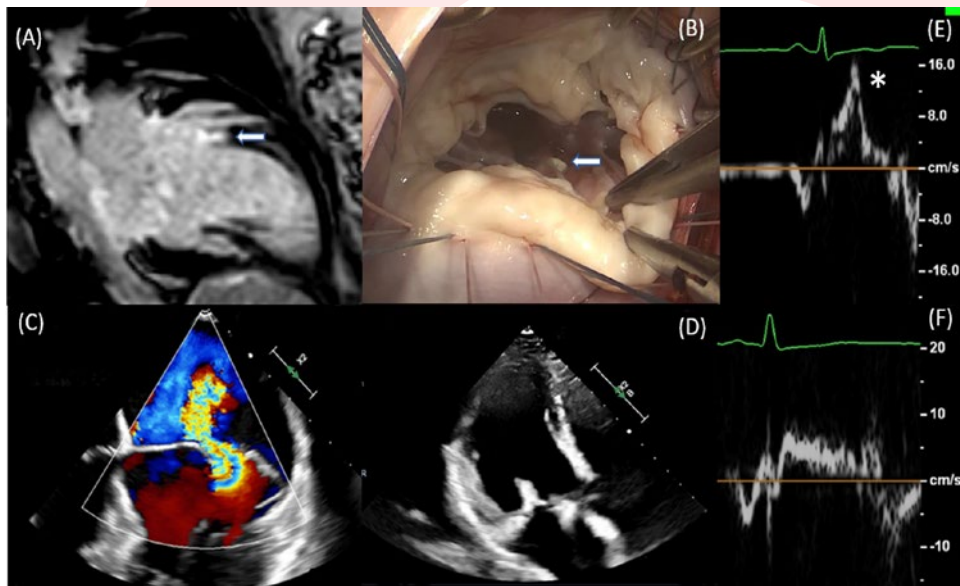
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**A:** cardiac MRI showing late gadolinium enhancement in the posteromedial papillary muscle. **B:** macroscopic correlation with area of fibrosis in the head of the posteromedial papillary muscle. **C:** mitral prolapse associated with curling and disjunction of the mitral annulus. **D:** mitral repair with adequate coaptation surface. **E:** preoperative pickelhaube sign. **F:** resolution of the pickelhaube sign after mitral repair.

Santiago Niño et al. *Malignant arrhythmia in mitral valve prolapse: is surgical treatment sufficient?*

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## Importance of assessing fragility and futility in percutaneous aortic valve implantation

### *Importancia de evaluar la fragilidad y la futilidad en el implante percutáneo de válvula aórtica*

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Degenerative aortic stenosis is the main reason for intervention in valvular disease in elderly people. Its prevalence increases significantly with age, affecting an estimated 3.4% of the general population and 12.4% of those over the age of 75 in developed countries<sup>1</sup>. There is little data on its prevalence in Latin American countries; it has proven to be similar, close to 3% in this age group<sup>2</sup>.

In 2001, Alain Cribier performed a transcatheter valve implantation (a procedure known as TAVI) in a patient with severe aortic stenosis considered inoperable due to the patient's high surgical risk. With the success of this TAVI, it was approved for treating patients with symptomatic severe aortic stenosis. In the following years, its indication was broadened, as it is a less invasive procedure that does not require extracorporeal circulation, and entails a short hospital stay and rapid recovery. Since then, it has become the method of choice for treating elderly patients. As a result, the number of percutaneously implanted valves has increased exponentially over the last few years.

A meta-analysis which included seven emblematic TAVI trials showed a significant reduction in all-cause mortality compared with surgical replacement (HR = 0.88; 95% CI: 0.78-0.99; p = 0.030) in patients with all types of surgical risk<sup>3</sup>. Although most procedures achieve

improved quality of life, the first studies showed that, in many cases, the outcome is not what was expected. Thirty-one percent of the patients included in the Placement of Aortic Transcatheter Valve (PARTNER I) study had died and 18% had not improved their quality of life<sup>4</sup>. Today, 20 years later, we have more advanced devices, improved diagnostic methods and more experience, which allow better outcomes. However, resources are limited, and we believe that avoiding futile interventions through a comprehensive assessment is a new challenge for cardiology.

Moreover, frailty was found in 59.9% of a series of patients with symptomatic severe aortic stenosis<sup>5</sup>. Frailty is a complex syndrome which is not age-dependent, but its prevalence increases with aging. It may have multiple causes and a dynamic course. It is characterized by decreased physiological reserves, making people more vulnerable to physiological stress and predisposing them to progressive deterioration and a poor disease course. Identifying frailty prior to implantation helps predict the risk of complications like delirium, falls or deconditioning during hospitalization, and the severity of the frailty can predict the risk of prolonged hospitalization, readmission, functional deterioration and death. Symptomatic aortic stenosis can contribute to

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increased frailty due to its functional, nutritional, psychological and social impact on the patient.

Consequently, frailty assessment has become increasingly relevant for decision making. However, despite being a routine practice in geriatrics, it continues to be a challenge for cardiologists.

There are several available tools for evaluating frailty which have proven to have an impact on the mortality of patients with aortic stenosis.

Options for initial screening include the scale validated by Fried et al., which is based on self-reported physical condition information<sup>6,7</sup>, and the Fatigue, Resistance, Ambulation, Illnesses and Loss of weight (FRAIL) scale, which shares the criteria of the physical model and adds comorbidity. For the prognosis of patients undergoing TAVI, short physical performance tests like walking speed and the Short Physical Performance Battery (SPPB)<sup>8</sup> along with the Rockwood Clinical Frailty Scale (CFS), which offers a different approach<sup>9</sup>, have also proven useful. Furthermore, the FRAILTY AVR study sought to compare the incremental predictive value of seven frailty scales for adverse outcomes following the valve procedure, and the prevalence of frailty ranged from 26% with the Rockwood CFS to 68% with SPPB. The Essential Frailty Toolset, which includes a short physical test, cognitive assessment using the Mini Mental State Examination and hemoglobin/albumin levels, has proven to have a better predictive capacity than frailty scales like Fried, Fried + Rockwood and SPPB<sup>10</sup>. Other scales that predict the patient's clinical course, like the Green scale or Comprehensive Geriatric Assessment-Frailty Index (CGA-FI), have also proven to be useful<sup>11</sup>. Likewise, malnutrition in frailty has been shown to increase all-cause mortality (87.9% vs. 2.9%;  $p < 0.001$ ; HR: 7.058; 95% CI: 5.174-9.629;  $p < 0.001$ )<sup>12</sup>.

We have mentioned only a few of the scales, but regardless of the scale used, some aspects like age, malnutrition, sarcopenia, loss of mobility, cognitive status, depression, comorbidities and lack of social support affect the outcome following TAVI.

In a Danish registry with almost 6,000 patients over a period of 12 years, frail patients had more heart failure, cerebrovascular disease and chronic kidney disease. Almost 75% had to be hospitalized in the first year after implantation and 5.8% died within the first year<sup>13</sup>.

It is important to consider that frailty can be improved with low-complexity interventions, especially nutrition and exercise. In fact, cardiac rehabilitation prior to TAVI improved the outcomes, with lower mortality rates<sup>14</sup>.

Although frailty is associated with more complications and adverse outcomes, improving the cardiovascular situation has also been shown to improve frailty in 48% of octogenarians, with some even reaching robustness<sup>15</sup>. We believe that this could be due to the fact that the disease itself causes functional frailty, limiting physical ability and producing a nutritional and emotional impact. Treating the main cause produces a rapid and significant improvement. Therefore, the challenge is to detect patients with multi-domain and multi-causal frailty.

Transcatheter aortic valve implantation affords an excellent survival rate and symptomatic benefit for most patients. However, a considerable group of patients does not totally benefit from the intervention despite a technically successful outcome. These cases can be considered futile interventions, as they do not improve one-year survival, functional capacity or quality of life. Several cardiological factors can be associated with futility, such as systolic dysfunction, atrial fibrillation, primary mitral regurgitation, pulmonary hypertension or acute decompensation. There are also extra-cardiac factors like severe pulmonary disease, oxygen dependence, kidney failure, anemia, metastatic cancer, frailty and a higher number of comorbidities that decrease the probability of recovery<sup>16</sup>.

The Futile TAVI Simple score (FTS) has been developed to predict futility, evaluating the patient's condition, including the most frequent comorbidities<sup>17</sup>. A score greater than 8 implies high risk, and the intervention is not recommended for these patients. Rather, optimal medical management is indicated, including palliative care.

We believe in patient-centered medical care in which the approach to elderly people presents clinical, nutritional, functional, mental and social obstacles that challenge us to develop a simple screening for cardiologists based on comprehensive assessment, an essential component for planning personalized treatment and even identifying vulnerabilities to decrease risk in a timely fashion.

We believe that a systematic assessment of frailty is the first step. Screening for frailty, incorporating multi-component frailty through different scales such as those mentioned above, helps determine the need for an exhaustive evaluation.

Involving staff specialized in geriatrics and gerontology early on contributes to planning personalized treatment before, during and after the intervention, to potentiate therapeutic success.

Are we really offering our patients the best?

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## Adverse events of amiodarone use

### Eventos adversos del uso de amiodarona

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### Abstract

**Introduction:** Amiodarone is an antiarrhythmic drug widely used to treat and prevent supraventricular and ventricular arrhythmias. However, it can be associated with various adverse events. Few studies have been conducted in Colombia on amiodarone adverse events. **Objective:** To determine the demographic, clinical and pharmacological characteristics associated with adverse events in patients on amiodarone at a cardiovascular clinic in the city of Medellín. **Materials and method:** A retrospective, observational, analytical cohort study was conducted through a chart review of patients treated with amiodarone from 2008 to 2021. Univariate, bivariate and multivariate analyses were performed using binomial logistic regression. **Results:** A total of 553 medical charts were reviewed, 221 of which met the eligibility criteria. The mean age was 63 years, with a predominance of males (57.5%). The majority had multimorbidity (73.3%), and the most common diagnosis for prescribing amiodarone was atrial fibrillation (84.4%). Altogether, 71 patients (32.1%) were reported to have amiodarone-related adverse events, with the most frequent being cardiovascular events (43.7%), followed by thyroid (29.6%) and ophthalmological (10%) events. The variable that was associated with amiodarone-related adverse events was multimorbidity (adjusted relative risk [RR] 1.65; 95% CI: 1.02-2.25;  $p = 0.039$ ). **Conclusions:** Amiodarone adverse events were common. The characteristic that explains 16.8% (Nagelkerke's  $R^2 [R^2_N]$ ) of the adverse events was multimorbidity, and the majority of the patients required treatment suspension.

**Keywords:** Amiodarone. Risk factors. Adverse events. Arrhythmia.

### Resumen

**Introducción:** La amiodarona es un fármaco antiarrítmico ampliamente utilizado para la prevención y el tratamiento de arritmias supraventriculares y ventriculares. Sin embargo, se puede asociar a diversos eventos adversos. En Colombia son pocos los estudios sobre eventos adversos relacionados con este medicamento. **Objetivo:** Determinar las características demográficas, clínicas y farmacológicas asociadas a eventos adversos en pacientes con uso de amiodarona en una clínica cardiovascular de la ciudad de Medellín. **Materiales y método:** Estudio observacional analítico de cohorte retrospectivo, basado en la revisión de historias clínicas de pacientes tratados con amiodarona durante el periodo 2008 a 2021. Se realizó un análisis univariado, bivariado y multivariado mediante regresión logística binomial. **Resultados:** Se revisaron 553 historias clínicas, de las cuales 221 cumplieron los criterios de elegibilidad. La edad promedio fue 63 años, con predominio del sexo masculino (57.5%).

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La mayoría presentó multimorbilidad (73.3%) y el diagnóstico más común para la prescripción de amiodarona fue la fibrilación auricular (84.4%). Se reportaron 71 (32.1%) eventos adversos relacionados con amiodarona, de los cuales los más frecuentes fueron los de origen cardiovascular (43.7%), seguidos por los tiroideos (29.6%) y por los oftalmológicos (10%). La variable que explicó la presencia evento adverso por amiodarona fue multimorbilidad (riesgo relativo –RR– ajustado 1.65; IC 95%: 1.02-2.25;  $p = 0.039$ ). **Conclusiones:** Los eventos adversos por amiodarona fueron frecuentes. La característica que explica el 16.8%  $R^2_N$  (Nagelkerke's  $R^2$ ) de los eventos adversos fue multimorbilidad y la mayoría de los pacientes requirieron la suspensión del tratamiento.

**Palabras clave:** Amiodarona. Factores de riesgo. Efectos adversos. Arritmia.

## Introduction

Amiodarone is a benzofuran derivative whose active metabolite is desethylamiodarone, which has a broad mechanism of action, blocking most of the cardiac ion channels and directly blocking the vascular alpha-adrenergic receptors. This is why it was initially conceived as a coronary vasodilator, with clinical use for the treatment of angina<sup>1</sup>. Furthermore, this medication has very distinctive pharmacokinetics, as it is highly lipid-soluble, with slow and variable absorption, and has an average bioavailability of 35 to 65%<sup>2,3</sup>. It has been suggested that age, sex and underlying diseases are toxicity predictors. However, these factors have not been found in all adverse effects<sup>4</sup>.

Amiodarone was developed in 1962, but its pronounced effectiveness as an antiarrhythmic was not reported until 1976<sup>5</sup>. Today, it is a widely known medication used to treat ventricular and supraventricular arrhythmias, which has been related to adverse effects in different organs: the skin, eyes, liver, heart, thyroid and lungs<sup>6</sup>.

The Food and Drug Administration (FDA) labels amiodarone only for treating ventricular fibrillation and recurrent ventricular tachycardia in hemodynamically unstable patients. However, in clinical practice, it is very commonly prescribed for atrial fibrillation<sup>7</sup>.

In Colombia, it is currently approved by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos (INVIMA) [National Institute for Food and Drug Surveillance] for treating ventricular tachyarrhythmias, supraventricular nodal tachycardia and Wolff-Parkinson-White syndrome<sup>8</sup>.

Periodic monitoring is important in patients on amiodarone, as, without proper assessment and control, the risks could be higher than the benefits<sup>9</sup>. Although most of the adverse effects have a specific treatment, many can improve with withdrawal of the medication, and fewer than 20% will be serious, life-threatening reactions<sup>10</sup>. The prevalence of adverse events within the first year has been reported to potentially reach 15% and could increase to 50% with

prolonged use<sup>7-9</sup>. In general, follow-up is recommended every three months during the first year and every six months thereafter, as medically required<sup>9,10</sup>.

The objective of this study was to determine the demographic, clinical and pharmacological characteristics associated with adverse events in patients on amiodarone, considering that this is one of the most frequently prescribed antiarrhythmic drugs<sup>11,12</sup>.

## Materials and method

This was an observational, analytical, retrospective cohort study based on a chart review of patients treated with amiodarone at a cardiovascular clinic in the city of Medellín from 2008 to 2021.

Patients over the age of 18 who were prescribed amiodarone in the outpatient or inpatient setting, with a minimum dose of 100 mg every 24 hours orally or intravenously, and who had at least two office visits recorded in their charts, one of which included the initial prescription of this medication, were included. Any amiodarone-related adverse events had to be clearly reported in the medical chart. Patients who were missing more than 20% of the data in their medical charts, as well as pregnant patients, were excluded.

Non-probability convenience sampling was conducted, considering the available time, resources and access to information.

Variables were classified as sociodemographic characteristics: age (< 65 or  $\geq 65$  years), sex, and body mass index (underweight  $\leq 18.4$ , normal 18.5-24.9, overweight 25-29.9, obesity  $\geq 30$ ); clinical characteristics: multimorbidity ( $\geq 2$  concomitant illnesses), associated illnesses, polypharmacy ( $\geq 5$  medications at the same time), baseline medications, and the diagnosis for which amiodarone was prescribed (supraventricular and ventricular arrhythmias); and pharmacological characteristics: route of administration, initial dose, maintenance dose, duration and suspension of treatment<sup>13-15</sup>.

A database was constructed in Excel® 2013, and the data was analyzed using the jamovi project 2021 version 1.6 statistical program.

The univariate analysis was done with descriptive statistics, according to the nature of the variables. Absolute and relative frequency distributions were used for qualitative variables. The Kolmogorov-Smirnov test was applied to quantitative variables to determine if they were normally distributed, and the average and standard deviation or median and interquartile range were calculated, accordingly. A bivariate analysis was run to identify the factors associated with the presence of adverse events. The Chi square test of independence was used for qualitative variables, and Fisher's exact test for variables with an expected value greater than 5. The level of significance was defined as less than or equal to 0.05 ( $p < 0.05$ ). Relative risk (RR) was used as the epidemiological measure of association, with its respective 95% confidence intervals.

A binomial logistic regression model was constructed in the multivariate analysis. Using the backward method, variables with a  $p < 0.25$  were included, taking the Hosmer-Lemeshow criterion into account.

All variables were tested to verify that they met the assumption of collinearity, and the odds ratios (ORs) were converted to RRs using L. Grant's formula<sup>16</sup>.

Data collection and analysis were approved by the Research Center at Clínica Cardio VID, according to the institutional and legal regulations establishing the scientific, technical and administrative norms for health research provided in Resolution 8430 of 1993. This was considered a no-risk study.

## Results

A chart review was conducted of 553 patients treated with amiodarone between 2008 and 2021 at a cardiovascular clinic in the city of Medellín. Of these, 221 met the eligibility criteria.

The average age was 63 years, with a predominance of males, with 127 patients (57.5%) and overweight patients, with 69 (39.2%). Most of the patients had multimorbidity, which was present in 73.3% of the patients (162); the most common illness was hypertension, with 124 patients (56.1%), followed by dyslipidemia with 98 patients (44.3%). A total of 65 patients (29.4%) had polypharmacy, and the predominant pharmacological groups were beta blockers in 148 patients (67%) and renin-angiotensin system drugs (angiotensin-converting enzyme [ACE] inhibitors and angiotensin receptor blockers [ARBs]) in 116 patients (52.5%). The most

common diagnosis for prescribing amiodarone was atrial fibrillation, with 184 patients (84.4%), followed by atrial flutter, with 24 patients (11%) (Table 1).

As far as treatment, half of the patients had an initial and maintenance dose less than or equal to 200 mg, with a treatment duration less than or equal to 189 days. The oral route was the most frequently used (145 [65.6%]). Amiodarone-related adverse events were reported in 71 patients (32.1%) (Table 2).

The predominant events were cardiovascular in 31 patients (43.7%), with the most frequent being sinus bradycardia (20 [64.5%]) and hypotension (5 [16.1%]). Thyroid events were reported in 21 patients (29.6%), predominantly hypothyroidism (18 [85.7%]). Altogether, 10% of the patients with adverse events had ophthalmological involvement, all of which were cases of cornea verticillata (Fig. 1). Furthermore, amiodarone treatment was suspended in 65.6% (145) of the patients with associated adverse events.

The factors related to the onset of amiodarone-related adverse events were female sex ( $p = 0.023$ ), multimorbidity ( $p = 0.010$ ), diuretic treatment ( $p = 0.013$ ), anticoagulants ( $p = 0.017$ ) and ventricular arrhythmia ( $p = 0.032$ ).

The multivariate model had a  $p < 0.001$  likelihood ratio (LR) adjustment and a variability of 16.8% (Nagelkerke's  $R^2 [R^2_N]$ ). The variables included were: age, sex, multimorbidity, beta blockers, diuretics, inhalers, anticoagulants and the diagnosis for which amiodarone was prescribed. Multimorbidity ( $p = 0.039$ ) continued to be statistically significant after adjusting for the other variables in the model (Table 3).

## Discussion

This study showed that most of the patients evaluated had two or more comorbidities, accounting for 73.3% of the sample. Systemic hypertension was the most frequent condition. Adverse events have been reported to have a high prevalence, which increases with prolonged use of the medication, reaching up to 50%. Amiodarone-related adverse events were reported in 32.1% of the study patients, after approximately six months of use, and therefore treatment had to be discontinued in 65.6% of the cases; that is, only 34.4% of the patients were able to use this medication long term.

The predominant adverse events were cardiovascular, with a frequency of 43.7%, and were clinically relevant (considering that bradycardia was the main cause, which, if associated with a long QT – greater than 500 ms - increases the proarrhythmic risk, and is

**Table 1.** Characteristics of patients treated with amiodarone (n = 221)

Characteristics	n	%
Age (years)*	63 ( $\pm$ 14.1)	
Sex		
Male	127	57.5
Female	94	42.5
Body mass index		
Underweight	2	1.1
Normal	65	36.9
Overweight	69	39.2
Obesity	40	22.7
Multimorbidity	162	73.3
Polypharmacy	65	29.4
Diagnosis for which amiodarone was prescribed		
Supraventricular arrhythmia	208	96.7
Ventricular arrhythmia	7	3.3

\*Mean and standard deviation.

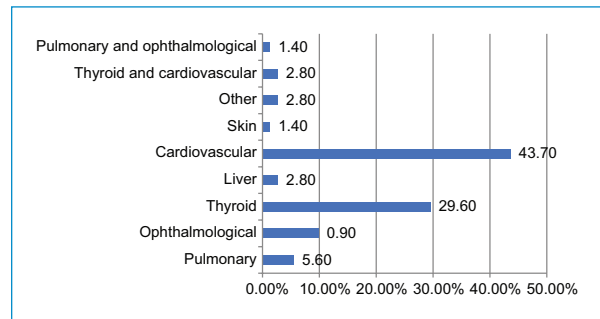
**Table 2.** Characteristics of amiodarone treatment

Characteristics	n	%
Initial dose (mg/day)*	200 (600)	
Maintenance dose (mg/day)*	200 (0)	
Days of treatment*	189 (517)	
Route of administration		
Oral	145	65.6
Intravenous	76	34.4
Adverse events	71	32.1
Amiodarone discontinuation required	145	65.6

\*Median and interquartile range.

a frequent indication for discontinuing amiodarone)<sup>17</sup>, followed by thyroid events with 29.6% and ophthalmological events with 10%. A comparison of our findings with the available scientific literature shows similarities, as adverse events are reported with similar frequencies; for example, cardiovascular events in 5 to 10%, thyroid events in 22% and ophthalmological events in 5%, which may even reach 98% with corneal microdeposits<sup>10,18</sup>.

The objective of this study was to determine the characteristics associated with adverse events in patients on amiodarone. Those with multimorbidity were found to have 1.65 times the risk of developing adverse events compared to those who had fewer

**Figure 1.** Types of amiodarone-related adverse events.

diseases ( $p = 0.039$ ). This is not a minor finding, as, considering that those with cardiovascular disease have high comorbidity and require multiple complementary drugs, this condition increases the risk of adverse events<sup>18,19</sup>. We also found that the most common diagnosis for which amiodarone was prescribed was atrial fibrillation, with 84.4%, followed by atrial flutter (although amiodarone is not FDA approved for treating atrial fibrillation, it is often used in the Southern Cone, and is considered effective for rhythm and rate control in more than 60% of patients, especially, but not exclusively, in patients with structural heart disease)<sup>7</sup>. Scientific articles have already reported that patients with underlying structural heart disease may have a higher risk of adverse events. Abnormal heart structures are usually accompanied by comorbidities; therefore, they are almost a determinant of this condition. The need for concomitant drug therapy seems to favor a greater risk of developing the outcomes in question<sup>11</sup>.

Amiodarone-related adverse events are frequent, widespread and multifactorial, and while they are well known and have been reported for decades, this medication continues to be used as a first-line treatment in cardiology today, due to its benefits, and is often the only option for some cardiovascular diseases.

In view of this scenario, understanding the patients' clinical conditions prior to beginning amiodarone treatment, having clear indications for its use, establishing a monitoring and follow up plan for potential long-term adverse events, and trying to identify at-risk patients may reduce the onset of adverse events which, while they may improve when the medication is discontinued, may impact on patients' quality of life and health status.

Therefore, identifying the high-risk population will allow amiodarone to be used effectively and safely. Based on our findings, we believe that this population



**Table 3.** Characteristics associated with amiodarone-related adverse events

Characteristics	Raw RR	95% CI	P value	Adjusted RR	95% CI	P value
Age ≥ 65 years	1.30	0.88-1.90	0.185	1.05	0.63-1.56	0.825
Female sex	1.56	1.06-2.28	0.023	1.42	0.95-1.91	0.081
Multimorbidity	1.99	1.12-3.51	0.010	1.65	1.02-2.25	0.039
Use of beta blockers	0.75	0.51-1.11	0.164	0.60	0.32-1.02	0.062
Use of diuretics	1.62	1.11-2.36	0.013	1.41	0.92-1.93	0.098
Use of inhalers	0.56	0.20-1.60	0.234	0.50	0.15-1.32	0.197
Use of anticoagulants	0.62	0.42-0.92	0.017	0.70	0.40-1.12	0.155
Ventricular arrhythmia	2.40	1.43-4.0	0.032	2.18	0.87-2.91	0.079

RR: relative risk.

may require shorter treatment periods, between six and 12 months long, as it is during this lapse of time when the prevalence of adverse events increases<sup>10,18</sup>. Furthermore, lower than usual initial and maintenance doses could be proposed in the higher-risk population, considering the known pharmacokinetic uncertainties. We believe that a prospective study could help create tools to rapidly and practically identify the risk of developing the outcomes in question with the use of this medication and, thus, try to reduce these adverse events which, so far, seem to be an inevitable cost of this therapy.

It is important to mention that, as this is a retrospective study, it could have several limitations. Therefore, further prospective studies are needed to appropriately evaluate the proposed hypotheses and identify more conditions potentially associated with the onset of adverse events, thus ensuring that patients have protection strategies available to provide greater safety in the use of a well-known medication which seems unlikely to disappear from clinical practice in the near future. Another limitation of this study is that it was conducted at a single healthcare facility, which is also a specialized institution, and therefore we would recommend performing further studies including patients from different facilities to improve the external validity of the results.

## Conclusions

Adverse events were frequent outcomes in this population, and multimorbidity explained 16.8% ( $R^2_N$ ) of their onset in the evaluated cohort.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical considerations

**Human and animal protection.** The authors declare that no human or animal experiments were conducted in the course of this study.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for publishing patient data.

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

**Use of artificial intelligence to generate text.** The authors declare that they have not used any type of generative artificial intelligence to draft this manuscript or create figures, graphs, tables or their respective captions or legends.



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# Access to cardiac surgery in Colombia: a situational analysis

## Acceso a la cirugía cardíaca en Colombia: un análisis situacional

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### Abstract

**Introduction:** At least 33.0% of patients with cardiovascular diseases will require heart surgery at least once in their lifetime, yet less than a quarter of the world's population has access to cardiac surgical care when needed. Despite Colombia's progress in cardiac surgical care delivery in recent decades, little is known regarding nationwide access to cardiac care. Therefore, global surgery seeks to study and build upon the current situation in areas with limited access to surgical healthcare and to strengthen healthcare systems. **Method:** Data on the cardiac surgical workforce were obtained from a survey of surgeons registered in the cardiac surgery directory and the Cardiothoracic Surgery Network in Colombia. Procedural data from 2018 - 2019 were obtained from national government data. **Results:** There were 110 cardiac surgeons or 1.8 cardiac surgeons per million inhabitants in Colombia, of which 85.0% were male. Densities in each of the 32 departments of Colombia varied from 4.6 surgeons per million inhabitants (Bogotá) to no surgeons in 14 departments. There were 52 institutions registered, with a median of 250 beds (interquartile range 130-350). One in five cardiac surgery departments offered a certified cardiac surgery fellowship program. Coronary artery bypass grafting was the most frequently performed procedure. **Conclusions:** This study identified data regarding the current situation of cardiac surgery in Colombia. Despite relatively favorable cardiac surgical workforce availability in Colombia, geographical variation and social and economic factors point to an urgent need to evaluate the quality-of-care policies related to cardiac surgical care in underserved populations.

**Keywords:** Global Health. Global Surgery. Cardiac Surgery. Colombia.

### Resumen

**Introducción:** Al menos el 33,0% de los pacientes con enfermedades cardiovasculares requerirán cirugía cardíaca al menos una vez en la vida; sin embargo, menos de una cuarta parte de la población mundial tiene acceso a atención quirúrgica cardíaca cuando la necesita. A pesar del progreso de Colombia en la prestación de atención quirúrgica cardíaca en las últimas décadas, se sabe poco sobre el acceso a la atención cardíaca en todo el país. Por lo tanto, la cirugía global busca estudiar y construir sobre la situación actual en áreas de acceso limitado a la atención médica quirúrgica y fortalecer los sistemas de salud. **Método:** Los datos sobre la fuerza laboral de cirugía cardíaca se obtuvieron a partir de una encuesta a

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*cirujanos registrados en el directorio de cirugía cardíaca y la Red de Cirugía Cardiotorácica de Colombia. Los datos de procedimiento de 2018 - 2019 se obtuvieron del gobierno nacional. Resultados: En Colombia había 110 cirujanos cardíacos o 1,8 cirujanos cardíacos por millón de habitantes, de los cuales el 85,0% eran hombres. Las densidades en cada uno de los 32 departamentos de Colombia variaron de 4,6 cirujanos por millón de habitantes (Bogotá) a ningún cirujano en 14 departamentos. Se registraron 52 instituciones, con una mediana de 250 camas (rango intercuartílico 130-350). Uno de cada cinco departamentos de cirugía cardíaca ofreció un programa de subespecialidad en cirugía cardíaca. La revascularización miocárdica fue el procedimiento realizado con mayor frecuencia. Conclusiones: Este estudio identificó datos sobre la situación actual de la cirugía cardíaca en Colombia. A pesar de la disponibilidad relativamente favorable de mano de obra quirúrgica cardíaca en Colombia, la variación geográfica y los factores sociales y económicos apuntan a una necesidad urgente de evaluar las políticas de calidad de atención relacionadas con la atención quirúrgica cardíaca en poblaciones desatendidas.*

**Palabras clave:** Salud Global. Cirugía Global. Cirugía Cardíaca. Colombia.

## Introduction

Five billion people worldwide lack access to safe, timely, and affordable surgical care when needed.<sup>1</sup> Every year, 313 million surgeries are done around the globe, of which only 6.0% are performed in the poorest third of the world's population<sup>1</sup>. This results in 17 million deaths annually from preventable surgical conditions. Cardiovascular diseases are currently the leading cause of death worldwide, with nearly 18 million per year, over 80.0% of which occur in low- and middle-income countries (LMICs)<sup>2,3</sup>. Over 33.0% of patients with cardiovascular diseases will require cardiac surgery at least once in their lifetime; however, 93.0% of the LMIC population, or three-quarters of the world's population, does not have access to cardiac surgical care when needed<sup>4</sup>.

Colombia is an upper-middle-income country with 48,258,494 inhabitants, where 28.0% of the population lives below the poverty line<sup>5</sup>. Colombia has seen a steady improvement in its socioeconomic and health metrics in recent decades, with the passing of Law 100 in 1993. This law resulted in various government-sponsored healthcare and public health programs, including a national health insurance scheme<sup>6</sup>. Despite these efforts aimed at improving the population's access to health services, the data available to determine the current status continues to be limited<sup>6</sup>.

The growing field of global surgery seeks to study and build upon the current situation in areas with limited access to surgical healthcare and to strengthen health systems to improve technical and human resources and guarantee adequate management of surgical conditions<sup>1</sup>. To achieve these objectives, it is essential to understand the baseline status in a country, as a starting point for nations to improve their health systems. Despite recent national interest in gaps in access to

emergency and essential surgical care<sup>6</sup>, little is known regarding access to cardiac surgical care in Colombia. Thus, the aim of this study is to describe the current situation in Colombia in terms of the available cardiac surgical workforce and infrastructure in order to better understand the existing gaps in cardiac surgical care access for populations in need.

## Materials and method

### Data sources

The primary data sources used for indicator collection were:

- The Colombian National Healthcare Information System (Sistema Integral de Información de la Protección Social - SISPRO)
- The most recent national survey by Departamento Administrativo Nacional de Estadística (DANE)<sup>5</sup>
- A self-developed survey, which was sent to all cardiac surgeons registered in the databases of Sociedad Colombiana de Cardiología y Cirugía Cardiovascular (SCCCV, Colombian Society of Cardiology and Cardiovascular Surgery) and the Cardiothoracic Surgery Network (CTSNet)
- The Registros Individuales de Prestación de Servicios de Salud (RIPS - Individual Records of Healthcare Service Provision) database, which contains operative procedural data without procedure location information. Here, we identified the Clasificación Única de Procedimientos en Salud (CUPS – Single Classification of Healthcare Procedures) codes of surgical procedures performed in an operating room to identify the cardiac surgeries performed.

Secondary data were obtained in the form of a scoping review performed on access to cardiac surgery in

Colombia, utilizing the PubMed/MEDLINE and World Health Organization Global Index Medicus databases for publications in the past 20 years.

## Survey

The supporting literature review revealed important aspects in terms of lack of access to healthcare that were used and included in the self-developed survey (Appendix 1, page 4-17). Each item was designed with the criteria of prevalence, impact, and ease of analysis in mind. The survey consisted of 21 multiple-choice items, which collected information on demographics, training and practice, infrastructure, and surgical capacity. The questionnaire was reviewed and approved by an academic working group consisting of Colombian cardiac surgeons and public health researchers over several rounds with iterative changes. Once a final version of the survey was completed, it was converted into an online format with the necessary security, confidentiality, and reliability, and used for data collection.

## Geographical analysis

Colombia consists of 32 departments. We obtained a list of the registered cardiac surgeons from the SCCCV and CTSNet as of January 2020<sup>7</sup>. Inclusion of surgical specialists and anesthesiologists in governmental databases may reflect differences in standard billing practices, requiring parallel approaches to identification, such as the CTSNet database and available literature<sup>6</sup>. After removing duplicate registrations, 110 cardiac surgeons were identified. Requests for survey participation were made via email, social networks, and personal/professional websites. Data were collected over a six-week period from December 2019 to February 2020. Participation was completely voluntary and survey responses were anonymous. All data were verified, checked for inconsistencies and errors, and entered into a comprehensive database. Finally, the collected results were exported to a spreadsheet for descriptive statistical analysis using Microsoft Excel (Microsoft, Redmond, WA, USA). Sociodemographic data from the 2018 DANE census was used for approximate regional density calculations<sup>5</sup>.

## Ethics

This project was classified as exempt by the Institutional Review Board at Clinica Universitaria Colombia. All cardiac surgeons took the anonymous survey

voluntarily, and survey results were reported in aggregate without identifying information.

## Results

### Workforce

The geographical analysis revealed significant regional maldistribution of the current cardiac surgeon workforce, based on the 89 total survey responses (80.9% response rate). The density distribution (1.8 cardiac surgeons per million inhabitants) varied from 4.6 surgeons per million inhabitants (Bogotá) to no surgeons in the remaining 14 departments (44.0%) (Table 1 and Fig. 1). Half of the institutions (53.0%,  $n = 47$ ) had one or two cardiac surgeons, with the remainder having three or more. Two or more cardiovascular anesthesiologists were available at 83.0% ( $n = 74$ ) of the institutions. Only 20% ( $n = 18$ ) of the cardiac surgery departments offered certified cardiac surgery fellowship programs. Only 56.0% ( $n = 50$ ) of cardiac surgeons were affiliated with a scientific society. Figure 2 shows the distribution of affiliations with the most relevant cardiac surgery societies. Only 15.0% ( $n = 13$ ) of the cardiac surgeons in Colombia are aware of a digital identification system (ORCID) to manage professional information (affiliations, grants, publications, and peer review). Altogether, 47.0% ( $n = 42$ ) of the institutions had more than three surgeons on call for 24/7 coverage, and nearly half of the cardiac surgeons (43.0%,  $n = 46$ ) worked in more than one institution (Fig. 3).

### Infrastructure

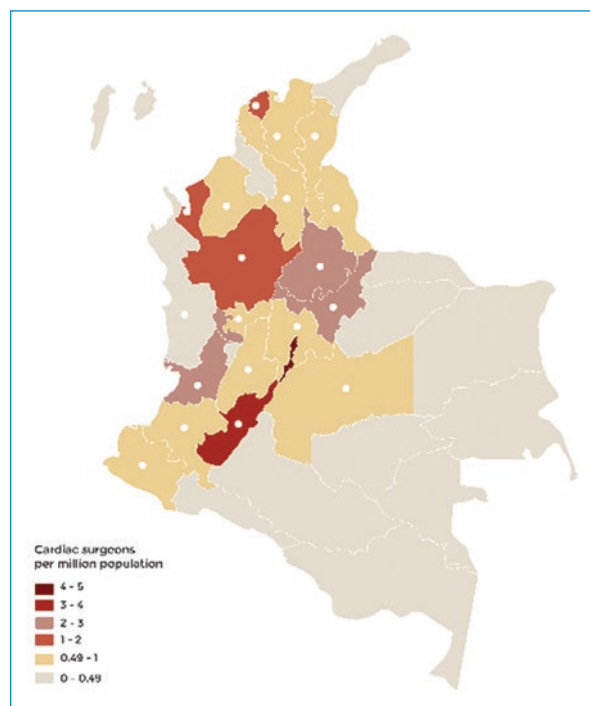
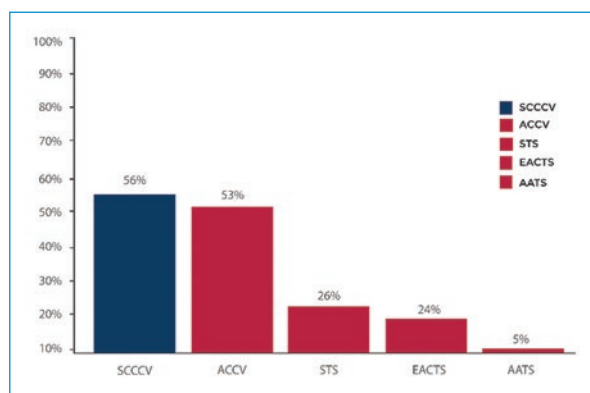
Nationwide, 52 institutions were registered, with a median of 250 beds (IQR: 130-350) not exclusive for cardiac surgery, and 81.0% of the institutions had one or two operating rooms equipped for cardiac surgery, which corresponds to one center per 928,000 inhabitants. The majority, 79.0% ( $n = 69$ ), were owned by private organizations, 10.0% ( $n = 9$ ) were public, and the remaining 11.0% ( $n = 10$ ) were associated with both the private and public sector. There were 11 to 50 cases per month in the cardiac surgery services.

### Service delivery

According to the Colombian Ministry of Health data, a total of 13,935 cardiac procedures were performed in 2018, and 10,703 in 2019 (Table 2).

**Table 1.** Number and density of cardiac surgeons in Colombia by administrative department

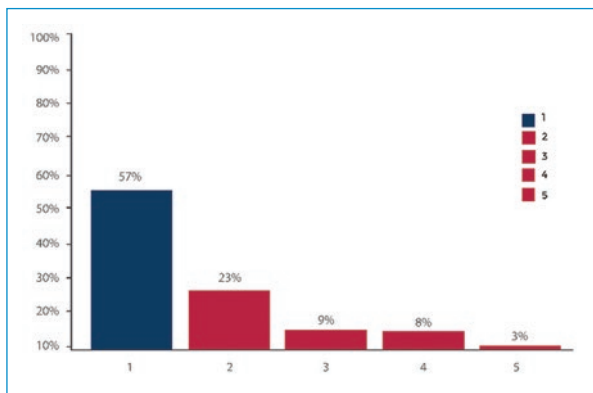
Department	Density	Percentage	Total
Amazonas	0	0.0%	0
Antioquia	1.5	11.0%	10
Arauca	0	0.0%	0
Atlántico	1.9	6.0%	5
Bogota D.C	4.5	39.0%	34
Bolivar	0.4	1.0%	1
Boyacá	2.4	3.0%	3
Caldas	1	1.0%	1
Caquetá	0	0.0%	0
Casanare	0	0.0%	0
Cauca	0.6	1.0%	1
Cesar	0.8	1.0%	1
Chocó	0	0.0%	0
Córdoba	0.5	1.0%	1
Cundinamarca	0.6	2.0%	2
Guainía	0	0.0%	0
Guaviare	0	0.0%	0
Huila	3.6	5.0%	4
La Guajira	0	0.0%	0
Magdalena	0.7	1.0%	1
Meta	0.9	1.0%	1
Nariño	0.6	1.0%	1
Norte de Santander	0.6	1.0%	1
Putumayo	0	0.0%	0
Quindío	0	0.0%	0
Risaralda	2.1	2.0%	2
San Andrés y Providencia	0	0.0%	0
Santander	2.7	7.0%	6
Sucre	0	0.0%	0
Tolima	0.7	1.0%	1
Valle del Cauca	2.9	15.0%	13
Vaupés	0	0.0%	0
Vichada	0	0.0%	0

**Figure 1.** Cardiac surgeons per million inhabitants in Colombia according to the results of the survey registered in the database (n = 89).**Figure 2.** Distribution of cardiac surgeons in the different scientific societies: Colombian Society of Cardiology and Cardiovascular Surgery (SCCCV), Colombian Association of Cardiovascular Surgery (ACCV), The Society of Thoracic Surgeons (STS), European Association for Cardio-Thoracic Surgery (EACTS), American Association for Thoracic Surgery (AATS).

As claimed by the cardiac surgeons in their survey answers, coronary artery bypass grafting (CABG) was the most frequently performed procedure, accounting for 47.0% (n = 76) of all isolated procedures and 86% of all procedures in 2019. Procedures

**Table 2.** Surgical Procedure Codes (CUPS) used to identify operative volume in Colombia: Colombian Ministry of Health data

Chapter	Group	Procedure	2018 Procedural Volume	2019 Procedural Volume
07-Circulatory System	36-Procedures in Cardiac Vessels	Coronary artery bypass graft	6,771	5,168
07-Circulatory System	35-Procedures in Heart Valves	Valvular disease	3,667 (84.0% Replacement) (16.0% Valve repair)	2,660 (86.0% Replacement) (14.0% Valve repair)
07-Circulatory System	35-Procedures in Heart Valves	Congenital	2,075	1,398
07-Circulatory System	37-Procedures in the Heart and Pericardium	Cox maze procedure	262	218
07-Circulatory System	38-Procedures in Blood Vessels	Aortic surgery	595	565
07-Circulatory System	37-Procedures in the Heart and Pericardium	ECMO	392	457
07-Circulatory System	35-Procedures in Heart Valves	TAVR	110	151
07-Circulatory System	35-Procedures in Heart Valves	Mitraclip	24	27
07-Circulatory System	37-Procedures in the Heart and Pericardium	Heart tumors	39	59
		Total	13,935	10,703



**Figure 3.** Number of institutions in which Colombian cardiac surgeons are active.

treating valvular heart disease were the second most common (24.0%, n = 38), followed by aortic pathologies (9.0%, n = 15), adult congenital heart disease (6.0%, n = 9), and arrhythmias (5.0%, n = 8). Minimally invasive procedures were performed in 79.0% (n=70) of the cardiac surgery departments. Overall, 81.0% (n = 72) of the surgeons were trained in modern techniques such as transcatheter valve replacements or other structural procedures as part of a multidisciplinary team with related specialties (i.e., the cardiac team). Additionally, 29.0% (n = 26) of

them performed surgeries implanting rapid deployment sutureless valve prostheses. Table 3 summarizes the survey results.

## Discussion

Global cardiac surgery is a growing discipline that studies and seeks to address gaps in access to cardiac surgical care across the globe<sup>2,4</sup>. There is a pressing need for cardiac surgery worldwide, with limited access in LMICs<sup>8</sup>. For example, regions such as Southeast Asia and Sub-Saharan Africa have one cardiac center for every 16 and 33 million inhabitants, respectively, while North America has one center for every 120,000 people<sup>2,9</sup>. We found that Colombia has one center for every 928,000 people, and approximately 1.8 surgeons per million inhabitants, which is above the reported global average (1.6 per million) but below the average of high-income countries (7.2 per million)<sup>2</sup>. Comparing Colombia with other LMICs, this number seems promising; however, it does not reflect adequate access to cardiac surgery services for the entire population, given that it remains far below the workforce density observed in high-income countries and is centralized in the major cities, with poor access for rural populations due to geographical barriers.

**Table 3.** Survey respondents' characteristics (total n = 110 cardiac surgeons)

Survey Answers	n (%)
Membership in Scientific Societies	
Colombian Society of Cardiology and Cardiovascular Surgery (SCCCV)	50 (56.0%)
Colombian Association of Cardiovascular Surgery (ACCV)	46 (53.0%)
The Society of Thoracic Surgeons (STS)	23 (26.0%)
European Association of Cardio-Thoracic Surgery (EACTS)	21 (24.0%)
American Association for Thoracic Surgery (AATS)	5 (5.0%)
Awareness of the ORCID ID	
Yes	13 (15.0%)
No	76 (85.0%)
Number of Institutions Concurrently Worked At	
1	51 (57.0%)
2	20 (23.0%)
3	8 (9.0%)
4	7 (8.0%)
5	3 (3.0%)
Type of Institution	
Private	69 (79.0%)
Public	9 (10.0%)
Mixed	10 (11.0%)
Number of Beds per Institution Mean (IQR)	250 (350-130)
Number of Adult Patients Operated on per Month per Service	
< 5	2 (2.0%)
5-10	9 (10.0%)
11-20	36 (40.0%)
21-50	34 (39.0%)
> 50	8 (9.0%)
Number of Cardiothoracic Surgeons in the Service	
1-2	47 (53.0%)
3-4	33 (37.0%)
5-6	6 (7.0%)
> 6	3 (3.0%)
Number of Minimally Invasive Surgeries Performed per Month per Service	
< 5	53 (60.0%)
5-10	11 (12.0%)
11-20	6 (7.0%)
> 20	0 (0.0%)
NA	19 (21.0%)
Number of Anesthesiologists Specialized in Cardiac Surgery per Institution	
0	0 (0.0%)
1	15 (17.0%)
2	23 (26.0%)
3	15 (17.0%)
> 3	36 (40.0%)
Number of Specialized Cardiac Operating Rooms per Institution	
0	0 (0.0%)
1	57 (64.0%)
2	15 (17.0%)
3	8 (9.0%)
4	6 (7.0%)
5	1 (1.0%)
> 5	2 (2.0%)

(Continues)

**Table 3.** Survey respondents' characteristics (total n = 110 cardiac surgeons) (continued)

Survey Answers	n (%)
TAVR Procedures Performed	
Yes	72 (81.0%)
No	17 (19.0%)
Aortic-Rapid Deployment Procedures Performed	
Yes	26 (29.0%)
No	63 (71.0%)

\*ORCID ID: Open Researcher and Contributor ID.

\*\*TAVR: Transcatheter aortic valve replacement.

In Latin America, there have been encouraging signs of economic growth in recent decades, resulting in growing health systems and specialized healthcare services, including cardiac surgery; however, evident gaps remain due to insufficient funding and capacity of the public sector. These gaps are also affected by factors ranging from nationwide political distress (e.g., Venezuela) and slower socioeconomic growth (e.g., Ecuador) to vast geographic barriers (e.g., Brazil) and remote locations (e.g., island states). For example, it is estimated that over 24,000 children with congenital heart disease (41% of the annual incidence) do not receive the treatment they need in South America<sup>10</sup>. As a result, various non-governmental organizations and bilateral academic partnerships have been supporting cardiac surgery development in Latin America, with sustainable but variable success. For example, the Friends of the Aldo Castaneda Foundation<sup>11</sup> established and runs the UNICAR cardiac center in Guatemala City, Guatemala, providing free access to cardiac surgery for regional patients in need, and Children's HeartLink supports the training of all health workers involved with cardiac care in Brazil, among other countries<sup>12,13</sup>.

There are 52 institutions performing cardiac surgery across Colombia, 79.0% of which are owned by private organizations. There are only one or two cardiac operating rooms per institution, and cardiac surgical procedures are expensive. However, the return-on-investment and cost-effectiveness are generally favorable, even in LMICs<sup>14-16</sup>. Nevertheless, the complexity of this field requires significant investments to create cost-efficient and high-quality departments<sup>14,17</sup>. In Colombia, the average range of procedures per month is between 11-50 adult cardiac surgical procedures per institution. The most frequently performed procedure is coronary artery bypass grafting (CABG) due to the high burden



of ischemic heart disease. This finding is consistent with reports from other countries<sup>18,19</sup>. Optimizing this volume, both to improve access to care and ensure better surgical outcomes in light of volume-outcome relationships, will be critical to reduce the preventable mortality associated with and persisting as a result of untreated congenital heart defects<sup>16</sup>.

Geographical differences in services continue to be a common problem in Colombia, where the density of surgeons by department varied from 4.6 in the capital to 0 in the poorest regions of our country. Although some form of regionalization is necessary to reduce unnecessary spending in light of limited resources (e.g., one regional center versus multiple low-volume centers near each other), Colombia's national socioeconomic and healthcare development provides room for increased expansion of specialty care beyond the capital city or the most affluent departments. Today, resources are concentrated in the municipalities and departments which traditionally have had adequate infrastructure, leaving limited access for emerging regions<sup>20</sup>.

The continuous interest and dedication of our surgeons, departments, and institutions in staying up to date with new techniques and progress deserves a mention. In a middle-income country like Colombia, it remains difficult to balance cost-benefit issues to maintain hard-won programs like heart transplantation, extracorporeal membrane oxygenation therapies, and ventricular assist devices. In 2018, there were a total of 3,400 potential organ donors. Of these, 766 were deemed eligible and 448 had organs procured, leading to a total of 398 actual donors across all kinds of transplants<sup>21</sup>. The drastic downslope of these figures denotes significant logistical challenges in organ procurement (transport, eligibility, and availability of resources). In the same year, about 2,500 patients were on a waiting list for any kind of transplant; 57 cardiac transplants (two combined heart-kidney transplants) were performed at the eight certified institutions in Colombia, with an average waiting list time of 109 days (1 day minimum and 1,087 days maximum)<sup>21</sup>. Further, minimally invasive procedures are performed in 78.0% of the cardiac surgery departments, while robotic heart surgery has recently become available in a small number of institutions<sup>22</sup>. Modern transcatheter technologies for the treatment of valve disease are available, and 80.0% of the surgeons are fully trained in these techniques. Accordingly, they can offer percutaneous procedures or open surgeries with less invasive techniques, along with the use of devices like rapid deployment or sutureless valves.

## What is being done

The Colombian Cardiac Surgery Society is a chapter of the Colombian Society of Cardiology and Cardiovascular Surgery. Recently, efforts have focused on the creation of an independent scientific society that gathers all cardiac surgeons nationwide. The Latin American Society of Cardiovascular and Endovascular Surgery, meanwhile, is a growing association that aims to improve existing cardiac institutions, turning them into excellence centers in Latin America. Additionally, the national patient registry is another strategy seeking to gather longitudinal and representative metrics and serving as a complete, uniform source of information to evaluate and improve therapies in the field<sup>23</sup>. At the community level, campaigns aimed at improving early diagnosis of cardiovascular diseases and providing timely identification and proper referral of patients in need of surgical intervention, have targeted rural areas with lower health coverage. Finally, it is essential to highlight the importance of global initiatives like the Global Cardiac Surgery Initiative, which seeks to reduce the gaps in access to cardiac surgical services worldwide by leveraging the diversity of trainees and young surgeons across the globe, and, as Sabatino and Dennis et al. say, challenge the health system's delivery of equitable surgical care<sup>24</sup>.

## Limitations

This study is an initial effort to better understand the current state of access to adult cardiac surgical care in Colombia. However, the data presented in this article have limitations inherent to all health questionnaires, such as in the design and writing of the questionnaire as well as response bias. We obtained an 80.9% response rate of the total sample (the total number of active cardiac surgeons in Colombia), thereby reducing underrepresentation while obtaining more accurate data on cardiac surgery in the country, in addition to acquiring objective, validated government data to support our study. Despite this, some cardiac surgeons not affiliated with any of the chapters used may have been missed in the data sources.

## Conclusion

This study describes the current situation of cardiac surgery in Colombia. Improving equity in terms of the workforce and infrastructure is crucial for achieving quality and equitable access to cardiac surgery. Despite

encouraging numbers of cardiac surgeons in Colombia, geographical and socioeconomic barriers create an urgent need to evaluate the quality and policies related to cardiac surgical care in underserved populations.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that no experiments were performed on humans or animals for this study.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for publishing patient data.

**Right to privacy and informed consent.** The authors have obtained approval from the ethics committee for analysis and publication of routinely acquired clinical data, and informed consent was not required for this retrospective observational study.

**Use of artificial intelligence for generating text.** The authors declare that they have not used any type of generative artificial intelligence for writing this manuscript, nor for creating images, figures, tables, or their corresponding captions.

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# Clinical and epidemiological characterization of patients with acute heart failure

## Caracterización clínica y epidemiológica de pacientes con falla cardiaca aguda

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### Abstract

**Objective:** to characterize the population of patients hospitalized for acute heart failure with an ejection fraction of less than 50% at Hospital Departamental de Villavicencio. **Materials and method:** this is a descriptive retrospective cohort study of patients hospitalized for acute heart failure with a left ventricular ejection fraction (LVEF) of less than 50% between January 1, 2020, and December 31, 2021. **Results:** a total of 206 participants were included, with a median age of 70 years. Altogether, 71.8% of the participants were men, and the most frequent comorbidities were hypertension (76.2%), coronary disease (47.1%), and diabetes (32%). The main etiologies of heart failure were ischemia (62.1%) and hypertension (27.2%), with 6.8% attributed to Chagas disease. The most common causes of decompensation were acute coronary syndrome (39.3%) and poor adherence to treatment (25.7%). The median hospital stay was 7.5 days, and the hospital mortality rate was 14.6%, with acute coronary syndrome being the leading cause of death (56.7%). There was a high need for intensive care unit (ICU) management (20.4%), which was higher in patients with slightly reduced LVEF compared to those with reduced LVEF (35.7% vs. 18%, RR = 1.98,  $p = 0.03$ ). However, the mortality rate was similar between both groups (17.9% vs. 14%, RR = 1.32,  $p = 0.54$ ). **Conclusion:** there was a high prevalence of ischemic heart disease, along with a high need for intensive care and high in-hospital mortality.

**Keywords:** Heart failure. Coronary disease. Hospitalization. Mortality.

### Resumen

**Objetivo:** caracterizar la población de pacientes hospitalizados por falla cardiaca aguda con fracción de eyección (FEVI) menor al 50% en el Hospital Departamental de Villavicencio. **Materiales y método:** estudio descriptivo de cohorte retrospectiva, de pacientes hospitalizados por falla cardiaca aguda con FEVI menor al 50%, entre el 1.º de enero de 2020 y el 31 de diciembre de 2021. **Resultados:** se incluyeron 206 participantes con mediana de edad 70 años, de los cuales el 71.8% fueron hombres. Las comorbilidades más frecuentes fueron hipertensión (76.2%), enfermedad coronaria (47.1%) y diabetes (32%); las principales etiologías de la falla cardiaca fueron isquémica (62.1%) e hipertensiva (27.2%), con un 6.8% de etiología chagásica; las causas de descompensación más frecuentes fueron el síndrome coronario agudo (39.3%) y la mala adherencia al tratamiento (25.7%). La mediana de estancia hospitalaria fue 7.5 días y la mortalidad hospitalaria de 14.6%, con el síndrome coronario agudo como principal causa de muerte (56.7%). Se encontró alto requerimiento de manejo en

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unidad de cuidado intensivo (UCI) (20.4%), siendo mayor en pacientes con FEVI levemente reducida, comparada con FEVI reducida (35.7 vs. 18%; RR0 = 1.98;  $p = 0.03$ ), con una mortalidad similar entre ambos grupos (17.9 vs. 14.; RR = 1.32;  $p = 0.54$ ). **Conclusión:** se encontró una alta prevalencia de cardiopatía isquémica, con elevado requerimiento de manejo en UCI y alta mortalidad hospitalaria.

**Palabras clave:** Falla cardíaca. Enfermedad coronaria. Hospitalización. Mortalidad.

## Introduction

Heart failure is a leading chronic disease worldwide. In 2010, the estimated prevalence according to the Global Burden of Disease<sup>1</sup> was 37.7 million cases globally. However, more recent data estimate an approximate prevalence in adults of 1 to 2%, increasing with age: close to 1% for adults under the age of 55 and more than 10% for adults over 70<sup>2</sup>.

Cardiovascular disease is the main cause of death in Colombia today. In 2021, According to data from the Ministry of Health and Social Protection<sup>3</sup>, the mortality rate for circulatory system diseases in 2021 was 153.5 per 100,000 inhabitants, with a rate of 4.49 per 100,000 inhabitants for heart failure, for a total of 2,220 deaths from heart failure that year.

The burden of morbidity and mortality caused by heart failure is high; in-hospital mortality from acute heart failure has been estimated at 4 to 10%<sup>2</sup>, and in-hospital treatment entails high costs for the health-care system<sup>4,5</sup>, a problem which is accentuated by the high percentage of readmissions after acute heart failure discharge<sup>6</sup>.

In light of the high social and economic burden caused by this disease and the lack of epidemiological and clinical data on acute heart failure in the hospital setting in our region, this study was designed to characterize the population of patients hospitalized for acute heart failure at Hospital Departamental de Villavicencio, in order to generate knowledge that can be used to improve the medical care of patients with this disease in our region.

## Materials and method

A retrospective cohort study was performed with a chart review of patients hospitalized between January 1, 2020, and December 31, 2021, with a heart failure diagnosis identified by the ICD-10 code recorded by the treating physician. The medical charts of patients with a documented left ventricular ejection fraction (LVEF) less than 50% in the database of echocardiograms performed at the institution during the same period were also reviewed. Patients over the age of 18 who

were admitted for at least 24 hours with a heart failure diagnosis based on the Framingham criteria and who also had an LVEF less than 50% on an echocardiogram within the previous year, or one performed during their hospitalization, were selected. Patients with a confirmed diagnosis of acute pulmonary thromboembolism, and patients with stage five chronic kidney failure or acute kidney failure requiring dialysis were excluded.

The data were collected in an Excel<sup>®</sup> 2021 file designed by the research group for the study. Socio-demographic, clinical, laboratory, imaging and echocardiographic information was taken from the electronic medical charts; the patients were classified according to LVEF as reduced ( $\leq 40\%$ ) and mildly reduced (41% to 49%). Their clinical progress during hospitalization was followed, recording in-hospital complications, length of hospital stay, need for intensive care unit (ICU) admission, vital status at discharge and cause of death of the deceased. In addition, the medical chart was reviewed up to 90 days after discharge to evaluate hospital readmissions during that period of time.

The statistical analysis was done using the STATA<sup>®</sup> 14 program. Measures of central tendency were used for quantitative variables, while measures of frequency were used for qualitative variables, with their respective measures of dispersion. A bivariate analysis was run comparing hospital outcomes between the group of patients with reduced LVEF and those with mildly reduced LVEF, using Student's t-test for the comparison of parametric variables and Chi square or Fisher's exact test for nonparametric variables.

This study was designed according to the ethical guidelines for scientific research on human subjects and was approved by the scientific research ethics committee at Hospital Departamental de Villavicencio prior to its execution.

## Results

The medical charts of 347 patients were reviewed, 240 of which met the inclusion criteria (107 were not included as they were duplicates due to readmissions or because acute heart failure was ruled out on

**Table 1.** Sociodemographic variables and comorbidities

Sociodemographic variable	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)
Age (years), Md (IQR)	70 (62-77)	70 (62-77)	72 (60-77.5)
Male sex, n (%)	148 (71.84)	130 (73.03)	18 (64.29)
Urban dwelling, n (%)	186 (90.29)	162 (91.01)	24 (85.71)
Health insurance regimen			
Subsidized, n (%)	121 (58.74)	108 (60.67)	13 (46.43)
Contributive, n (%)	57 (27.67)	45 (25.28)	12 (42.86)
Special, n (%)	21 (10.19)	19 (10.67)	2 (7.14)
Uninsured, n (%)	7 (3.40)	6 (3.37)	1 (3.57)
Comorbidities	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)
Hypertension, n (%)	157 (76.21)	136 (76.4)	21 (75)
Coronary artery disease, n (%)	97 (47.09)	83 (46.63)	14 (50)
Stent revascularization, n (%)	28 (13.59)	23 (12.92)	5 (17.86)
Surgical revascularization, n (%)	18 (8.74)	16 (8.99)	2 (7.14)
Type 2 diabetes, n (%)	66 (32.04)	54 (30.34)	12 (42.86)
Chronic kidney disease, n (%)	53 (25.72)	47 (26.4)	6 (21.4)
COPD, n (%)	39 (18.93)	34 (19.1)	5 (17.86)
Atrial fibrillation, n (%)	38 (18.45)	36 (20.22)	2 (7.14)
Hypothyroidism, n (%)	26 (12.62)	22 (12.36)	4 (14.29)
Smoking, n (%)	24 (11.65)	20 (11.24)	4 (14.29)
Use of cardiac devices			
Pacemaker, n (%)	3 (1.46)	3 (1.69)	0 (0)
Cardioverter-defibrillator, n (%)	11 (5.34)	11 (6.18)	0 (0)
Cardiac resynchronizer, n (%)	0 (0)	0 (0)	0 (0)

LVEF: left ventricular ejection fraction; COPD: chronic obstructive pulmonary disease; Md: median; IQR: interquartile range; n: number.

medical chart review). Thirty-four patients were excluded because they had an acute pulmonary embolism or stage five chronic kidney disease or acute kidney failure requiring dialysis. In the end, a total of 206 patients were included.

The sociodemographic characteristics and comorbidities are described in [Table 1](#); among these, it is notable that most of the participants were male (71.8%), the median age was 70 years with an interquartile range (IQR) of 62-77 years, 90.3% lived in urban areas and most belonged to the subsidized health insurance regimen (58.7%).

The most common comorbidities were hypertension (76.2%), followed by coronary heart disease (47.1%) and diabetes mellitus (32%); the prevalence of atrial fibrillation was higher in patients with reduced LVEF, compared to patients with mildly reduced LVEF (20.2 vs. 7.1%).

Regarding pharmacological treatment prior to admission ([Table 2](#)), the most frequently used medications were beta blockers in 42.2%, followed by antiplatelet agents in 36.4%, loop diuretics in 29.6%, and angiotensin II receptor blockers (ARBs) in 29.1%. In the subgroup of patients who were admitted with a prior diagnosis of chronic heart failure with reduced LVEF, based on an echocardiogram (n = 75), 58.7% were on beta blockers, 54.7% were on angiotensin converting enzyme inhibitors (ACE inhibitors) or ARBs, 30.7% were on mineralocorticoid receptor antagonists (MRAs), 10.7% were on angiotensin receptor -neprilysin inhibitors (ARNIs) and 10.7% were on sodium-glucose cotransporter-2 inhibitors (SGLT2 inhibitors). Of these patients, 50.7% were receiving combination therapy consisting of a beta blocker + ACE inhibitor/ARB/ARNI, 22.7% were being treated with a beta blocker + MRA + ACE inhibitor/ARB/ARNI, and 6.7% were receiving

**Table 2.** Outpatient pharmacological treatment

A. By type of heart failure			
Medication	Total (n = 206)	New onset heart failure (n = 59)	Exacerbated chronic heart failure (n = 147)
Beta blocker, n (%)	87 (42.23)	14 (23.73)	73 (49.66)
ARB, n (%)	60 (29.13)	14 (23.73)	46 (31.29)
ACE inhibitor, n (%)	35 (16.99)	5 (8.47)	30 (20.41)
MRA, n (%)	34 (16.5)	3 (5.08)	31 (21.09)
ARNI, n (%)	11 (5.33)	0 (0)	11 (7.48)
SGLT2 inhibitor, n (%)	9 (4.37)	1 (1.69)	8 (5.44)
Loop diuretic, n (%)	61 (29.61)	10 (16.95)	51 (34.69)
Antiplatelet agent, n (%)	75 (36.41)	13 (22.03)	62 (42.18)
Statin, n (%)	60 (29.13)	10 (16.95)	50 (34.01)
Anticoagulant, n (%)	20 (9.71)	4 (6.78)	16 (10.88)
Calcium antagonist, n (%)	18 (8.74)	3 (5.08)	15 (10.2)
Digoxin, n (%)	6 (2.91)	0 (0)	6 (4.08)
B. In patients with chronic heart failure and previously known LVEF			
Medication	Total (n = 82)	LVEF ≤ 40% (n = 75)	LVEF 41-49% (n = 7)
Beta blocker, n (%)	48 (58.54)	44 (58.67)	4 (57.14)
ACE inhibitor or ARB, n (%)	45 (54.88)	41 (54.67)	4 (57.14)
MRA, n (%)	25 (30.49)	23 (30.67)	2 (28.57)
SGLT2 inhibitor, n (%)	8 (9.76)	8 (10.67)	0 (0)
ARNI, n (%)	9 (10.98)	8 (10.67)	1 (14.28)
Loop diuretic, n (%)	34 (41.46)	29 (38.67)	5 (71.43)
BB + ACE inhibitor/ARB/ARNI, n (%)	41 (50)	38 (50.67)	3 (42.85)
BB + MRA + ACE inhibitor/ARB/ARNI, n (%)	18 (21.95)	17 (22.67)	1 (14.28)
BB + MRA + SGLT2 inhibitor + ACE inhibitor/ARB/ARNI, n (%)	5 (6.09)	5 (6.67)	0 (0)

ARB: angiotensin II receptor blocker; ACE inhibitor: angiotensin converting enzyme inhibitor; SGLT2 inhibitor: sodium-glucose cotransporter-2 inhibitor; ARNI: angiotensin receptor-neprilysin inhibitor; BB: beta blocker; MRA: mineralocorticoid receptor antagonist; LVEF: left ventricular ejection fraction.

combination therapy with a beta blocker + MRA + SGLT2 inhibitor + ACE inhibitor/ARB/ARNI.

Regarding the clinical variables on admission recorded in [Table 3](#), the main symptom was dyspnea, followed by edema (these two symptoms occurred more in patients with reduced LVEF than in those with mildly reduced LVEF) and, in third place, chest pain, which was more frequent in the group with mildly reduced LVEF. The New York Heart Association (NYHA) functional class on admission was Class III in 55.8% of the participants, Class II in 28.2% and Class IV

in 15.1%. The hemodynamic profile of the decompensation on admission was warm-wet in most cases (78.3%), followed by cold-wet (15.5%) and warm-dry (4.4%), with no significant differences in distribution between the LVEF groups.

A total of 28.6% of the cases had new onset acute heart failure, while 71.4% experienced worsening of previously identified heart failure. The most common decompensation triggers ([Table 4](#)) were acute coronary syndrome, especially in the group of patients with mildly reduced LVEF (causing decompensation in

**Table 3.** Clinical variables on admission

Variable	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)
Symptoms on admission			
Dyspnea, n (%)	188 (91.26)	165 (92.7)	23 (82.14)
Edema, n (%)	133 (64.56)	124 (69.66)	9 (32.14)
Chest pain, n (%)	95 (46.12)	75 (42.13)	20 (71.43)
Orthopnea, n (%)	93 (45.15)	87 (48.88)	6 (21.43)
Paroxysmal nocturnal dyspnea, n (%)	79 (38.35)	72 (40.45)	7 (25)
Palpitations, n (%)	58 (28.16)	50 (28.09)	8 (28.57)
NYHA class on admission			
I, n (%)	2 (0.97)	1 (0.56)	1 (3.57)
II, n (%)	58 (28.16)	48 (26.97)	10 (35.71)
III, n (%)	115 (55.83)	102 (57.30)	13 (46.43)
IV, n (%)	31 (15.05)	27 (15.17)	4 (14.29)
Hemodynamic profile (Stevenson)			
Warm-Dry, n (%)	9 (4.37)	7 (3.93)	2 (7.14)
Warm-Wet, n (%)	161 (78.26)	139 (78.09)	22 (78.57)
Cold-Wet, n (%)	32 (15.53)	29 (16.29)	3 (10.71)
Cold-Dry, n (%)	4 (1.94)	3 (1.69)	1 (3.57)

LVEF: left ventricular ejection fraction; NYHA: New York Heart Association; n: number.

**Table 4.** Decompensation trigger and heart failure etiology

Decompensation trigger	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)
Acute coronary syndrome, n (%)	81 (39.32)	62 (34.64)	19 (67.86)
Poor adherence, n (%)	53 (25.73)	49 (27.37)	4 (14.29)
Cardiac arrhythmia, n (%)	49 (23.79)	44 (24.58)	5 (17.86)
Infection, n (%)	40 (19.42)	38 (21.23)	2 (7.14)
Other triggers, n (%)	16 (7.77)	15 (8.38)	1 (3.57)
Not identified, n (%)	3 (1.46)	3 (1.68)	0 (0)
More than one trigger, n (%)	44 (21.35)	39 (21.9)	5 (17.8)
Heart failure etiology	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)
Ischemia, n (%)	128 (62.14)	106 (59.22)	22 (78.57)
Hypertension, n (%)	56 (27.18)	50 (27.93)	6 (21.43)
Arrhythmia, n (%)	44 (21.36)	41 (22.91)	3 (10.71)
Valve disease, n (%)	20 (9.71)	19 (10.61)	1 (3.57)
Chagas, n (%)	14 (6.79)	13 (7.26)	1 (3.57)
Unknown, n (%)	4 (1.94)	4 (2.23)	0 (0)
More than one etiology, n (%)	55 (26.69)	50 (28.08)	5 (17.85)

LVEF: left ventricular ejection fraction; n: number.

two-thirds of these cases), followed by poor adherence to pharmacological treatment, which was more common in the group of patients with reduced LVEF. Infection was also a more common trigger in the group of patients with reduced LVEF.

Within the heart failure etiologies, the most frequent was ischemic heart disease (62.1%), followed by hypertensive heart disease (27.2%) and arrhythmia (21.4%). Two or more heart failure etiologies were documented in 26.7% of the cases; disaggregated by LVEF group,

**Table 5.** Hospital outcomes and causes of death

Hospital outcomes	Total (n = 206)	LVEF ≤ 40% (n = 178)	LVEF 41-49% (n = 28)	P value
Length of hospital stay (days), Md (IQR)	7.5 (4-11)	6.5 (4-11.5)	8 (4-11)	0.58
Need for ICU, n (%)	42 (20.38)	32 (17.97)	10 (35.71)	0.03
Need for vasopressors, n (%)	34 (16.5)	26 (14.6)	8 (28.57)	0.06
Need for inotropes, n (%)	14 (6.79)	12 (6.74)	2 (7.14)	0.93
In-hospital mortality, n (%)	30 (14.56)	25 (14.04)	5 (17.85)	0.54
90-day readmission, n (%)	35 (19.88)	32 (20.91)	3 (13.04)	0.36
Causes of death	Total (n = 30)	LVEF ≤ 40% (n = 25)	LVEF 41-49% (n = 5)	P value
Acute coronary syndrome, n (%)	17 (56.66)	15 (60)	2 (40)	0.81
Pulmonary septic shock, n (%)	9 (30)	7 (28)	2 (40)	0.43
Respiratory failure due to SARS-CoV-2 pneumonia, n (%)	2 (6.66)	1 (4)	1 (20)	0.9
Skin and soft tissues septic shock, n (%)	1 (3.33)	1 (4)	0 (0)	-
Bacteremia, n (%)	1 (3.33)	1 (4)	0 (0)	-

LVEF: left ventricular ejection fraction; ICU: intensive care unit; Md: median; IQR: interquartile range; n: number.

the ischemic etiology was more prevalent in the group of patients with mildly reduced LVEF (78.6 vs. 59.2%), while a mixed etiology (more than one cause) was higher in patients with reduced LVEF (28.1 vs. 17.9%).

The laboratory tests on emergency room admission showed a median creatinine of 1.18 mg/dl (IQR 0.91-1.45), sodium of 139 meq/L (IQR 135-141), potassium of 4.28 meq/L (IQR 3.93-4.8), leukocytes at 8,720 cel/mcL (IQR 6,560-11,380), hemoglobin of 13 g/dl (IQR 12-14.2) and a median blood glucose level of 123.5 mg/dl (IQR 104.05-160), with an average TSH of 3.58 mIU/L (with a standard deviation  $\sigma$  of 3.2) and an average albumin of 3.28 g/dl ( $\sigma$  of 0.67).

Regarding hospital outcomes (Table 5), the median length of hospital stay was 7.5 days (IQR 4-11 days). Altogether, 20.4% of the participants were admitted to the ICU, 16.5% required vasopressor support, and 6.8% required inotropic support. Hospital mortality was 14.6%, and 19.9% of the patients required readmission during the first 90 days after discharge.

The main causes of in-hospital mortality were acute coronary syndrome (56.7%), with 8.6% of these deaths due to acute ST-elevation myocardial infarction, followed by bacterial infections (36.7%) and acute respiratory failure due to SARS-CoV-2 (6.7%).

Comparing the outcomes between patients with mildly reduced LVEF and those with reduced LVEF, there were no significant differences in length of

hospital stay between these two groups (8 vs. 6.5 days,  $p = 0.58$ ). The need for ICU admission was significantly higher in patients with mildly reduced LVEF (35.7 vs. 18%;  $p = 0.03$ ), with a tendency to require more vasopressor support in this same group (28.6 vs. 14.6%;  $p = 0.06$ ). Meanwhile, there were no significant differences in in-hospital mortality (17.9 vs. 14%;  $p = 0.54$ ), the causes of death, or the 90-day hospital readmission rate (13 vs. 20.9%;  $p = 0.36$ ) between the groups.

## Discussion

One of the notable sociodemographic characteristics found was the advanced average age of the participants, with most being males, although our study found a higher percentage of males compared to other studies of patients hospitalized for heart failure<sup>7-10</sup>. Most of the participants belonged to the subsidized health insurance regimen, as our institution is a public entity.

As described in the literature, the most frequent comorbidity was hypertension, but our study found a high percentage of patients with a history of coronary artery disease (47.1%), higher than recorded in other national studies such as the ones by Muñoz-Mejía<sup>9</sup> (23.8%), Ruales-Mora<sup>10</sup> (8.9%), Calvachi-Prieto<sup>11</sup> (38.4%), and the RECOLFACA<sup>12</sup> registry (28.1%); as well as international studies like the Brazilian BREATHE<sup>13</sup> registry (26.6%), the Chilean ICARO<sup>14</sup> registry (22%) and the



Argentinian ARGEN-IC<sup>15</sup> registry (17.3%). However, compared to large-scale registries in the United States, the prevalence of coronary artery disease was close to that reported in the OPTIMIZE-HF<sup>7</sup> registry (45.7%) and lower than in the ADHERE<sup>16</sup> (57%) study and the European ESC-HF-LT<sup>17</sup> registry (53.8%).

As far as pharmacological treatment, there was a low percentage of outpatient heart failure medication prescription for patients who already had a diagnosis of heart failure with reduced LVEF on admission to the emergency room, despite recognized evidence of mortality and readmission reductions, with only 30.7% being prescribed MRAs. Regarding combined medications, 50.7% had been prescribed a beta blocker + ACE inhibitor/ARB/ARNI, unlike what was documented in the PINNACLE<sup>18</sup> registry, which, in 2017, showed that 72.8% of the patients with heart failure with reduced LVEF were using a combination of a beta blocker + ACE inhibitor/ARB/ARNI. The SGLT2 inhibitors had not been included in the clinical practice guidelines for heart failure management at the time of data collection, which is why few patients had this prescription.

In this same group of patients with reduced LVEF, the combined use of a beta blocker + MRA + ACE inhibitor/ARB/ARNI was found in only 22.7% of the cases, which indicates low adherence to the heart failure treatment guidelines<sup>2,7,19,20</sup>, an aspect which should be improved to optimize heart failure control in our region's patients.

The most frequent symptom on admission to the emergency room was dyspnea, which occurred in more than 90% of the cases. Most of the patients were in NYHA Functional Class III and three-fourths had a wet-warm hemodynamic profile. These findings were similar to those reported in other national studies<sup>9-11</sup>.

In our study, the main cause of heart failure decompensation was acute coronary syndrome, in 39.3% of the cases, a higher percentage than reported in other Colombian studies such as those by Muñoz-Mejía<sup>9</sup> (7.2%), Ruales-Mora<sup>10</sup> (7.1%), and Arcos-Medina<sup>21</sup> (21.9%), as well as the RECOLFACA<sup>12</sup> registry (13.7%) and the Chilean ICARO<sup>14</sup> registry (9%). We associated these findings with the higher percentage of patients with a history of ischemic heart disease found in our study, compared to these reference studies.

On the other hand, there was a high percentage of patients with poor adherence to treatment as the reason for decompensation (25.7%), although this finding in this type of patients is usually high, with percentages ranging from 8.9 to 50%<sup>7,9,10,12,13</sup>.

The main heart failure etiology was ischemic heart disease, in 62.1% of the cases, higher than reported in

other national studies (in which it was the cause of 21.8 to 47.8% of the heart failure)<sup>9-12</sup>, although similar to what was found in the study by Arcos-Medina<sup>21</sup> (60.5%). This higher percentage of coronary artery disease in our study's patients could be explained by their socio-economic differences, considering that most of them belonged to the subsidized health insurance regimen, which implies that they had a lower income and educational level. These factors can lead to healthcare access barriers, inadequate medical follow up and lower adherence to healthy lifestyles, as well as a potentially lower delivery of medications and a lack of comprehensive treatment programs and follow up in these patients, resulting in less control of cardiovascular risk factors. This has already been described in the literature and is seen in the PURE<sup>22</sup> study, which reported a higher incidence of cardiovascular events and mortality in patients in low and middle-income countries, possibly related to less accessibility of health services and technology, less risk factor control, less delivery of medications and a lack of medical follow up for patients in rural areas.

Furthermore, a considerable percentage of the heart failure in our study was due to Chagas disease (6.8%), higher than what has been reported in other Colombian studies<sup>9,10,12</sup>, which could be related to a higher prevalence of Chagas disease in areas for which we are a referral center (Casanare, Arauca and Guaviare).

Regarding hospital outcomes, there was a high need for ICU treatment and greater in-hospital mortality (14.6%), which was higher than described in other studies. For example, the OPTIMIZE-HF<sup>7</sup> registry reported an in-hospital mortality of 3.8%, similar to that reported in the ADHERE<sup>16</sup> registry, which was 4%, while in the Latin American registries, the Argentinian ARGEN-IC<sup>15</sup> registry had a 7.9% in-hospital mortality and the Chilean ICARO<sup>14</sup> registry had 4.5%. Only the Brazilian BREATHE<sup>13</sup> registry had a similar mortality, at 12.6%. We believe that the factors related to this high in-hospital mortality include difficulties with access and timely emergency room consultation, which leads to patients being more critically ill and having more complications on admission. In addition, possible delays in reperfusion therapy for patients with acute coronary syndrome must be considered, since our hospital does not have a hemodynamics unit, and patients who require interventionist cardiology procedures have to be referred to other healthcare facilities with a higher level of care, with the delays these processes entail.

It is important to clarify that patients with acute heart failure were included in the mortality analysis, whose

prognosis is mainly determined by the cause of cardiac decompensation, severity of myocardial involvement and timely etiological treatment (as in the case of reperfusion in acute coronary syndrome, and the treatment of arrhythmias or infections), unlike patients with acute decompensated chronic heart failure with other etiologies like nonadherence to treatment or disease progression, whose treatment is focused on maintaining perfusion goals and resolving congestion.

A comparison of outcomes between the reduced vs. mildly reduced LVEF groups showed no significant differences in terms of mortality, readmissions, length of hospital stay or need for inotropes and vasopressors. On the other hand, a greater and statistically significant percentage of patients with mildly reduced LVEF required ICU admission, perhaps due to the main cause of decompensation being acute coronary syndrome and having a higher percentage of patients with respiratory infection complications. However, it should be noted that the small number of patients with a fatal outcome limits the statistical power of a differential analysis between the causes of death, as well as a comparative analysis of mortality between the LVEF groups. Therefore, we believe a new study should be performed, designed to analyze in-hospital mortality, to determine its associated factors in these patients.

Regarding this study's limitations, it is important to note that its retrospective nature determined the quality of the available information, which was restricted to what was recorded in the medical charts. Also, since it was carried out at a single hospital which cares mostly for patients in the subsidized health insurance regimen, there is a risk of referral bias, and the data may not be generalizable to the majority of heart failure patients in the country.

Furthermore, patients with a preserved ejection fraction were not included in the study, and, therefore, the data cannot be extrapolated to this sub-group. Natriuretic peptide tests were not available at the institution, which may have limited the ability to rule out a heart failure diagnosis, and precluded the prognostic benefit of this test.

## Conclusions

Heart failure is a clinical syndrome covering a broad spectrum ranging from an initial, asymptomatic phase up to the advanced stage in which palliative care is offered to control symptoms. The epidemiological and clinical characteristics of the study cohort were similar to those of other national populations with acute heart

failure, differentiated by a higher prevalence of ischemic heart disease, a high need for ICU admission during hospitalization and higher in-hospital mortality. Acute coronary syndrome was the main cause of death, associated with low outpatient prescription of disease-modifying drugs. Therefore, we believe it is relevant to reinforce medical staff adherence to heart failure clinical practice guidelines in our region's outpatient setting, as well as improve patient education programs and create heart failure clinics in the region to optimize treatment, adherence and follow up of these patients and achieve better control of their risk factors. In addition, a study should be designed to analyze in-hospital mortality and determine its associated factors in this group of patients.

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## Conflicts of interest

There are no conflicts of interest.

## Ethical responsibilities

**Human and animal protection.** The authors declare that the procedures followed in this study conformed to the ethical norms for responsible human experimentation and were in line with the World Medical Association and the Declaration of Helsinki.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for the publication of patient data.

**Right to privacy and informed consent.** The authors have obtained approval from the ethics committee for the analysis and publication of routinely obtained clinical data. Patient informed consent was not required, as this was a retrospective observational study.

**Use of artificial intelligence to generate text.** The authors declare that they have not used any type of generative artificial intelligence in drafting this manuscript or in creating figures, graphs, tables or their respective captions or legends.

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# The effectiveness of a cardiopulmonary rehabilitation program in healthcare workers with COVID-19 infection

## Efectividad de un programa de rehabilitación cardiopulmonar en trabajadores de la salud con infección por COVID-19

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### Abstract

**Objective:** To evaluate, in a healthcare worker population with COVID-19, the severity of the disease and the impact of an outpatient Phase II exercise-based cardiopulmonary rehabilitation program (CPRP) on functional capacity, function measured by the Post-COVID-19 Functional Status (PCFS) scale, and job reinstatement. **Materials and method:** A quasi-experimental study was conducted, involving 48 healthcare workers with COVID-19. Severity of infection, cardiopulmonary function, and PCFS were assessed at the beginning and end. The CPRP included three weekly sessions of personalized continuous and interval exercises lasting 20 to 60 minutes, with an intensity of 60 to 80% of maximum heart rate over one month. **Results:** There were 19 moderate cases and 29 severe cases. The average age was 54 (SD: 15.5) years, and 41.7% were employees, 47.9% were obese, and 39.6% were hypertensive. A total of 68.8% had typical pneumonia, 29.2% experienced post-traumatic stress, 43.8% had depressive syndrome, and 50% had anxiety disorders. Cardiopulmonary capacity improved from New York Heart Association (NYHA) Class II (5.7 SD: 1.2) to NYHA Class I (8.2 SD: 2.0). Independence in activities of daily living (PCFS scale) improved, and 36 patients returned to work. There were no severe complications. **Conclusion:** This study demonstrated a positive impact of the CPRP on cardiopulmonary function and independence in daily and instrumental activities among healthcare workers with COVID-19, with 75% returning to their regular duties.

**Keywords:** COVID-19. Cardiopulmonary rehabilitation. Health care workers. Exercise test. Disability.

### Resumen

**Objetivo:** Evaluar, en una población trabajadora de la salud con COVID-19, la gravedad de la enfermedad y el impacto de un programa de rehabilitación cardiopulmonar ambulatorio fase II basado en ejercicio, en la capacidad funcional, la función medida con la Escala de Estado Funcional posCOVID y el reintegro laboral. **Materiales y método:** Se realizó un estudio cuasiexperimental en 48 trabajadores de la salud con infección por COVID-19. Al inicio y al final se les evaluó gravedad de la infección, función cardiopulmonar y estado funcional post COVID-19 (por sus siglas en inglés PCFS). Se hizo un programa de rehabilitación cardiopulmonar con tres sesiones semanales de ejercicio continuo e interválico individualizado, con una duración de 20 a 60 minutos y una intensidad del 60 al 80% de la frecuencia cardíaca máxima durante un mes. **Resultados:** Hubo 19 casos moderados y 29 graves. La edad

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promedio fue 54 (DE: 15.5) años, 41.7% eran empleados, 47.9% obesos y 39.6% hipertensos. El 68.8% tuvo neumonía típica, el 29.2% estrés postraumático, el 43.8% síndrome depresivo y el 50% trastornos de ansiedad. La capacidad cardiopulmonar pasó de NYHA II (5.7 DE: 1.2) a NYHA I (8.2 DE: 2.0). Mejoró la independencia en actividades de la vida diaria (AVD) (escala Estado Funcional Post COVID-19) y 36 pacientes regresaron a su trabajo. No hubo complicaciones graves. **Conclusión:** Este estudio demostró el impacto positivo de un programa de rehabilitación cardiopulmonar en la función cardiopulmonar y la independencia en actividades diarias e instrumentales en trabajadores de la salud con COVID-19, pues un 75% de estos que regresó a sus labores habituales.

**Palabras clave:** COVID-19. Rehabilitación cardiopulmonar. Trabajadores de la salud. Prueba de esfuerzo. Discapacidad.

## Introduction

COVID-19 infections can cause severe cardiopulmonary and systemic problems<sup>1</sup> which restrict activities of daily living and social interaction, according to the International Classification of Functioning (ICF)<sup>2</sup>.

The Infection Severity Scale was created to evaluate COVID-19 sequelae; it categorizes the disease as mild, moderate or severe based on clinical factors like hospitalization, supplementary oxygen and ventilatory support. It has been used to stratify patients after COVID-19 and trace symptoms for up to six months after infection<sup>3</sup>. The Post-COVID-19 Functional Status (PCFS) scale was developed by a group of investigators in Holland to monitor patients four and eight weeks after discharge and evaluate functional sequelae after six months<sup>4</sup>. It has been validated in several countries around the world, including Spanish speaking countries like Chile and Mexico<sup>5,6</sup>. It is an ordinal scale with six steps progressing from 0 (no symptoms) to 5 (death), and covers the entire range of functional outcomes. A higher score indicates greater functional limitations.

Exercise-based cardiopulmonary rehabilitation programs (CPRPs) are one of the most frequently used and useful strategies for treating these sequelae<sup>7,8</sup>, and their goal is to improve cardiorespiratory function, functional capacity and quality of life, as well as help patients to reintegrate socially<sup>9</sup>. As described in a letter to the editor of *Revista Española de Cardiología*, exercise-based cardiac rehabilitation during COVID-19 is a small step for healthcare systems, but a giant leap for patients<sup>10</sup>. In 2020, the journal of the Asociación Colombiana de Medicina Física y Rehabilitación [Colombian Association of Physical Medicine and Rehabilitation] published a supplement on rehabilitation during and after the pandemic, including cardiopulmonary rehabilitation<sup>11,12</sup>.

Healthcare staff were among the most affected by this pandemic, with high morbidity and mortality and functional limitations<sup>13</sup>. Likewise, a meta-analysis in 2021 found that the most affected staff were nurses, with severe complications in 5% of this population<sup>14</sup>. Despite all this, there are few studies evaluating the

impact of cardiopulmonary rehabilitation programs on this population with regard to function and social and work reinstatement.

The objective of this study was to evaluate, in a population of healthcare staff with COVID-19, the severity of the disease and the impact of an exercise-based ambulatory Phase II CPRP on functional capacity, function measured by the PCFS and reinstatement at work.

## Materials and method

This was a quasi-experimental pre-post intervention study of healthcare staff patients with COVID-19 infection, using convenience sampling. The sample included 48 patients, 19 of whom had moderate infections, and 29 had severe infections. Patients seen at an ambulatory rehabilitation institution who were over the age of 18, had moderate or severe infection, underwent evaluation before and after a CPRP and voluntarily agreed to participate were included.

The COVID-19 severity scale<sup>3</sup> was applied at the beginning of the CPRP. Cardiopulmonary function in metabolic equivalents (METs, measured with a stress test) was evaluated at the beginning and end of the program, along with the PCFS. The instruments used included a sociodemographic questionnaire, clinical history and reinstatement at work or in activities of daily living.

The intervention program was carried out in the institution's cardiac rehabilitation gym, which has telemetry equipment and various physical fitness machines (elliptical trainer, treadmill, cycloergometer, upper body ergometer, multifunctional weight equipment, and balance training equipment, among others). This rehabilitation program has been described and applied in other studies<sup>15</sup>.

Each patient attended 12 to 24 ambulatory cardiac rehabilitation (Phase II) sessions, three times a week, lasting one hour per session.

A functional treadmill (using the Bruce or modified Bruce protocol) or cycloergometer test (with an incremental protocol of 25 watts every two minutes) was used to measure cardiopulmonary function at the beginning and end of the CPRP, according to the

patients' individual characteristics and the American College of Sports Medicine recommendations<sup>8</sup>. The functional outcome of the test was measured in METs. Warm-up and aerobic exercises were performed in the subsequent sessions, with complementary breathing technique, strength, balance and coordination training. Each exercise session consisted of:

- A warm-up period of approximately 10 minutes, with exercises to maintain joint range of motion and flexibility.
- Thirty minutes of aerobic interval exercise including calisthenics, walking on the treadmill, recumbent bicycle, and arm rowing and pedaling.
- Complementary exercise with alternating days of respiratory, strength, coordination and balance exercises.

The intensity of the aerobic exercise was determined using three estimates according to the American College of Sports Medicine guidelines<sup>16</sup>: work between 40 to 80% of the  $VO_2$  peak, 60 to 80% of the heart rate reserve and work based on perceived exertion, using a Borg score less than 13.

Home training was provided on the use of the respiratory threshold stimulator for 20 to 30 minutes a day, three to five times a week, at 25 to 35% of the maximum inspiratory pressure<sup>17</sup>.

For patients with low functional capacity or accessibility problems, initial sessions were performed using interactive telemedicine. Prior to reinstatement at work, patients attended a readaptation workshop with physical, occupational and psychological therapy, where physical fitness was reinforced, and work was simulated through occupational therapy. The psychology department provided relaxation and stress management techniques. Patients received an educational brochure on the disease, risk factors and benefits of exercise. The on-site sessions were conducted following the biological safety norms for patients and healthcare staff. At the end of the program, a final stress test was performed, measuring the variables taken on enrollment to determine whether the functional goals had been met, according to the patients' age and health condition. When the goals were met, the patients were discharged and referred back to their attending physician.

### Statistical analysis

Absolute and relative frequency tables were constructed by the type of infection (severe and moderate) for sociodemographic characteristics, risk factors, COVID-19 complications and post-COVID-19 symptoms. The results are given according to the pre-test and post-test information after the CPRP.

An analysis was made of the beginning and end of the program in relation to each of the three dimensions of the PCFS scale, 1: activities of daily living at home, work or study; 2: instrumental activities of daily living; 3: participation in usual social roles. Each of the items comprising the dimensions presented response options on an ordinal likert scale with response options of "none," "not significant," "mild," "moderate" and "severe." Wilcoxon's nonparametric test for related samples was done to detect differences in the METs obtained on the stress tests at the beginning and end of the program for both groups, and the size of the nonparametric effect was calculated to determine the magnitude of the difference between the two measurements<sup>18</sup>. The type of work reinstatement was also recorded at the beginning and end of the program: disability, reinstatement with no modifications, and reinstatement with modifications.

The ethical principles of the Declaration of Helsinki were followed. All patients signed and accepted the informed consent form in line with Resolution 8430 of 1993, which regulates the performance of biomedical research in the country<sup>19</sup>. This study was considered to pose minimal risk for its participants because its design and execution did not represent a danger or injury to their health or physical, psychological or social integrity. The RStudio version 4.2.2 statistical program was used for analysis and results.

## Results

Information was obtained from 48 patients diagnosed with COVID-19, who were divided into two groups. Patients with moderate infection were in the first group, and those with severe infection were in the second group. [Table 1](#) shows the sociodemographic characteristics by group. The average age of the population was 54 years ( $\pm 15.5$ ); all of the participants were healthcare workers; 58.3% were men and 41.7% were women. Altogether, 39.6% had moderate infection and 60.4% had severe infection; none of the referred patients had mild infection. A total of 58.4% had higher education (nurses, administrative staff and physicians), and patients from low and middle-income strata accounted for 54.2%. A total of 41.7% worked as employees ([Table 1](#)).

As far as clinical characteristics are concerned, none of the patients were treated with immunomodulators or had uncontrolled immunodepression. The most frequent COVID-19 risk factors were dyslipidemia (47.9%), obesity (47.9%), hypertension (39.6%) and diabetes mellitus (20.8%) ([Table 2](#)). The average hospital length of stay for those with moderate infection was 13.6 ( $\pm 6.9$ ) days, and only one of these patients was in the ICU for

**Table 1.** Sociodemographic characteristics of patients with COVID-19 with moderate and severe respiratory infections who attended the CPRP in the city of Medellín, 2021-2022

Sociodemographic characteristics	Moderate infection		Severe infection		Total	
	n = 19	%	n = 29	%	n = 48	%
Sex						
Male	9	47.4	19	65.5	28	58.3
Female	10	52.6	10	34.5	20	41.7
Age						
Mean (SD)	54 (15.4)		54 (15.5)		54 (15.5)	
Highest level of education achieved						
Primary	0	0.0	6	20.7	6	12.5
Basic secondary	1	5.3	1	3.4	2	4.2
Middle secondary	4	21.1	8	27.6	12	25.0
Technical or technological	6	31.6	4	13.8	10	20.8
College	5	26.3	10	34.5	15	31.3
Graduate studies	3	15.8	0	0.0	3	6.3
Socioeconomic status						
Low and middle	9	47.4	17	58.6	26	54.2
High	10	52.6	12	41.4	22	45.8
Employment situation						
Employee	8	42.1	12	41.4	20	41.7
Freelancer	1	5.3	6	20.7	7	14.6
Unpaid work	4	21.1	5	17.2	9	18.8
Age pension	6	31.6	6	20.7	12	25.0

SD: standard deviation.

**Table 2.** Risk factors of patients with COVID-19 with moderate and severe respiratory infections who attended the CPRP in the city of Medellín 2021-2022

Risk factors	Moderate infection		Severe infection		Total	
	n = 19	%	n = 29	%	n = 48	%
Obesity	8	42.1	15	51.7	23	47.9
Dyslipidemia	11	57.9	12	41.4	23	47.9
Hypertension	6	31.6	13	44.8	19	39.6
Diabetes <i>mellitus</i>	4	21.1	6	20.7	10	20.8
Smoking	4	21.1	7	24.1	11	22.9
Prior lung disease	1	5.3	3	10.3	4	8.3
Coronary disease	1	5.3	3	10.3	4	8.3

three days. For patients with severe infection, the average hospital length of stay was 39.5 ( $\pm$  33.2) days, and ICU length of stay was 21.4 ( $\pm$  24.7) days. Altogether, 68.4% had moderate infection due to typical pneumonia, 5.3% had coronary disease, 10.5% had new onset diabetes, 31.6% had anxiety disorders, and 42.2% lost an average of 6 ( $\pm$  4.5) kilos. Among those with severe illness, 100% had pneumonia, 13.8% had coronary disease, and there was a higher percentage of psychiatric problems: 62.1% had depressive syndrome and the

same percentage had an anxiety disorder. Among patients with moderate infections, 5.3% had neuropathies, with the same percentage of patients having mixed polyneuropathy. Out of all the patients, 43.8% had depressive syndrome and 50.0% had an anxiety disorder ( $\pm$  54.2) (Table 3).

During the CPRP, patients with moderate infection had an average of 13.9 ( $\pm$  6.2) sessions, while those with severe infections had 21.3 ( $\pm$  9.9). None of the patients had complications due to syncope, reinfarction,

**Table 3.** COVID-19 complications in patients with moderate and severe respiratory infections who attended the CPRP in the city of Medellín 2021-2022

COVID-19 Complications	Moderate infection		Severe infection		Total	
	n = 19	%	n = 29	%	n = 48	%
<b>Cardiac</b>						
Coronary disease	1	5.3	4	13.8	5	10.4
Viral myocarditis	0	0.0	2	6.9	2	4.2
Venous thromboembolism	0	0.0	2	6.9	2	4.2
Heart failure	1	5.3	4	13.8	5	10.4
<b>Pulmonary</b>						
Atypical pneumonia	2	10.5	9	31.0	11	22.9
Typical pneumonia	13	68.4	20	69.0	33	68.8
Restrictive lung disease	3	15.8	2	6.9	5	10.4
Mixed lung disease	2	10.5	4	13.8	6	12.5
Thromboembolism	0	0.0	3	10.3	3	6.3
Acute pulmonary edema	0	0.0	1	3.4	1	2.1
<b>Neurological</b>						
Neuropathy	1	5.3	3	10.3	4	8.3
Mixed polyneuropathy	1	5.3	2	6.9	3	6.3
Central vertigo	0	0.0	1	3.4	1	2.1
<b>Psychiatric</b>						
Post-traumatic stress	3	15.8	11	37.9	14	29.2
Depressive syndrome	3	15.8	18	62.1	21	43.8
Anxiety disorder	6	31.6	18	62.1	24	50.0
Delirium	0	0.0	1	3.4	1	2.1
<b>Metabolic</b>						
New-onset diabetes	2	10.5	5	17.2	7	14.6
Weight loss in kilos in the last month	8	42.1	18	62.1	26	54.2
Amount of weight loss - Mean (SD)	6 (± 4.5)		9.1 (± 5.1)		15.1 (± 31.5)	

malignant arrhythmias and acute coronary syndrome, nor did any patients die during the program. A total of 31.6 and 79.3% of the patients with moderate and severe infections expressed that they had felt discouraged, depressed or hopeless during the 30 days prior to the survey. Altogether, 36.8 and 79.3% felt little interest or pleasure in doing the things they usually enjoyed. During the program, 20.8% experienced desaturation, 16.7% had increased dyspnea, 4.2% had decompensated heart failure, and 4.2% had decompensated diabetes. Only 2.1% had COPD complications.

The post-COVID-19 symptoms experienced by the patients are considered to be sequelae of the disease. Thus, for every 10 patients with moderate or severe infection, nine reported having residual muscle pain; three had lumbar pain; five had sleep problems; seven had smell and taste disorders; four had anxiety; and five had depression (Table 4). A total of 41.7% were referred to internal medicine, 10.4% to neurology, 27.1% to pulmonology, 20.8% to cardiology, 22.9% to psychiatry and 10.4% to occupational medicine; these percentages were higher in patients with severe COVID-19 infections.

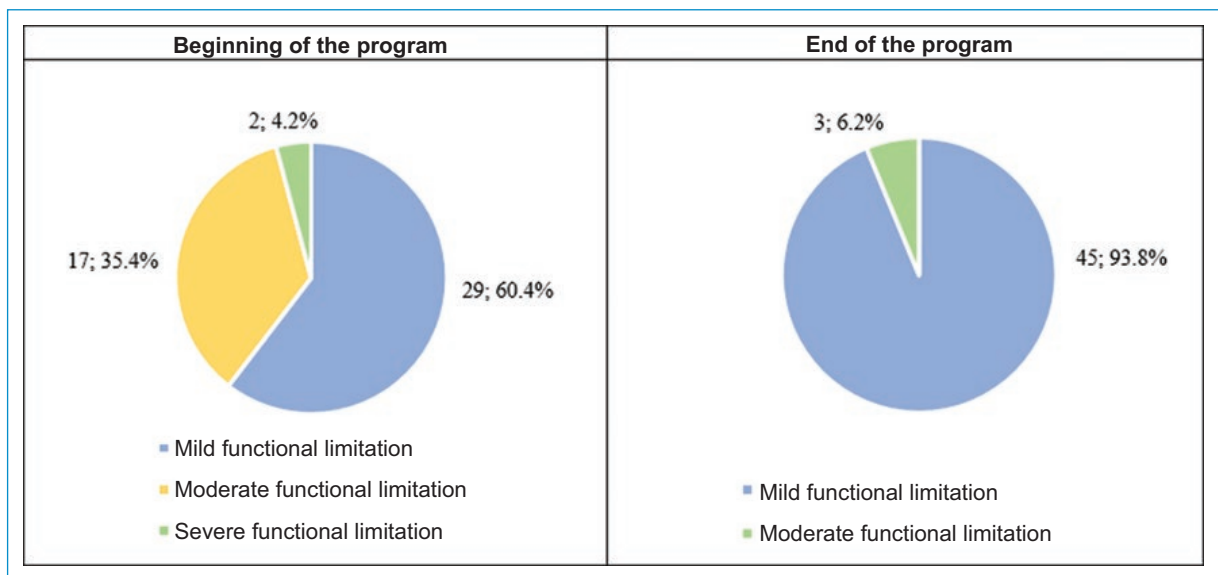
On the stress test, patients with moderate COVID-19 infections had an increase of 2 METs, going from 6 (IQR: 5.5-7.0) at the beginning of the program to 8 (IQR: 7.0-10.0) at the end. Patients with severe infections had an increase of 3 METs, going from 5 (IQR: 4.0-7.0) to 8 (IQR: 7.0-9.6) at the end of the program. For both groups, the median METs achieved on the stress test were higher at the end of the program ( $p = 0.00$ ), and the nonparametric effect size ( $r = 0.88$ ) indicates that the difference is substantially large.

An analysis of the PCFS scale at the beginning and end of the program showed that, initially, 12.5% had moderate functional limitations in eating, 18.8% in using the bathroom and performing routine hygiene and 25.0% in walking; at the end of the program, approximately 85% had improved (Table 5). Altogether, 27.3% had moderate functional limitations in performing housekeeping tasks, 31.3% in traveling locally, and 29.2% in going shopping. At the end of the program, approximately two-thirds of the patients had no limitations and the others had mild or non-significant limitations (Table 5). Regarding participation in their usual social roles, 31.3 to 35.4% of the participants had moderate limitations; at the end of the program 50 to 72.9% had no limitations (Table 6).



**Table 4.** Post-COVID-19 symptoms in patients with moderate and severe infections who attended the CPRP in the city of Medellín 2021-2022

Post-COVID-19 symptoms	Moderate infection		Severe infection		Total	
	n = 19	%	n = 29	%	n = 48	%
Muscle pain	17	89.5	27	93.1	44	91.7
Sternal pain	1	5.3	8	27.6	9	18.8
Lumbar pain	6	31.6	9	31.0	15	31.3
Cough	11	57.9	22	75.9	33	68.8
Hair loss	12	63.2	14	48.3	26	54.2
Sleep problems	8	42.1	17	58.6	25	52.1
Fatigability	17	89.5	28	96.6	45	93.8
Smell and taste disorders	10	52.6	24	82.8	34	70.8
Cognitive disorders	2	10.5	2	6.9	4	8.3
Anxiety	4	21.1	17	58.6	21	43.8
Depression	4	21.1	19	65.5	23	47.9
Headache	1	5.3	0	0.0	1	2.1
Vertigo	0	0.0	1	3.4	1	2.1



**Figure 1.** Overall score on the Post-COVID-19 Functional Status (PCFS) scale at the beginning and end of the CPRP in Medellín, 2021-2022. The data is presented in frequencies and percentages.

An analysis of the COVID-19 symptoms according to the total PCFS score indicated that, at the beginning of the program, the symptoms which forced patients to avoid, reduce or carry out their usual activities more slowly led to 33.3% of the patients having moderate functional limitations, which dropped to only 2.1% at the end of the program. Those with mild functional limitations due to COVID-19

symptoms went from 39.6% at the beginning of the program to only 6.3% at the end. Altogether, 31.3% of the patients had mild functional limitations related to COVID-19 symptoms at the beginning of the program, which decreased to only 16.7% at the end of the program.

In the scale's overall score at the beginning of the program, 60.4% of the patients with COVID-19 had mild

**Table 5.** Change in activities of daily living on the Post-COVID-19 Functional Status (PCFS) scale at the beginning and end of the CPRP, in Medellín 2021-2022

Dimension	Categories	Functional limitation											
		None		Not significant		Mild		Moderate		Severe			
		n	%	n	%	n	%	n	%	n	%		
Basic activities of daily living	Help with eating	Beginning of the program	19	39.6	9	18.8	14	29.2	6	12.5	0	0	
		End of the program	42	87.5	3	6.3	3	6.3	0	0	0	0	
	Help with using the bathroom	Beginning of the program	16	33.3	9	18.8	13	27.1	9	18.8	1	2.1	
		End of the program	41	85.4	5	10.4	2	4.2	0	0	0	0	
	Help with routine hygiene	Beginning of the program	16	33.3	8	16.7	14	29.2	9	18.8	1	2.1	
		End of the program	41	85.4	4	8.3	3	6.3	0	0	0	0	
	Help with walking	Beginning of the program	16	33.3	6	12.5	14	29.2	12	25.0	0	0	
		End of the program	40	83.3	5	10.4	3	6.3	0	0	0	0	
	Instrumental activities of daily living	Help with household tasks	Beginning of the program	6	12.5	11	22.9	17	35.4	13	27.1	1	2.1
			End of the program	35	72.9	10	20.8	2	4.2	1	2.1	0	0
		Help with local travel	Beginning of the program	4	8.3	9	18.8	19	39.6	15	31.3	1	2.1
			End of the program	32	66.7	11	22.9	5	10.4	0	0	0	0
Help with local shopping		Beginning of the program	4	8.3	10	20.8	19	39.6	14	29.2	1	2.1	
		End of the program	32	66.7	11	22.9	5	10.4	0	0	0	0	

functional limitations, and 35.4% had moderate functional limitations. These results changed after the intervention; at the end of the program, only 6.2% of the patients had moderate functional limitations and 93.8% had mild functional limitations (Fig. 1).

## Discussion

Most patients in this study were classified as post severe COVID-19 on admission, with frequent symptoms consisting of (in descending order) muscle pains, cough, fatigability, and depression. Functionality measured by PCFS showed that, after the CPRP, 98.3% of the patients achieved normality. Functional aerobic capacity measured by stress tests, in METs, also normalized, as most of the patients went from New York Heart Association Functional Class II to Functional Class I. Work reinstatement was successful in all patients, and most returned to their usual jobs. There were no significant complications during the CPRP, and adherence was high.

The foregoing shows that this comprehensive, exercise-based CPRP was effective and safe in a population of healthcare workers with COVID-19, with regard to overall functionality, functional aerobic capacity and

successful work reinstatement. These results of cardiac rehabilitation programs have been proven, with good levels of evidence, in other cardiopulmonary health conditions like chronic obstructive pulmonary disease<sup>20</sup>, coronary disease<sup>21</sup> and heart failure<sup>22</sup>.

There are few studies like the one described here in post-COVID-19 patients, involving a population of healthcare workers and using validated functional indicators and a stress test to adequately measure functional capacity at the beginning and end. A systematic review of rehabilitation interventions in post-acute COVID-19 patients found 519 primary studies which showed improved symptoms (dyspnea, kinesiophobia, anxiety, muscle strength, functional capacity and quality of life). However, the studies were very heterogenous, which did not allow strong scientific evidence to be derived<sup>23</sup>.

Most similar studies use the six-minute test as the measure of aerobic capacity, which is less objective than the stress test<sup>24</sup>. The stress test is a cardiopulmonary diagnostic study that requires specific technology and special training to perform, and therefore is not used in most cardiopulmonary rehabilitation centers as part of the comprehensive care package.

**Table 6.** Change in participation in social roles on the Post-COVID-19 Functional Status (PCFS) scale in COVID-19 patients according to CPRP pre and post-tests, Medellín 2021-2022

Participation in usual social roles	Functional limitation									
	None		Not significant		Mild		Moderate		Severe	
	n	%	n	%	n	%	n	%	n	%
Occupational adaptation										
Beginning of the program	3	6.3	15	31.3	15	31.3	15	31.3	0	0.0
End of the program	33	68.8	13	27.1	2	4.2	0	0.0	0	0.0
Need to avoid or reduce occupational activities										
Beginning of the program	0	0.0	18	37.5	15	31.3	15	31.3	0	0.0
End of the program	33	68.8	11	22.9	4	8.3	0	0.0	0	0.0
Care of relatives										
Beginning of the program	3	6.3	15	31.3	15	31.3	15	31.3	0	0.0
End of the program	35	72.9	8	16.7	5	10.4	0	0.0	0	0.0
Problems in social relationships										
Beginning of the program	0	0.0	14	29.2	17	35.4	17	35.4	0	0.0
End of the program	27	56.3	15	31.3	6	12.5	0	0.0	0	0.0
Limited participation in social activities										
Beginning of the program	0	0.0	10	20.8	22	45.8	16	33.3	0	0.0
End of the program	24	50.0	18	37.5	6	12.5	0	0.0	0	0.0

As a strength, this study is important in being a specific assessment of a healthcare worker population post-COVID-19, acquired as an occupational disease, who had access to a CPRP with a comprehensive prescription of therapeutic exercise (aerobic, respiratory, strength, coordination and balance) according to the effectiveness and safety norms provided in the international guidelines<sup>16</sup>. The CPRP also included occupational therapy, work adaptation workshops and psychological support, which facilitate the process of work reinstatement, considering that, initially, most patients had functional deterioration and psychological disorders. The work adaptation workshop is a methodology that facilitates work reinstatement, as it prepares workers through activities and schedules similar to those of their usual occupation. We found no similar studies of CPRPs in healthcare workers.

This CPRP follows the ICF paradigm that comprehensively addresses the biopsychosocial consequences of a health condition and impacts not only morbidity and mortality, but also functionality and social participation.

A limitation of this study is that the population referred to the CPRP was treated in a heterogeneous fashion at various hospitals, which did not allow variables like unified emergency and hospital treatment protocols or referral criteria to be determined. Another limitation was not having a longer follow up to see if the functional gains were maintained and evaluate late complications after COVID-19. Subsequent follow up of these patients in other studies has shown prolonged symptom persistence<sup>25,26</sup>.

This study’s practice implications validate the application and development of comprehensive CPRPs in patients with COVID-19. We recommend that future studies perform controlled clinical trials to evaluate different interventions and outcomes and conduct longer follow ups. Observational studies will also allow the natural history of this disease to be clearly established. These studies could determine the most effective and safe treatment and rehabilitation strategies. Another practice implication was the significant improvement in the activities of daily living dimensions, which was slightly lower in the instrumental activities and in participation. These patients should continue in an intervention program at home to achieve longer-term results.

## Conclusions

This quasi-experimental study evaluated 48 healthcare workers with COVID-19 infection who attended an exercise-based CPRP. The main risk factors, in descending order, were obesity, dyslipidemia and hypertension, similar to those of the general population. Most of the patients were classified as severe on admission, with frequent complications like typical pneumonia and psychological disorders (depression, anxiety and post-traumatic stress). The CPRP involved work readaptation and psychological support strategies according to the social, work and psychological characteristics of this population. In addition, it was safe, had good adherence, and had no complications during its implementation. Altogether, 98.3% of the

participants improved their functional capacity measured in METs through a stress test, and most improved their activities of daily living. Work reinstatement was successful for most.

In summary, this program showed safety and efficiency in improving functional independence and aerobic capacity, with successful work reinstatement in the previously described population. However, this study's most significant contribution was documenting the creation of a rehabilitation program in a new health condition in which there was no clinical experience or prior studies. Furthermore, the fundamental principles and strategies of cardiopulmonary rehabilitation were proven to be valid: personalized exercise prescription, psychosocial support, education and functional and work reinstatement strategies.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical responsibilities

**Human and animal protection.** The authors declare that no experiments were conducted on humans or animals for this study.

**Data confidentiality.** The authors declare that they followed their workplace protocols for publishing patient data.

**Right to privacy and informed consent.** The authors obtained informed consent from the patients and/or subjects referred to in the article. The corresponding author is in possession of this document.

**Use of artificial intelligence to generate text.** The authors declare that they did not use any type of generative artificial intelligence in drafting this manuscript, nor for creating figures, graphs, tables or their respective captions or legends.

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# Factors related to in-hospital cardiovascular complications in the female gender

## Factores relacionados con complicaciones cardiovasculares intrahospitalarias en el género femenino

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### Abstract

**Introduction:** heart disease is the leading cause of death in the world for both men and women. The presentation of ischemic heart disease varies depending on multiple factors, including gender. **Materials and method:** this was an observational, cross-sectional study with an analytical component of all patients admitted for ACS at Hospital Docente Clínico-Quirúrgico Comandante Manuel Fajardo between January 2016 and December 2020. **Results:** female patients had a median age of 73 (IQR: 62-80), significantly higher than males, with a higher prevalence of arterial hypertension and diabetes mellitus ( $n = 353$  and  $n = 143$ , respectively, and  $p < 0.01$ ). Age, creatinine level, and ST-elevation acute coronary syndrome (STE-ACS) were identified as triggering factors for cardiac complications (RR: 1.01; 95% CI: 1.00-1.07;  $p = 0.03$ ; RR: 1.01; 95% CI: 1.00-1.02;  $p = 0.01$ ; and RR: 2.77; 95% CI: 1.31-5.87;  $p = 0.02$ , respectively). **Conclusions:** women with ACS were older than men, with a higher prevalence of arterial hypertension and diabetes mellitus, while the predictive variables of in-hospital cardiovascular complications were age, serum creatinine, and STE-ACS.

**Keywords:** Non-ST-segment elevation acute coronary syndrome. ST-segment elevation acute coronary syndrome. Cardiovascular complications. Female.

### Resumen

**Introducción:** las enfermedades del corazón son la primera causa de muerte en el mundo tanto en el hombre como en la mujer. La presentación de la cardiopatía isquémica varía dependiendo de múltiples factores, entre ellos el género. **Materiales y método:** estudio observacional, transversal con componente analítico de todos los pacientes ingresados con síndrome coronario agudo en el Hospital Docente Clínico-Quirúrgico Comandante Manuel Fajardo, entre enero del 2016 y diciembre del 2020. **Resultados:** el género femenino presentó una mediana edad de 73 (RIC: 62-80), significativamente superior a la del género masculino, con mayor prevalencia de hipertensión arterial y diabetes mellitus ( $n = 353$  y  $n = 143$ , respectivamente;  $p < 0.01$ ). Se identificaron la edad, el valor de la creatinina y el síndrome coronario agudo con elevación

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del ST como factores desencadenantes de complicaciones cardíacas (RR: 1.01; IC 95%: 1.00-1.07;  $p = 0.03$ ; RR: 1.01; IC 95%: 1.00-1.02;  $p = 0.01$ ; y RR: 2.77; IC 95%: 1.31-5.87;  $p = 0.02$ , respectivamente). **Conclusiones:** las mujeres con síndrome coronario agudo presentaron una edad superior a la de los hombres, con mayor prevalencia de hipertensión arterial y diabetes mellitus, mientras las variables predictoras de complicaciones cardiovasculares intrahospitalarias identificadas fueron la edad, el valor de creatinina sérica y el síndrome coronario agudo con elevación del ST.

**Palabras clave:** Síndrome coronario agudo sin elevación del segmento ST. Síndrome coronario agudo con elevación del segmento ST. Complicaciones cardiovasculares. Femenino.

## Introduction

Heart disease is the first cause of death, worldwide (17.9 million), in both men and women<sup>1</sup>. In the Americas in 2019, the ischemic heart disease mortality rate was 108.1 per 100,000 inhabitants, specifically 95.8 in women; in Central America and the Caribbean, the mortality rates were 95.6 and 87.0, respectively, in females<sup>2</sup>. In that same year, 874,613 people died in the United States, 41.3% due to ischemic heart disease<sup>3</sup>. This was similar in Cuba, in 2021, with a total of 25,849 deaths, for a rate of 231.1 per 100,000 inhabitants, and 214.8 for women<sup>4</sup>.

Ischemic heart disease may be chronic and insidious or present as an acute coronary event. The frequency of its presentations varies depending on many factors, including gender, with non-ST-elevation acute coronary syndrome (NSTEMI-ACS) being the most common in women. Today, despite reperfusion therapy, in-hospital cardiovascular complications constitute a health problem for these patients, especially for women. Several hypotheses have tried to explain this event, including hypotheses related to inflammatory markers and hemostasis<sup>5</sup>.

However, the role of risk factors in cardiovascular complications during an acute coronary event is determinant. Within the group of patients with acute coronary syndrome (ACS), women's ages are four to five years higher than men's ages, as are the number of comorbidities (diabetes mellitus, hypertension or heart failure). Atypical symptoms are more common in females and are generally accompanied by prodromes like excessive fatigue, sleep disorders, anxiety, and arm weakness or discomfort, especially in patients under the age of 65<sup>5,6</sup>.

Despite the high incidence of ACS in the Cuban population, its gender-related behavior in patients hospitalized in coronary intensive care at our hospital, cardiovascular risk factors and in-hospital complications are unknown. This study was performed to describe this syndrome in women, as well as determine possible associations between traditional cardiovascular disease risk factors and in-hospital cardiac complications.

## Materials and method

This was an observational, cross-sectional study with an analytical component of all patients with ACS admitted to the coronary intensive care unit at Hospital Docente Clínico-Quirúrgico Comandante Manuel Fajardo in Havana between January 2016 and December 2020. The study population consisted of all patients over the age of 18, with a diagnosis of ACS, admitted consecutively to the coronary intensive care unit from January 2016 to December 2022, and the patients who were discharged alive from this unit. On the other hand, patients who did not have 95% of the study variables in the database designed for the study, and patients admitted to Hospital Manuel Fajardo with a negative ACS diagnosis were excluded.

A 12-lead electrocardiogram (EKG) was done at the first medical contact. There was also a daily follow up EKG of progress both at rest and using the Cardiocid VV model A5102. Laboratory tests were run on admission to the coronary intensive care unit, including creatine kinase isoenzyme MB (CKMB) or troponin T. In addition, operators with more than five years of experience performed a progress echocardiogram within 72 hours of admission to the unit, using an Aloka Pro-sound Alpha 10 echocardiography machine.

Data were extracted from the log of patients admitted to the hospital's intensive care unit and their clinical charts, and all personal data were removed.

The demographic and clinical variables included age, sex, personal medical history (ischemic heart disease, hypertension, diabetes mellitus, dyslipidemia, obesity), and non-lethal in-hospital complications: hemodynamic (acute heart failure, acute pulmonary edema, cardiogenic shock), electrical (atrioventricular blocks, supra-ventricular tachycardias and ventricular tachycardia), and clinical (reinfarction, post-infarction angina) complications.

The laboratory variables were CKMB (measured in  $\mu\text{mol/L}$ ), troponin T (measured in  $\text{ng/L}$ ) and serum creatinine (measured in  $\mu\text{mol/L}$ ).

Finally, the imaging variables included left ventricular ejection fraction.

Continuous variables were expressed as means with standard deviation (SD) or medians (interquartile range [IQR]), according to whether the data were normally or asymmetrically distributed, as evaluated with the Kolmogorov-Smirnov test. Categorical variables are presented as numbers and percentages.

The Chi square test was employed for comparisons between qualitative variables, using relative risk (RR) to determine the intensity of this association, as well as Student's t test for the comparison of means between quantitative variables. A confidence level of 95% was sought, with a pre-established critical rejection region ( $\alpha$ ) of 0.05, associated with the probability value,  $p$ . A bivariate logistic regression model was used to determine the correlation between the analyzed variables and the onset of shock, with a 79.7% success rate. The SPSS version 25 statistical program was used for data analysis.

The investigators participating in this study followed the applicable ethical and legal norms, specifically the Declaration of Helsinki, and informed consent was obtained from the patients, along with approval from the hospital's ethics committee.

## Results

A total of 836 patients diagnosed with ACS were included, 42% of whom were females. The median age in women (Mdn = 73, IQR: 62-80) was significantly higher than in men (Mdn = 63, IQR: 56-74), with a  $p < 0.01$ . The most common past medical problems were ischemic heart disease (60%), hypertension and diabetes mellitus, which were more common in women ( $n = 353$  and  $n = 143$ , respectively;  $p < 0.01$ ), while smoking was significantly higher in men ( $n = 306$ ;  $p < 0.01$ ) [Table 1](#).

The most common ACS presentation in women was NSTEMI-ACS ( $n = 304$ ), while ST-elevation acute coronary syndrome (STEMI-ACS) was most common in males, with a statistical significance of  $p < 0.01$ . Coronary angiography was performed in 29.2% of the patients hospitalized for ACS, with no statistically significant differences between the sexes ([Table 1](#)). The median creatinine (Mdn = 88; IQR: 74-103) and CKMB (Mdn: 20; IQR: 10-20) were significantly lower in women ( $p < 0.01$ ); the rest of the values are described in [Table 1](#).

Altogether, 19.4% of the patients had cardiovascular complications, with no statistically significant gender differences. Among female patients, a history of

ischemic heart disease was significantly related to in-hospital cardiovascular complications ( $p = 0.03$ ). There was a similar result for age, creatinine and left ventricular ejection fraction, all with a statistical significance of  $p < 0.01$  ([Table 2](#)).

Finally, a multivariate analysis was run to determine the correlation between given variables in female patients and the onset of in-hospital cardiovascular complications, finding that age, creatinine levels and STEMI-ACS were triggers for cardiac complications (RR: 1.01; 95% CI: 1.00-1.07;  $p = 0.03$ ; RR: 1.01; 95% CI: 1.00-1.02;  $p = 0.01$ ; and RR: 2.77; 95% CI: 1.31-5.87;  $p = 0.02$ ) ([Fig. 1](#)).

## Discussion

As highlighted in many articles, acute ischemic heart disease occurs more often in older people, which coincides with the results of our study<sup>7-9</sup>. The protective effect of estrogen contributes to female patients with ACS having a higher mean age than men. The impact of cardiovascular risk factors on the vascular endothelium and progression of arteriosclerosis, the physiological changes of the cardiovascular system itself, as well as a higher number of associated risk factors in older patients, contribute to these events occurring in people generally over the age of 60.

Although the traditional risk factors for ischemic heart disease are the same in both sexes, the differences in their prevalence and impact vary by sex<sup>10</sup>. This difference is even more evident in ACS, as women are generally older and have more comorbidities (hypertension, diabetes mellitus, dyslipidemia and heart failure)<sup>11,12</sup>. In the seventh report of the joint national committee on prevention and treatment of high blood pressure, more than two thirds of people after 65 years of age are, preferentially women, were living with high blood pressure<sup>13</sup>. Jhieh-Yuan et al.<sup>14</sup> and Richards et al.<sup>15</sup> obtained a similar result with hypertension and diabetes mellitus, while smoking prevailed in men. In our study analysis and De la Torre et al.'s recently published study in geriatric patients<sup>16</sup>, hypertension and diabetes mellitus were more prevalent among women.

The frequency and distribution of the types of ACS presentation will depend on several factors, including gender; women have NSTEMI-ACS more often, while STEMI-ACS is more common in men, which was similar to the findings of our study<sup>17-19</sup>. In the Cuban study by Sellen-Sanchén et al.<sup>20</sup>, the incidence of NSTEMI-ACS in women was significantly higher than in men. Hormonal differences between the sexes, as well as gender

**Table 1.** Distribution of the variables by sex

Variables	Female	Male	p
Age, median (IQR)	73 (62-80)	63 (56-74)	< 0.01
Medical history	n (%)	n (%)	p
Ischemic heart disease	212 (49.8%)	214 (50.2%)	0.29
Hypertension	353 (51.9%)	327 (48.1%)	< 0.01
Diabetes mellitus	143 (58.4%)	102 (41.6%)	< 0.01
Dyslipidemia	28 (52.8%)	25 (47.2%)	0.46
Obesity	72 (52.6%)	65 (47.4%)	0.24
Smoking	173 (36.2%)	306 (63.8%)	< 0.01
Type of ACS	n (%)	n (%)	p
NSTE-ACS	304 (51.9%)	282 (48.1%)	< 0.01
STE-ACS	97 (38.8%)	153 (61.2%)	
Angiography results	n (%)	n (%)	p
Coronary angiographies performed	119 (48.8%)	125 (51.2%)	0.78
LCA stenosis	19 (55.9%)	15 (44.1%)	0.37
ADA stenosis	78 (53.8%)	67 (46.2%)	0.06
Circumflex artery stenosis	67 (54.0%)	57 (46.0%)	0.10
RCA stenosis	66 (45.8%)	78 (54.2%)	0.27
Multivessel disease	36 (56.3%)	28 (43.8%)	0.16
PCI treatment	72 (49.3%)	74 (50.7%)	0.84
In-hospital complications	n (%)	n (%)	p
	82 (50.6%)	80 (49.4%)	0.45
Laboratory tests, median (IQR)	n (%)	n (%)	p
Creatinine	88 (74-103)	96 (82-111)	< 0.01
CK-MB	20 (10-20)	27 (16-46)	< 0.01
LV ejection fraction, median (IQR)	n (%)	n (%)	p
	60 (52-66)	56 (46-64)	< 0.01

IQR: interquartile range; ACS: acute coronary syndrome; NSTE-ACS: non-ST-elevation acute coronary syndrome; STE-ACS: ST-elevation acute coronary syndrome; LCA: left coronary artery; ADA: anterior descending artery; RCA: right coronary artery; PCI: percutaneous coronary intervention; CK-MB: creatine kinase isoenzyme MB; LV: left ventricle.

differences in the distribution of certain classical vascular risk and their association with different forms of ACS, lead to these results.

Today, women undergo fewer cholesterol checks and less lipid-lowering treatment, and use less heparin and fewer beta blockers and PCI than men. They must deal daily with more pre-hospital delays and delays in the optimal treatment times for pharmacological or interventionist reperfusion<sup>21,22</sup>. In the

GENESIS-PRAXY study, women with STE-ACS were less likely to receive reperfusion therapy than men. Likewise, women with NSTE-ACS had a lower likelihood of undergoing PCI, although the proportions of men and women with NSTE-ACS who underwent cardiac catheterization were similar<sup>23</sup>. Despite this evidence, the population studied by our investigators showed no significant gender differences in percutaneous treatment.



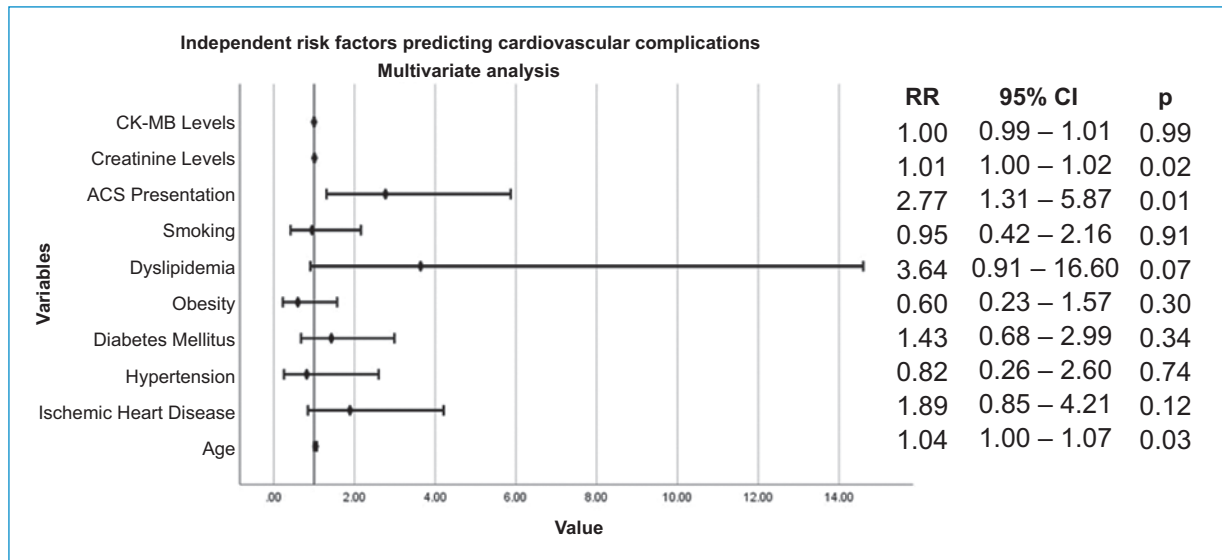


Figure 1. Independent risk factors predicting cardiovascular complications in women.

Table 2. Risk factors in women related to the onset of complications

Variables	Complications		p
	Yes, n (%)	No, n (%)	
Ischemic heart disease	52 (24.5%)	160 (75.5%)	0.03
Hypertension	76 (21.5%)	277 (78.5%)	0.15
Diabetes mellitus	35 (24.5%)	108 (75.5%)	0.14
Dyslipidemia	6 (21.4%)	22 (78.6%)	0.90
Obesity	14 (19.4%)	58 (80.6%)	0.82
Smoking	29 (16.8%)	144 (83.2%)	0.11
STE-ACS	24 (24.7%)	73 (75.3%)	0.23
NSTE-ACS	58 (19.1%)	246 (80.9%)	
Age, median (range)	77.5 (55)	71.0 (58)	< 0.01
Creatinine	92.0 (309)	87.0 (399)	< 0.01
LVEF	56.0 (49)	61.0 (66)	< 0.01

STE-ACS: ST-elevation acute coronary syndrome; NSTE-ACS: non-ST-elevation acute coronary syndrome; LVEF: left ventricular ejection fraction.

Furthermore, regardless of ACS patients' admission to coronary care units and interventionist treatment, in-hospital complications are not uncommon. Factors like age, creatinine level and STE-ACS have been related to more in-hospital cardiovascular complications; however, there are few studies in females.

Older groups, as in our study, have an increased risk of in-hospital cardiovascular complications. The

cardiovascular physiology in elderly patients, greater number of associated comorbidities, and delayed medical care and reperfusion treatment contribute to age in either gender constituting a determining factor in the onset of complications. Recent studies conclude that women and the elderly have a higher risk of developing heart failure as a complication of ACS<sup>24,25</sup>. The results of the studies by Dakhil<sup>26</sup> and Angeli et al.<sup>27</sup> also corroborate this assertion.

Serum creatinine measurement on admission is one of the most important variables in the initial prognostic stratification of patients with ACS. Elevated creatinine concentrations increase the risk of in-hospital complications and death. Despite male patients having higher serum creatinine concentrations, its role in cardiac complications in women has been shown in our study. According to studies by Qian<sup>28</sup> and Brankovic et al.<sup>29</sup>, elevated serum creatinine in patients with ACS contributed to an increased risk of heart failure and death; the same occurs with the risk of cardiogenic shock in patients with acute myocardial infarction<sup>30</sup>.

Based on Cruz et al.<sup>31</sup> and Cenko et al.'s<sup>32</sup> results, female patients diagnosed with STE-ACS had a higher percentage of hemodynamic complications. This result was similar in a cohort study in the United States; women with STE-ACS with or without PCI reperfusion therapy had a higher risk of clinical complications and heart failure<sup>33</sup>. On the other hand, the study by Berrabes et al.<sup>34</sup> showed increased electrical complications

and cardiogenic shock in patients with STE-ACS. Myocardial injury in STE-ACS may be persistent, with myocardial thickening and filling pressure abnormalities, while women experience delayed reperfusion treatment and undergo fewer coronary arteriographies than men.

## Limitations

The main limitations of this study lie in the characteristics of the study itself and its having been conducted at a single center. Since there was no follow up of patients after discharge, cardiac complications of ACS outside of the hospital were not detected. Not knowing which patients had successful pharmacological or PCI reperfusion treatment makes it difficult to analyze their probable relationship with the onset of cardiovascular complications.

## Conclusions

Women with ACS were older than men and had a higher prevalence of hypertension and diabetes mellitus. The most common presentation in this group was NSTEMI-ACS, while the variables that predicted in-hospital cardiovascular complications were age, serum creatinine levels and STE-ACS.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical responsibilities

**Human and animal protection.** The authors declare that no experiments were conducted on humans or animals for this study.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for publishing patient data.

**Right to privacy and informed consent.** The authors have obtained informed consent from the patients and/or subjects referred to in the article. The corresponding author is in possession of this document.

**Use of artificial intelligence to generate text.** The authors declare that they have not used any kind of

generative artificial intelligence in drafting this manuscript or creating figures, graphs, tables or their respective captions or legends.

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# Malignant arrhythmia in mitral valve prolapse: is surgical management enough?

## Arritmia maligna en prolapso de la válvula mitral: ¿es suficiente el tratamiento quirúrgico?

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### Abstract

Mitral valve prolapse is a well-known condition that is generally benign, but can be associated with cardiac arrhythmias, particularly malignant ventricular arrhythmias and sudden cardiac death. This association and its outcome have been described in medical literature, but the low incidence leads to a lack of evidence regarding its management and stratification. We present the case of a young woman whose initial manifestation was syncope, followed by severe mitral regurgitation and frequent ventricular extrasystoles. She underwent surgical repair with mitral valve plasty and cryoablation of the anterior papillary muscle. The clinical outcome was favorable, as evidenced by an improvement in symptoms and control of the arrhythmia burden.

**Keywords:** Mitral valve prolapse. Arrhythmic mitral valve prolapse. Premature ventricular contractions. Ventricular arrhythmia. Cryoablation. Surgical ablation.

### Resumen

El prolapso de la válvula mitral es una enfermedad ampliamente conocida, la cual es benigna en la mayoría de casos; sin embargo, puede estar en asociación con alteraciones del ritmo cardiaco, específicamente arritmias ventriculares malignas y muerte cardiaca súbita. Pese a que esta asociación y su desenlace están descritos en la literatura médica, su baja incidencia conduce a la falta de evidencia en cuanto a su manejo y estratificación. Se presenta el caso de una mujer joven, cuya manifestación inicial fue síncope, con posterior desarrollo de insuficiencia mitral grave, con hallazgo de extrasístoles ventriculares frecuentes, en quien se realizó tratamiento quirúrgico con plastia mitral y crioablación del músculo papilar anterolateral. La evolución clínica fue satisfactoria, ya que se evidenció mejoría de la sintomatología y control de la carga arrítmica.

**Palabras clave:** Prolapso de la válvula mitral. Prolapso arrítmico de la válvula mitral. Contracciones ventriculares prematuras. Arritmia ventricular. Crioablación. Ablación quirúrgica.

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## Introduction

Mitral valve prolapse is one of the most common valve diseases. It may be asymptomatic for a long period of time and may present with a variety of clinical signs and symptoms ranging from mild and non-arrhythmic manifestations to the potential onset of severe mitral regurgitation with left ventricular dilation and, in specific cases, ventricular arrhythmias which may be associated with sudden cardiac death, with a 1.2 to 1.4% rate of occurrence per year<sup>1,2</sup>. These characteristics give this disease great clinical interest.

The pathophysiological substrate to explain fatal ventricular arrhythmias may be related to anatomical substrates, like the onset of patchy fibrosis between the mitral valve, papillary muscles and adjacent inferobasal left ventricular myocardium and triggers linked to the stretching of papillary muscles, causing early depolarization that initiates and perpetuates the triggered activity<sup>3</sup>. In addition, underlying mechanisms have been described, including increased adrenergic activity, catecholamine regulation disturbances, and abnormalities in the renin-angiotensin-aldosterone system<sup>4</sup>.

In the recent description and characterization of this condition, the different clinical studies have identified risk factors directly associated with sudden cardiac death and malignant arrhythmias in patients with mitral valve prolapse, including female sex, prolapse of both valve leaflets, mitral annulus abnormalities (like dilation and disjunction), electrocardiographic repolarization abnormalities (specifically in the inferior-lateral leads), frequent premature ventricular contractions and myocardial fibrosis in the papillary muscles<sup>1,5</sup>.

The case presented below shows the benefit of appropriate stratification in a symptomatic patient with high risk factors, in whom early surgical intervention not only improved her quality of life, but also reduced the arrhythmic burden. This case provides an avenue to inquire about the protective role of surgery in malignant arrhythmias due to mitral valve prolapse and highlight the benefit of multidisciplinary clinical follow up.

## Clinical case

We present the case of a previously healthy 38-year-old woman who initially presented due to syncope, with a finding of mitral valve prolapse of both leaflets and mild to moderate regurgitation, for whom clinical monitoring was initially considered. On follow up after her pregnancy, she had increased clinical signs of heart failure and echocardiographic progression of the mitral

regurgitation from moderate to severe, with prolapse of both leaflets (predominantly the posterior leaflet) associated with 8 mm annular disjunction, the pickelhaube sign and left cavity dilation with 60% ventricular function (Fig. 2C and E). Multidisciplinary stratification was done, including 24-hour Holter monitoring which showed frequent ventricular extrasystoles with two predominant morphologies, including right ventricular outflow tract and posteromedial morphologies, with an arrhythmic burden of 11%, as well as frequent supraventricular extrasystoles (Fig. 1). In addition, cardiac magnetic resonance imaging (Fig. 2A) showed myocardial linear late gadolinium enhancement between the basal segment of the anterolateral wall and the papillary muscles. Based on her clinical exam, progression and imaging findings, she was referred for surgery.

Surgery revealed (Fig. 2B) a mitral valve with degenerative changes suggestive of Barlow's disease, prolapse of both leaflets, predominantly P2, and disjunction of the posterior mitral annulus. In addition, fibrotic foci were found on the posteromedial and anterolateral papillary muscles, as was seen initially on cardiac magnetic resonance imaging.

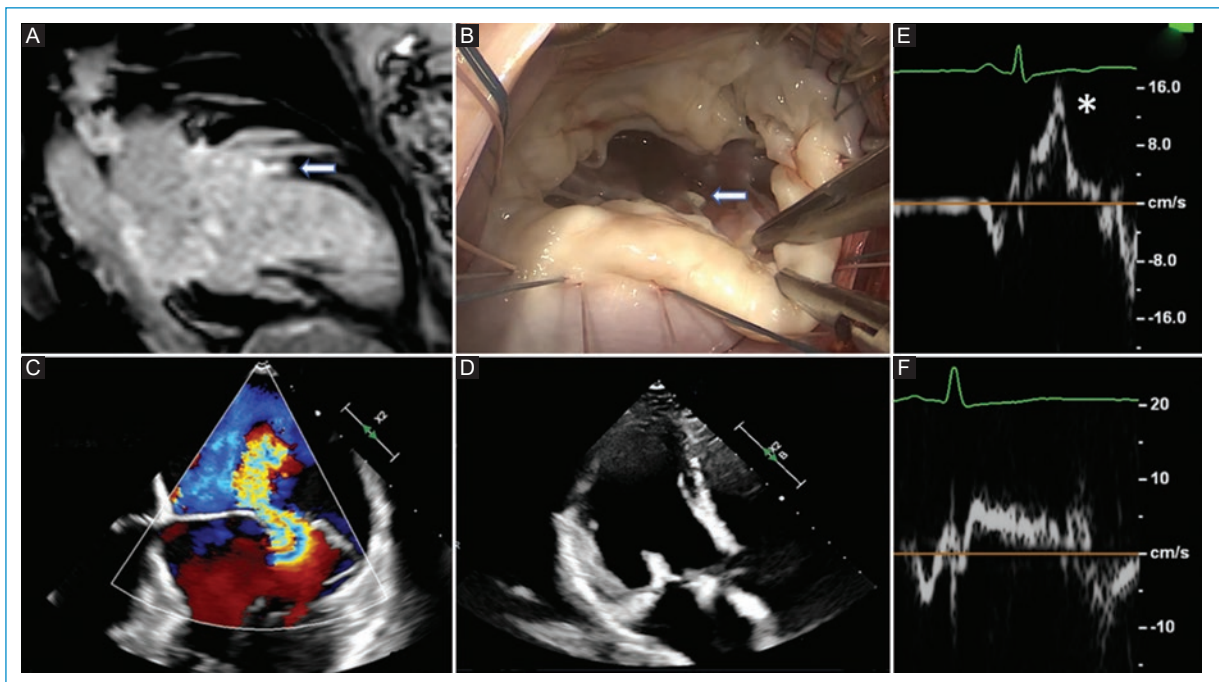
Intraoperative cryoablation was performed on the described papillary muscles for 120 seconds, (anteriorly, posteriorly and at their tips), guided by visual inspection of the fibrosis. The mitral valve was repaired through a triangular resection of P2 and annuloplasty with a Physio II 36 mm mitral ring. An intraoperative transesophageal echocardiogram showed a repaired mitral valve with no residual regurgitation.

The postoperative echocardiogram revealed a 40% ejection fraction and a normally functioning mitral repair with no residual regurgitation (peak velocity 0.9 m/s; mean gradient: 2 mmHg) (Fig. 2D) as well as a resolved pickelhaube sign (Fig. 2F). Further, the follow up Holter three days after the procedure reported ventricular ectopy, a reduced arrhythmic burden at 8%, couplet episodes and one idioventricular rhythm episode lasting four beats.

The patient continued to be followed by the multidisciplinary team together with the electrophysiology service, finding a sinus rhythm with ventricular extrasystoles, with an arrhythmic burden of 10% and couplets on 72-hour Holter monitoring follow up at six months. In addition, an electrocardiogram reported ventricular extrasystoles with a right bundle branch block morphology, possibly originating from the outflow tract; this focus was not seen prior to surgery, did not improve with the surgical intervention and was therefore probably not related to the mitral valve



**Figure 1.** Presurgical Holter showing frequent ventricular extrasystoles with two morphologies, as well as frequent supraventricular extrasystoles.



**Figure 2.** **A:** cardiac magnetic resonance imaging showing late gadolinium enhancement in the posteromedial papillary muscle. **B:** macroscopic correlation with the area of fibrosis in the head of the posteromedial papillary muscle. **C:** mitral valve prolapse associated with mitral annulus *curling* and disjunction. **D:** mitral valve repair with an adequate coaptation surface. **E:** preoperative pickelhaube sign. **F:** resolution of the pickelhaube sign after mitral valve repair.

prolapse. Due to these findings, she required percutaneous modulation of the arrhythmogenic substrate by electrophysiology, resulting in complete resolution of the arrhythmic burden.

## Discussion

This arrhythmic phenotype of mitral valve prolapse is closely related to mitral annular disjunction, due to its pathophysiological relationship with local and

progressive fibrosis of the papillary muscles and the inferolateral wall of the left ventricle<sup>6</sup>. While mitral valve prolapse and mitral annular disjunction may coexist or be independent entities, it is clear that mitral annular disjunction is a predictor of the risk of arrhythmias<sup>7</sup>. The prevalence of mitral valve prolapse and mitral annular disjunction ranges from 20 to 58%. Although not all types of mitral annular disjunction are associated with ventricular arrhythmias, those that are are directly concordant with advanced myxomatous disease.

Miller et al.<sup>6</sup> described the mechanisms that interact with the development of sustained ventricular arrhythmias and sudden death in patients with mitral valve prolapse: a) a substrate (scar), b) a trigger (automaticity, reentry and triggered activity), and c) a transient modulator (a hyperadrenergic state, hemodynamics, and electrolytes). Other strongly associated factors include ST segment changes, which can be understood as changes secondary to a structural abnormality, and marked leaflet redundancy<sup>6</sup>. The pickelhaube sign has been described as a new echocardiographic sign and a sign of early electrical dysfunction during electrophysiological tests for arrhythmic mitral valve prolapse syndrome. It is defined as a high-velocity mid-systolic acceleration spike caused by mechanical traction on the posteromedial papillary muscle by the prolapsing myxomatous leaflets leading to abrupt movement of the adjacent posterobasal left ventricular wall towards the apex. It represents the mechanical stress on the valvular and subvalvular apparatus caused by mitral prolapse and mitral annular disjunction<sup>8,9</sup>.

The survival of patients with mitral valve prolapse and ventricular arrhythmias is directly related to the complexity of the premature contractions and the arrhythmic burden, as these are related to the probability of sudden death<sup>10</sup>. However, only 10% of patients with mitral valve prolapse have severe arrhythmias, predominantly those who have left atrial and ventricular dilation and degenerative myxomatous disease<sup>11</sup>.

The available evidence to date has reported a relationship between the severity of the ventricular arrhythmias in these cases and the related fatal outcomes. However, the role of arrhythmogenic focus ablation and its timing (before, during or after surgery) in preventing the risk of malignant arrhythmias is unclear, as well as whether mitral valve repair is sufficient<sup>10</sup>. El-Ashmawi et al.<sup>12</sup> published a case series in which patients with malignant arrhythmic mitral valve prolapse underwent mitral valve repair with cryoablation towards the fibrosis foci, and showed a short-term reduction of the arrhythmic burden. However, we cannot affirm that our patient

had a significant reduction in the arrhythmic burden after cryoablation but can state that her symptoms improved with mitral repair.

The subgroup of patients with mitral valve prolapse, annular disjunction and ventricular arrhythmias requires stratification and multidisciplinary assessment by an extended Heart Team (cardiology, cardiovascular surgery, electrophysiology and radiology) to identify those who would benefit from early surgical treatment, direct intraoperative ablation and multidisciplinary follow up, as these patients, like the case we have presented, may require percutaneous interventions. Currently, Holter monitoring, cardiac magnetic resonance imaging and echocardiography are used for stratification to identify risk factors, determine the arrhythmic burden and correlate scars with potential arrhythmogenic substrates, and establish the treatment plan.

## Conclusion

In this report of a patient with mitral valve prolapse, we found improved symptoms when cryoablation of the arrhythmogenic substrate in the late gadolinium enhancement sites was combined with mitral valve repair. However, so far, surgical cryoablation does not ensure a reduced risk of sudden death, despite prior indications to this effect. Therefore, this subgroup of patients requires comprehensive multidisciplinary stratification, assessment and management before and after surgery. In addition, a randomized study is needed to determine if intraoperative muscle ablation reduces the arrhythmic burden, compared with isolated mitral repair.

## Ethical considerations

Approved by the Research Ethics Committee at La Cardio.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical disclosures

**Human and animal protection.** The authors declare that no experiments were conducted on humans or animals in the course of this study.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for publishing patient data.

**Right to privacy and informed consent.** The authors have obtained informed consent from the patients and/or subjects referred to in the article. The corresponding author is in possession of this document.

**Use of artificial intelligence to generate text.** The authors declare that they have not used any type of generative artificial intelligence for writing this manuscript or creating figures, graphs, tables or their respective captions or legends.

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## Extraction of intracardiac lead located in the posterior interventricular vein, with a mechanical rotational cutting sheath, in a patient with a persistent left superior vein cava

### *Extracción de electrodo intracardiaco ubicado en la vena interventricular posterior, con vaina de corte rotacional mecánica, en paciente con vena cava superior izquierda persistente*

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#### Abstract

The use of cardiac electronic devices has increased over the last decades, which has generated an increase in the number of lead extraction procedures, as a greater number of patients with multiple comorbidities undergo cardiac electronic device implantation. Currently, the percutaneous technique is preferable in most patients, given its excellent clinical results and lower morbidity and mortality compared to surgical extraction. Nonetheless, some clinical scenarios increase procedural difficulty, including anatomical variants, or the need to extract passive fixation leads. We present a case of a patient with a pacemaker due to complete atrioventricular block, who had diaphragmatic stimulation caused by a passive fixation ventricular lead implanted in a posterolateral coronary sinus vein through a persistent left superior vena cava, and who underwent successful transvenous lead extraction.

**Keywords:** Cardiac device. Transvenous extraction. Lead.

#### Resumen

El uso de dispositivos cardiacos implantables ha aumentado en los últimos años, lo que ha generado un aumento en el número de procedimientos de extracción de electrodos a medida que se intervienen pacientes con un mayor número de comorbilidades. En la actualidad, la técnica percutánea de extracción es de elección en la mayoría de los pacientes debido a los excelentes resultados alcanzados y a una morbi-mortalidad asociada inferior a la de la extracción quirúrgica. No obstante, algunos pacientes pueden presentar retos que aumentan el grado de dificultad técnica del procedimiento, entre los que se encuentran variantes anatómicas, calcificaciones extensas o la necesidad de extraer electrodos de fijación pasiva. Se expone el caso de la extracción de un electrodo disfuncionante en una paciente portadora de marcapasos por bloqueo auriculoventricular completo, con estimulación diafragmática por electrodo ventricular de fijación pasiva implantado a través de una vena cava superior izquierda persistente en una vena posterolateral del seno coronario.

**Palabras clave:** Dispositivos cardiacos. Extracción transvenosa. Electrodo.

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## Introduction

The number of cardiac implantable electronic devices (CIEDs) has increased in the last few years due to population aging, increased life expectancy and more indications for their use<sup>1</sup>, which, in turn, has led to a growing number of device-related complications<sup>2</sup>. This increased number of complications, coupled with various technological advances in extraction tools, has led to an increased number of transvenous lead extraction procedures. Today, the main indications for percutaneous lead extraction are infections (52.4% of cases), including isolated pocket infections, bacteremia and infective endocarditis; followed by lead dysfunction (38.1% of the cases), which may be secondary to lead fracture, insulation failure or loss of lead integrity<sup>2,3</sup>. Other less frequent indications include the presence of multiple abandoned leads, venous access stenosis or thrombosis, non-magnetic resonance-conditional devices, or chronic pain<sup>3-5</sup>.

The time elapsed since implantation determines the method of lead extraction. Most can be removed through simple traction if they have been implanted for less than one year, while leads with longer implantation times require more advanced extraction techniques including femoral approaches, mechanical rotational cutting sheaths with and without motors, the use of laser sheaths, and even hybrid procedures<sup>6</sup>. Advances in this field notwithstanding, intracardiac lead extraction is a complex procedure that is not complication-free, despite the operators' expertise<sup>7</sup>. The Spectranetics® TightRail (Phillips, Colorado Springs, USA) mechanical rotational cutting sheath has positioned itself as a useful tool in this field, and some case reports with good clinical success rates of up to 100% have even been published, with no or a few minor complications reported in some studies<sup>6,8,9</sup>. Although there are no direct comparisons between the different extraction methods, retrospective studies have shown a tendency to have higher clinical success rates (97 vs. 76.9%), and more minor (3 vs. 2%) and major (3 vs. 0%) complications with mechanical sheath extraction vs. laser sheaths<sup>10</sup>. However, anatomical variants and some lead characteristics (e.g., passive fixation leads) significantly increase the procedure's degree of technical difficulty and, therefore, the risk of complications.

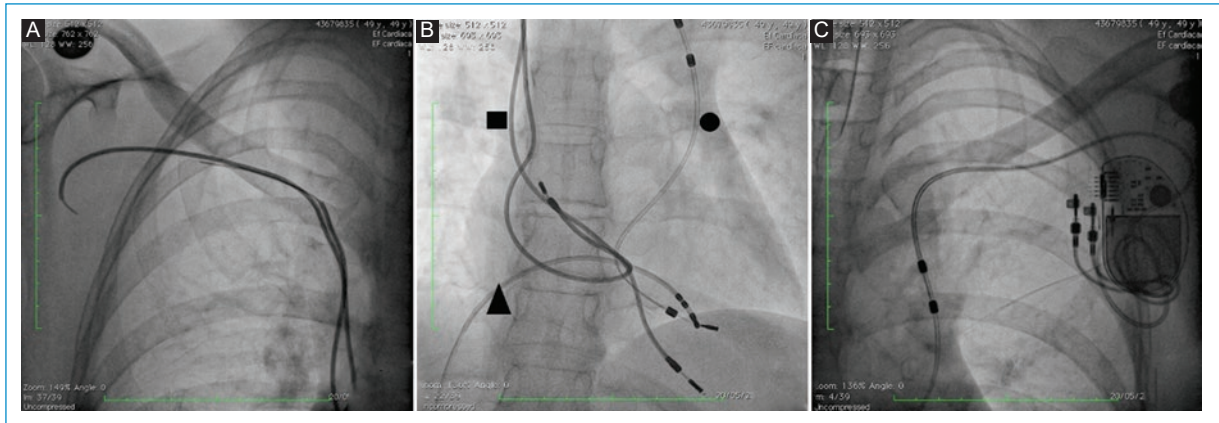
We present a case of successful extraction of a ventricular lead located in a posterolateral coronary sinus vein using a Spectranetics® TightRail mechanical rotational cutting sheath in a patient with persistent left superior vena cava.

## Clinical case

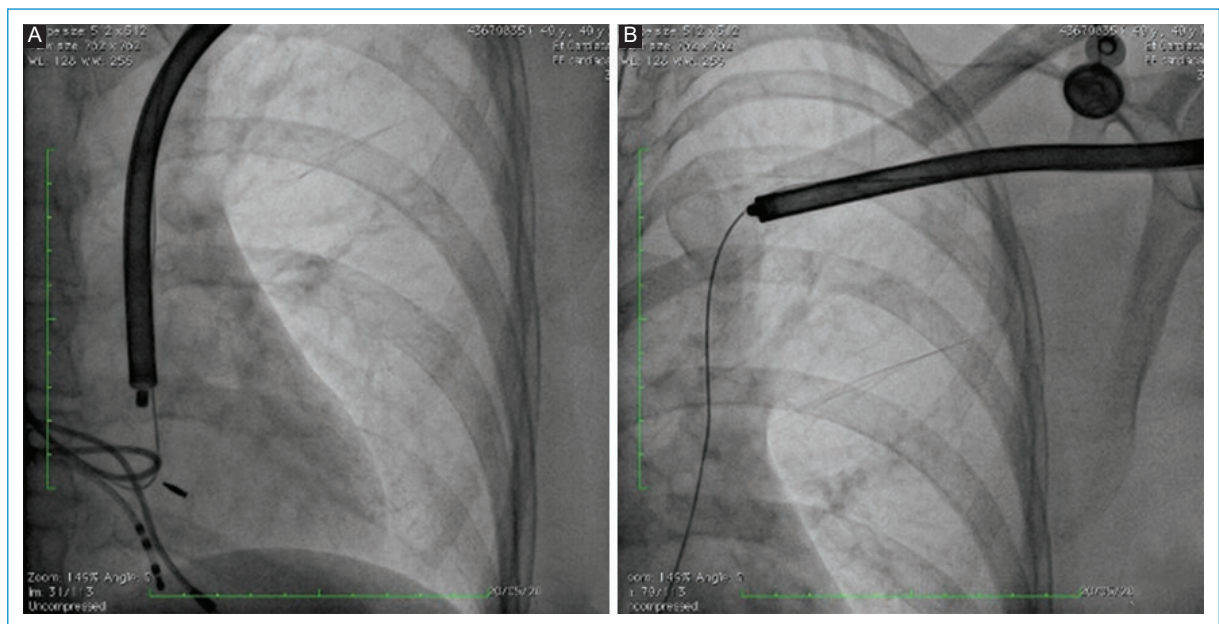
This was a 49-year-old woman with a pacemaker due to complete atrioventricular (AV) block, with multiple prior interventions. The first was a right-side implantation of two passive fixation leads in 1997; later, in 2003, the right-sided leads malfunctioned, and the device was therefore extracted, with amputation of the distal leads and abandonment of their intravascular portion. During this procedure, a left-sided pacemaker with a passive fixation lead was implanted through a persistent left superior vena cava, leaving the lead in a posterolateral coronary sinus vein. In 2016, she underwent another procedure because the device's battery had worn out. The patient was seen in the pacemaker reprogramming department, and diaphragmatic stimulation as well as ventricular stimulation dependency were found while measuring the ventricular threshold. Therefore, tool extraction of the VDD lead was proposed, along with a new implantation of a permanent dual-chamber pacemaker, since the patient wanted to undergo the least possible intervention.

## Description of the procedure

The right common femoral vein was punctured under general anesthesia, through which a quadripolar catheter was advanced to the apex of the right ventricle (Fig. 1). Then, anatomical plane dissection was performed up to the left subpectoral region, from which the device was extracted, and the lead was freed using an electric scalpel as far as the left infraclavicular region, where a hemostatic suture was placed. After verifying the integrity of the lumen, the distal portion of the lead was cut, a Spectranetics® Lead Locking Device (LLD) (Phillips, Colorado Springs, USA) was advanced through the lumen, a Spectranetics® TightRail 13 Fr mechanical rotational cutting sheath was advanced over this device up to the most proximal portion of the lead (passing through the subclavian vein and persistent left superior vena cava) and, assisted by counter-traction, almost the entire lead was extracted, leaving a remnant of less than 1 cm (Fig. 2). Before removing the sheath, a 1.5 m 0.032" guidewire was advanced and, using the retained guidewire technique, the permanent dual-chamber pacemaker was implanted, with no diaphragmatic stimulation found at maximal output (Fig. 3). Since the remaining electrodes were not causing any complications, no attempt was made to remove them.



**Figure 1.** Fluoroscopic images of the device and leads. **A:** AP projection of the right-sided leads. They are amputated at their distal tips. **B:** anterior-posterior projection of the cardiac silhouette, showing abandoned right-sided leads (black box), a VDD lead entering through the persistent left superior vena cava (black circle) and a temporary pacemaker (black triangle). **C:** AP projection of the left-sided VDD lead. The lead pathway is shown from the left subclavian vein, entering the heart through the persistent left superior vena cava.



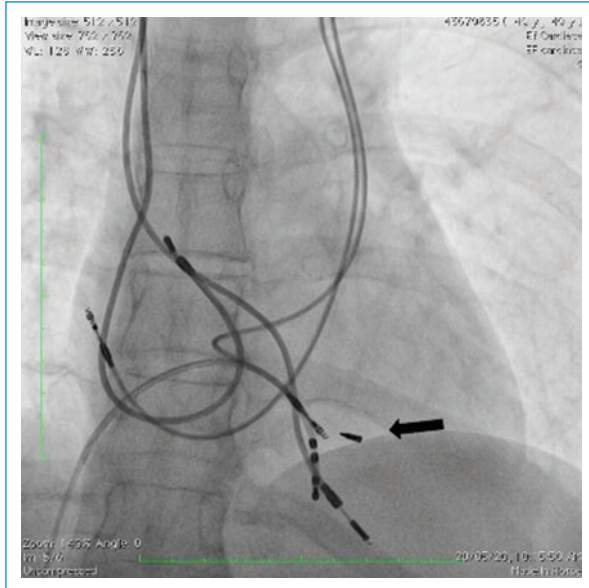
**Figure 2.** An image of device extraction using Spectranetics®. **A:** AP projection of the left side of the chest, showing the Spectranetics® TightRail device following the lead pathway. **B:** AP projection of the left side of the chest, showing how almost the entire lead is extracted. It also shows the guidewire used for the new implant.

## Discussion

We present a case of successful extraction of a passive fixation lead from a posterolateral coronary sinus vein with a mechanical extraction technique using a Spectranetics® TightRail mechanical rotational cutting sheath to improve the diaphragmatic stimulation symptoms in a patient with complete AV block, persistent left

superior vena cava and multiple intracardiac leads. While lead extraction due to diaphragmatic stimulation is uncommon, given the patient's symptoms and high risk of venous thrombosis with further lead insertion, it was decided to extract the lead before inserting a new one.

Today, percutaneous techniques for intracardiac lead extraction have become the method of choice for performing this type of procedure, and many



**Figure 3.** Chest x-ray following extraction of the VDD lead and implantation of a permanent dual chamber pacemaker. Anterior-posterior projection showing the final outcome. The arrow indicates the residual fragment of the extracted lead. The two previously abandoned leads are seen along with the two newly implanted leads.

successful cases have been reported, with different indications and using different approaches<sup>6,8,9,11-13</sup>. However, anatomical variants (in this case, persistent left superior vena cava), coupled with the location of the lead in the coronary sinus and its being a passive fixation lead, increased the procedure's degree of difficulty and risk of complications. There have been few cases of lead extractions in a left superior vena cava; one of these was attempted with mechanical and laser sheaths, and was finally able to be extracted through the femoral approach<sup>14</sup>. In another case, a high-energy lead was able to be extracted by laser<sup>12</sup>, and, in another patient, laser extraction was not successful<sup>15</sup>. Nevertheless, unlike the rest of the cases (in which the lead was located in the right ventricle), the location of the lead in our case (in a coronary sinus vein) is especially rare. Although this may have been due to an implantation error, this location, coupled with its being a passive fixation lead, made extraction especially difficult, increasing the risk of venous rupture. The previously reported cases described a marked difficulty in advancing the extraction sheath (especially laser sheaths) through the acute angle formed between the subclavian and left superior vena cava. Due to the tool's flexibility,

the use of rotational sheaths could be useful for patients with long-dwelling leads implanted through a persistent left superior vena cava.

## Conclusion

The use of a mechanical rotational cutting sheath to extract intracardiac leads, regardless of the indication, could be a useful and safe alternative in cases with persistent left superior vena cava.

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## Conflicts of interest

The authors declare no conflicts of interest.

## Ethical considerations

**Human and animal protection.** The authors declare that no studies were conducted on animals or humans in the course of this study.

**Data confidentiality.** The authors declare that they have followed their workplace protocols for patient data publication.

**Right to privacy and informed consent.** The authors have obtained informed consent from the patients and/or subjects referred to in this article. The corresponding author is in possession of this document.

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## Artificial intelligence applied to the diagnostic accuracy of left ventricular hypertrophy using electrocardiographic criteria

### *Inteligencia artificial aplicada a la precisión diagnóstica de hipertrofia ventricular izquierda mediante criterios electrocardiográficos*

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We were interested to read Cáceres et al.'s<sup>1</sup> article titled "Diagnostic accuracy of electrocardiographic criteria for left ventricular hypertrophy compared with echocardiographic findings," whose objective was to determine the diagnostic accuracy of electrocardiographic criteria compared to echocardiograms. Thus, we would like to contribute the following:

An electrocardiogram (ECG) is a basic, low-cost test that provides useful information on left ventricular hypertrophy (LVH); however, its sensitivity is 15 to 30%. Today, new strategies have been sought to provide more accurate diagnoses. Thus, with the advent of new technologies, artificial intelligence (AI) has recently achieved a very promising performance in terms of diagnoses and medical imaging, and has proven to have a better diagnostic performance than conventional methods, including the cardiologist's assessment<sup>2</sup>.

Liu et al.<sup>3</sup> developed an AI-based ECG model to detect LVH and predict cardiovascular death, with a sensitivity of 90.3% and a specificity of 69.3%, and compared it with the diagnosis made by cardiologists using a 12-lead ECG, with a sensitivity of 38.2% and specificity of 89.7%. Therefore, they noted that AI has more diagnostic accuracy and is a very useful tool for detecting LVH, even when patients have a variety of comorbidities. The cases diagnosed with this model were consistently associated with greater

cardiovascular mortality when validated externally with a Japanese cohort, concluding that automated ECG AI performs very well not only for early diagnosis, but also for predicting cardiovascular mortality.

Artificial intelligence significantly surpassed the conventional LVH criteria applied manually by cardiologists, including the Romhilt-Estes score, Cornell criteria and Sokolow-Lyon criteria. Kashou et al.<sup>4</sup> developed an AI-ECG algorithm in which they evaluated 20,000 patients with simultaneous ECGs and echocardiograms and determined that the algorithm combining ECG and electrocardiogram data functioned much better than the different scoring systems currently in use, as it obtained a 159.9% greater sensitivity than the specialists' performance. Although Cáceres et al.<sup>1</sup> stated that the Pegue-ro-Lo Presti electrocardiographic criteria were more sensitive and specific than other criteria, AI has been proven to surpass them, making it the most accurate diagnostic method today.

In conclusion, some criteria manually employed in medical practice have proven to have greater diagnostic accuracy than others; however, AI has less interpretive bias and greater sensitivity and specificity than all the currently proposed methods and their combinations. We recommend continuing research in this field, and having authors include AI in the proposed designs and comparisons to ensure that the most accurate method

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to date is being studied. It is advisable to continue performing studies to describe populations with different demographic characteristics and thus give rise to future interventions in this field, without ignoring the infrastructure, financial and digital capacity limitations that hospitals may have in adequately implementing these AI-based strategies and innovating in Colombian clinical practice.

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## Conflicts of interest

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## Ethical considerations

**Human and animal protection.** The authors declare that no experiments were conducted on humans or animals in the course of this study.

**Data confidentiality.** The authors declare that no patient data appear in this article. Furthermore, the authors have examined and followed the SAGER guidelines according to the type and nature of the study.

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**Use of artificial intelligence to generate text.** The authors declare that they have not used any type of generative artificial intelligence in drafting this manuscript or creating figures, graphs, tables or their respective captions or legends.

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## Optimization of protection in pediatric interventional radiology in Latin America and the Caribbean: participation and challenges for Colombia

### *Optimización de la protección en radiología intervencionista pediátrica en América Latina y el Caribe: participación y desafíos para Colombia*

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Dear Editor,

In its annex on pediatric exposures, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) recognized that future research areas should include the evaluation of the potential effects of radiation used on these patients during medical interventional procedures with fluoroscopic guidance<sup>1</sup>. These procedures include interventional cardiology (IC), which is increasingly used in pediatrics as a minimally invasive procedure that can replace more complicated surgical options. When fluoroscopy-guided IC procedures are performed in children, the dose of radiation may be relatively high and may cause tissue reactions, such as skin lesions<sup>2,3</sup>. For a given dose of radiation, children generally have a higher risk of tumor induction than adults. It is estimated that the risk of radiation-induced cancer in people exposed during childhood may be two to three times higher than in the average population<sup>4-6</sup>.

Therefore, measuring and possibly reducing the dose in pediatric patients, while maintaining image quality (protection optimization) should be a priority. Thus, the *Optimización de la Protección en Radiología Intervencionista Pediátrica en América Latina y el Caribe* (OPRI-PALC) [Protection Optimization in Pediatric Interventional

Radiology in Latin America and the Caribbean] program was born in 2018 as a joint response of the Pan-American Health Organization (PAHO) and World Health Organization (WHO), in cooperation with the International Atomic Energy Agency (IAEA), to help the member states meet the requirements of the International Basic Safety Standards<sup>7</sup>, particularly related to ensuring that pediatric patients are exposed to the minimum doses need to achieve their diagnostic or therapeutic goals<sup>8</sup>.

The objectives of this international proposal, which currently involves 33 facilities in 13 countries in the region, including Colombia, are:

- To promote a radiation safety culture in pediatric interventional medicine.
- To improve the quality of these procedures in the participating facilities.
- To establish optimization strategies based on the measurement and use of diagnostic reference levels (DRLs).
- To produce a consensus document for the region offering guidance for improving the optimization of radiation protection.

Understanding that establishing DRLs is a challenge as well as a necessity in pediatrics, because it is the

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most important tool for optimizing radiation protection in interventional studies, our group has been part of the first OPRIPALC results<sup>9,10</sup>. Finally, we would like to invite more Colombian facilities to join this international effort to progress together on a national research agenda to determine the DRLs in our country for the different types of interventional procedures, beginning with pediatric patients.

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## Ethical disclosures

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