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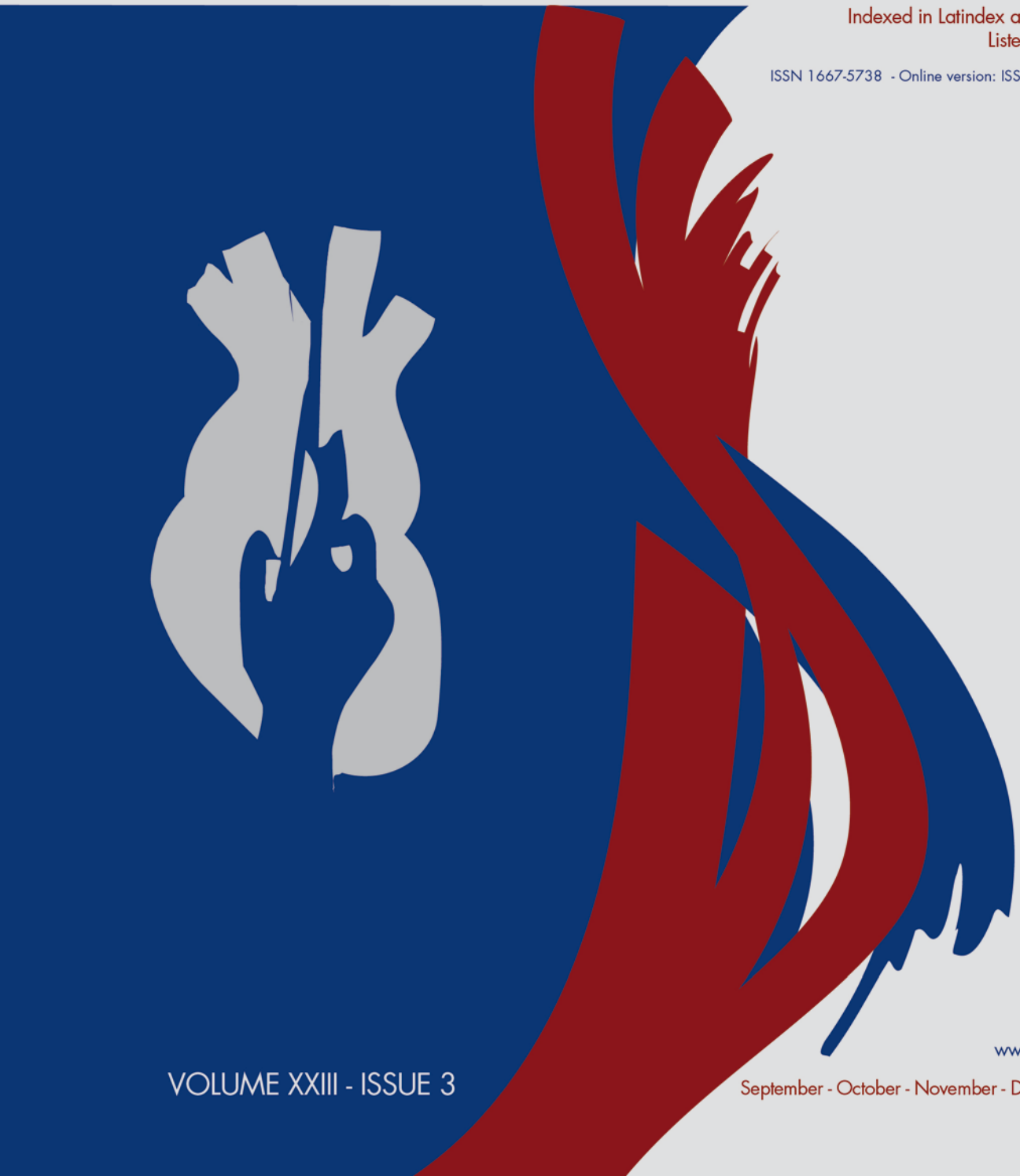

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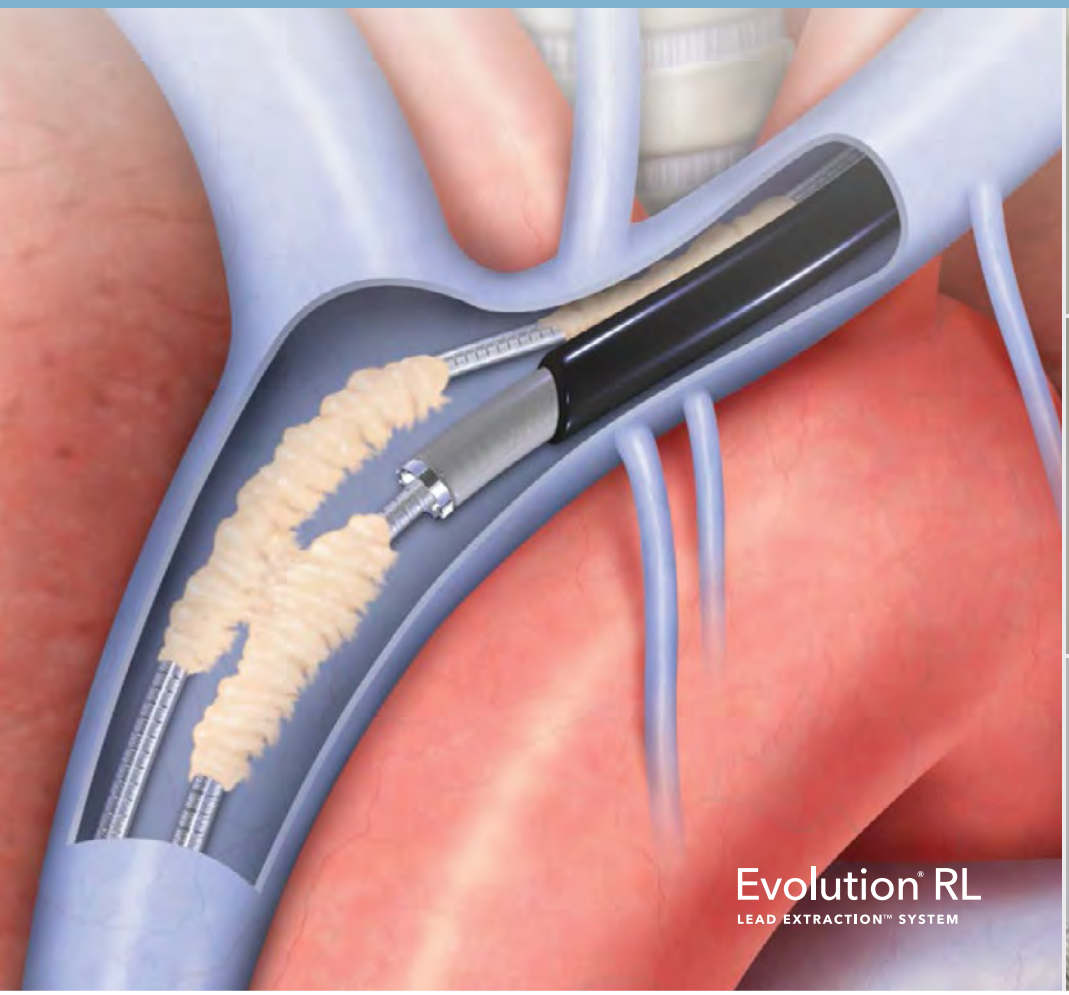

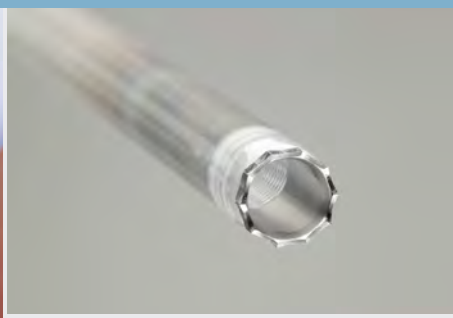

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SUMMARY

ORIGINAL ARTICLE

PREVALENCE OF CHRONIC VENOUS INSUFFICIENCY IN WORKERS OF THE HOSPITAL DE ALTA COMPLEJIDAD EL CALAFATE IN ARGENTINA

ABSTRACT

Introduction: Chronic venous insufficiency (CVI) is a frequent, yet underdiagnosed condition associated with significant health, social, and occupational impact. Prolonged standing has been identified as a crucial occupational risk factor.

Objective: To estimate the prevalence of symptomatic CVI among healthcare workers at the Hospital de Alta Complejidad El Calafate (Argentina), identify risk factors, and provide evidence for preventive strategies.

Methods: A cross-sectional observational study was conducted between February and April 2024. An anonymous, semi-structured, self-administered digital survey was distributed to all permanent staff (n = 588). Independent variables included sociodemographic, occupational, and clinical factors. The dependent variable was the self-reported presence of CVI symptoms. Logistic regression models were used to assess associations.

Results: A total of 239 valid responses were analyzed (response rate: 40.6%). Participants were predominantly women (74.9%), with a median age of 40 years (interquartile range, 34-47 years). Mean body mass index was 27.9 (standard deviation: 5.27); 27.6% met criteria for obesity, although only 17.6% self-identified as obese ($p < 0.0001$). Significant associated factors included female sex, prolonged standing ≥3 hours, family history of varicose veins, and arterial hypertension. Women reported a higher prevalence of CVI symptoms, as well as higher exposure to hormonal therapy and multiple pregnancies.

Conclusion: The prevalence of CVI symptoms in healthcare workers at a high-complexity hospital was considerable, particularly among women and those with occupational and familial risk factors. These findings support the implementation of preventive measures tailored to high-risk hospital staff.

Keywords: *cross-sectional studies; venous insufficiencies; healthcare workers; occupational health; Argentina.*

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INTRODUCTION

Chronic venous insufficiency (CVI) is defined as the functional inability of the venous system of the lower limbs to return blood, due to abnormalities in the venous wall and/or the valvular apparatus, leading to venous stasis caused by reflux.[1] The Union Internationale de Phlébologie (UIP) considers CVI as the set of changes in the lower limbs produced by sustained venous hypertension, including hyperpigmentation, eczema, lipodermatosclerosis, and ulcers.

Several publications have addressed its health, social, economic, and occupational impact.[2] Prolonged standing has been documented as a key risk factor. In the supine position, venous pressure in the lower limbs is approximately 10 mmHg, whereas in the standing position, it increases to 90 mmHg. While walking, this pressure is reduced to an average of 22 mmHg within fewer than a dozen steps, thanks to the propulsion generated by deep muscle contraction.

Pathophysiologically, prolonged standing prevents the effective activation of the calf muscle pump, thereby favoring sustained elevation of venous pressure and the progressive onset of signs and symptoms of the disease. This biomechanical relationship has led to the identification of certain professions as high-risk groups. In particular, hospital work has been suggested as a predisposing environment.[3]

Several individual and occupational factors have been associated with CVI, including female sex, advanced age, multiple pregnancies, overweight or obesity, sedentary lifestyle, smoking, occupational heat exposure, family history of venous disease, previous deep vein thrombosis, use of hormonal therapy, and chronic constipation.[4-7]

The objective of this study was to estimate the prevalence of symptomatic CVI among workers at the Hospital de Alta Complejidad El Calafate (Argentina), characterize the at-risk population, and contribute evidence for designing preventive strategies.

The hospital, located in the city of El Calafate (Santa Cruz province, Argentina), operates under a tripartite management model (70% national jurisdiction, 25% provincial, and 5% municipal). It belongs to the National Network of High-Complexity Hospitals known as "SAMIC" (Comprehensive Medical Care System for the Community). Its influence extends beyond the programmatic area of its department (Lago Argentino) to the healthcare corridor of the coal basin (Río Turbio and 28 de Noviembre). Moreover, due to its professional development, infrastructure, and technology, it has become a provincial referral center.

MATERIALS AND METHODS

We conducted an observational cross-sectional study to investigate the association between individual and group characteristics and the presence of signs and symptoms consistent with chronic venous insufficiency (CVI) among workers at the Hospital de Alta Complejidad El Calafate (Argentina).

The sample size was estimated based on an expected prevalence of 50% ± 10%, a design effect of 1.5, and different confidence levels. For a 95% confidence level, 125 participants were required; for a 90% confidence level, at least 92 participants were needed. The methodological selection was based on feasibility criteria, drawing on published prevalence data in healthcare personnel. The instrument used was a semi-structured digital survey, validated through a pilot test by expert professionals. A non-response rate of 31.3% was estimated, according to the National Survey on Employment Conditions, Work, Health, and Safety.[8]

The survey was sent to all permanent staff members (n = 588) via institutional email, the same used for salary receipts. A self-administered, anonymous Google form was available from February 11 to April 17, 2024. Participation was also encouraged through WhatsApp and by being present in hospital departments. Temporary or non-listed staff at the time of data collection were excluded.

Independent variables included: age, sex, prolonged standing or sitting without active breaks (≥3 hours), physical activity, exposure to high temperatures, body mass index (BMI), age group, job seniority, organizational division, type of task, family history of varicose veins, arterial hypertension, diabetes, smoking, hormonal therapy, oral contraceptive use, and number of pregnancies. The dependent variable was the self-reported presence of CVI symptoms. Variables such as physical activity (active/sedentary) and pregnancies (0–1 vs. ≥2) were dichotomized following reference criteria.

Measures of occurrence and association were estimated along with their respective 95% confidence intervals (CI95%), and statistical significance tests were performed. Univariate analyses and multivariate logistic regression were performed, including variables with $p < 0.05$ in the previous analysis. Models were evaluated based on their explanatory capacity, as measured by the coefficient of determination (pseudo-R^2), Akaike Information Criterion (AIC), variance inflation factor (VIF), and likelihood ratio test.

The multivariate logistic regression model in the sample was as follows:

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Where:
edad: age
generoVarón: male gender
tres_horasSi: three hours Yes
exp-tempSi: exposition to high temperatures Yes
imc: bmi
antec_fliaresAlMenosUnProgenitorConVárices: family history, at least one parent with varicose veins
antec_fliaresAmbosPadresConVárices: family history, both parents with varicose veins
activ_fisica_biActivo/a: physical activity, active
hta: hypertension

For a graphical representation of the model, a logarithmic scale was used to visualize odds ratios (OR) and 95% CIs symmetrically and comparatively.

The Hospital Research and Teaching Committee evaluated the project. According to the Ministry of Health Resolution 1480/2011, it was classified under exception "B," as individual identification was not possible.[9] Responses were anonymous, and participants confirmed that their data were non-traceable.

Informed consent was voluntary and recorded through exclusive acceptance boxes (Yes/No). In case of refusal, the form submission was blocked.

A sample size calculation was performed using OpenEpi v3.01 (2013). Data processing was conducted using Microsoft Excel (version 16.61) and RStudio (version 4.3.3).

RESULTS

A total of 247 responses were obtained, with a response rate of 42.0% and an effective rate of 40.6%, corresponding to 239 valid responses. This ensured adequate representativeness for the total population of 588 workers, with a confidence level close to 99%, a sampling error of 10%, and a design effect of 1.5.

Of the 239 participants, 176 were women (73.6%) and 63 were men (26.3%). The sample included staff from various areas: administration, kitchen, nursing, pharmacy, sterilization, imaging, surgical instrumentation, physical therapy, laboratory, laundry, housekeeping, medicine, nutrition, dentistry, and other technical services.

A comparison of age groups between the original hospital population (SAMIC) and the surveyed population revealed no significant differences (all p-values > 0.1). However, there was a higher proportion of women responding compared with their representation in the hospital workforce ($p = 0.001$).

The median age was 40 years (IQR: 34–47). The mean BMI was 27.9 (SD: 5.27). A total of 43.5% identified as physically active, 21.8% reported exposure to high temperatures at work, 17.6% had arterial hypertension, 8.4% diabetes, and 22.6% smoked. Among respondents, 17.6% self-perceived as obese, while the prevalence of obesity by BMI was 27.6%. Half of those classified as obese according to BMI did not perceive themselves as such. The association between perceived and measured obesity was statistically significant ($p < 0.0001$).

Regarding family history, 31.4% reported no family history of varicose veins, 51.5% had at least one affected parent, and 17.2% had both parents affected. The median job seniority was 8.4 years (IQR: 3.5-9.1). In terms of organizational departments, 45.2% worked in the Medical Department (DM), 20.1% in the Administration and Operations Department, and 22.6% in the Technical and Care Services Department; the rest were distributed among the Executive Department, the Infrastructure and Technology Department, and the Board of Directors. About physical activity, 24.3% reported high-impact exercise, 43.1% low-impact activity, and 18% weightlifting. A total of 5.9% reported receiving hormonal therapy, and 39.7% had no cardiovascular risk factors.

Table 1 presents the characteristics stratified by gender. Significant differences were observed in family history of varicose veins, job seniority, and use of hormone therapy. Women also showed a higher proportion of no reported physical activity and a higher prevalence of CVI symptoms. Among them, 26.8% reported use of oral contraceptives and 55.9% reported two or more pregnancies.

The overall prevalence of symptoms compatible with CVD was 75.3% (n = 180; 95%CI: 69.8-80.1), significantly higher in women (81.6%; 95%CI: 75.9-87.2) than in men (56.7%; 95%CI: 44.1-69.2), with p <0.001. Symptomatic individuals were older, had a higher BMI, and a greater prevalence of hypertension (*Table 2*). They also showed a stronger family history of varicose veins. A history of ≥2 pregnancies was more frequent among symptomatic individuals, although it did not reach statistical significance ($p = 0.06$). The proportion without CVRFs was lower among those with symptoms (45.8% versus 54.2%).

TABLE 1. Characteristics of participants according to expressed gender (n = 239)

Characteristic	Women (n = 179)	Men (n = 60)	*p*
Age (median, IQR)	40.00 (34.00-47.00)	40.50 (33.00-47.00)	0.907
Family history (n, %)			**<0.001**
No parent with varicose veins	53 (29.6)	22 (36.7)	
At least one parent with varicose veins	96 (53.6)	27 (45.0)	
Both parents with varicose veins	30 (16.8)	11 (18.3)	
BMI (mean, SD)	27.79 (5.62)	28.16 (4.10)	0.636
Seniority (years) (median, IQR)	8.66 (4.97-9.57)	6.69 (2.90-8.80)	**0.016**
Physical activity = Active (n, %)	78 (43.6)	26 (43.3)	1
High-impact activity = Yes (n, %)	40 (22.3)	18 (30.0)	0.306
Low-impact activity = Yes (n, %)	77 (43.0)	26 (43.3)	1
Weightlifting = Yes (n, %)	34 (19.0)	9 (15.0)	0.615
High temperature exposure = Yes (n, %)	39 (21.8)	13 (22.0)	1
Hypertension = Yes (n, %)	33 (18.4)	9 (15.0)	0.682
Diabetes = Yes (n, %)	16 (8.9)	4 (6.7)	0.779
Smoking = Yes (n, %)	41 (22.9)	13 (21.7)	0.984
Obesity = Yes (n, %)	33 (18.4)	9 (15.0)	0.682
Hormone therapy = Yes (n, %)	13 (7.3)	1 (1.7)	0.201
No cardiovascular risk factor (n, %)	61 (34.1)	34 (56.7)	**0.003**
Signs and sSymptoms of CVD = Yes (n, %)	146 (81.6)	34 (56.7)	**<0.001**

Source: Own elaboration.
CVD: chronic venous disease, IQR: interquartile range, SD: standard deviation.

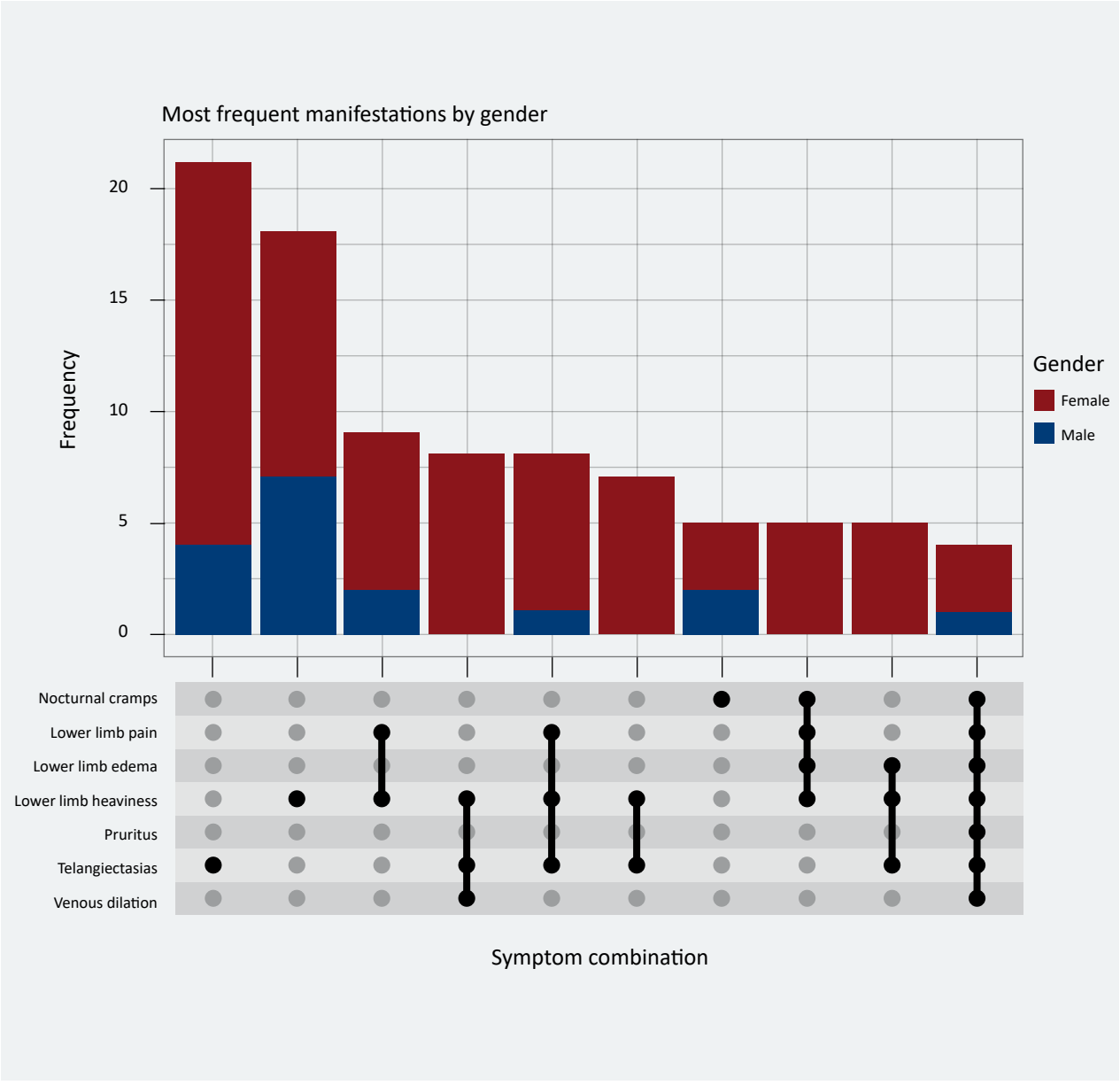
TABLE 2. Characteristics of participants according to the presence of symptoms (n = 239)

Characteristic	Asymptomatic (n = 59)	Symptomatic (n = 180)	*p*
Age (median, IQR)	38.00 (32.00-44.00)	41.50 (35.00-48.00)	**0.008**
Gender = Male (n, %)	26 (44.1)	34 (18.9)	**<0.001**
Family history (n, %)			**<0.001**
No parent with varicose veins	31 (52.5)	44 (24.4)	
At least one parent with varicose veins	25 (42.4)	98 (54.4)	
Both parents with varicose veins	3 (5.1)	38 (21.1)	
BMI (mean, SD)	26.51 (4.13)	28.33 (5.53)	**0.021**
Seniority (years) (median, IQR)	8.17 (3.14-8.96)	8.55 (4.78-9.85)	0.265
Physical activity = Active (n, %)	32 (54.2)	72 (40.0)	0.078
High-impact activity = Yes (n, %)	17 (28.8)	41 (22.8)	0.445
Low-impact activity = Yes (n, %)	27 (45.8)	76 (42.2)	0.745
Weightlifting = Yes (n, %)	11 (18.6)	32 (17.8)	**1**
High temperature exposure = Yes (n, %)	8 (13.6)	44 (24.6)	0.111
Two or more pregnancies = Yes (n, %)	18 (30.5)	82 (45.6)	0.060
Hypertension = Yes (n, %)	2 (3.4)	40 (22.2)	**0.002**
Diabetes = Yes (n, %)	3 (5.1)	17 (9.4)	0.436
Smoking = Yes (n, %)	14 (23.7)	40 (22.2)	0.952
Obesity = Yes (n, %)	6 (10.2)	36 (20.0)	0.127
Oral contraceptives = Yes (n, %)	11 (18.6)	38 (21.1)	0.825
Hormone therapy = Yes (n, %)	1 (1.7)	13 (7.2)	0.211
No cardiovascular risk factors (n, %)	32 (54.2)	63 (35.0)	**0.014**

Source: Own elaboration.
IQR: interquartile range, SD: standard deviation.

The symptoms appeared either in isolation or concurrently, mainly in women (*Figure 1*), with the most frequent combination being pain and heaviness in the lower limbs (LL). Telangiectasias, heaviness in the lower limbs, and nocturnal cramps were the only symptoms that occurred in isolation. Regarding specific symptoms, Figure 1 shows their frequency and co-occurrence.

FIGURE 1. Signs and symptoms of chronic venous insufficiency



Source: Own elaboration.

In the univariate analysis (*Table 3*), the following were significant: age, standing without breaks, BMI, hypertension, and family history. Physical activity showed a protective trend (OR = 0.55), although it did not reach statistical significance (p = 0.074). A history of ≥2 pregnancies and the use of contraceptives were not significantly associated with symptoms.

Among professions, "maintenance staff" showed a lower frequency of CVI (OR = 0.26; 95% CI: 0.09-0.64; p = 0.005), while "kitchen," "nursing," and "medicine" showed ORs >1, suggesting a trend toward a higher risk, although without statistical significance.

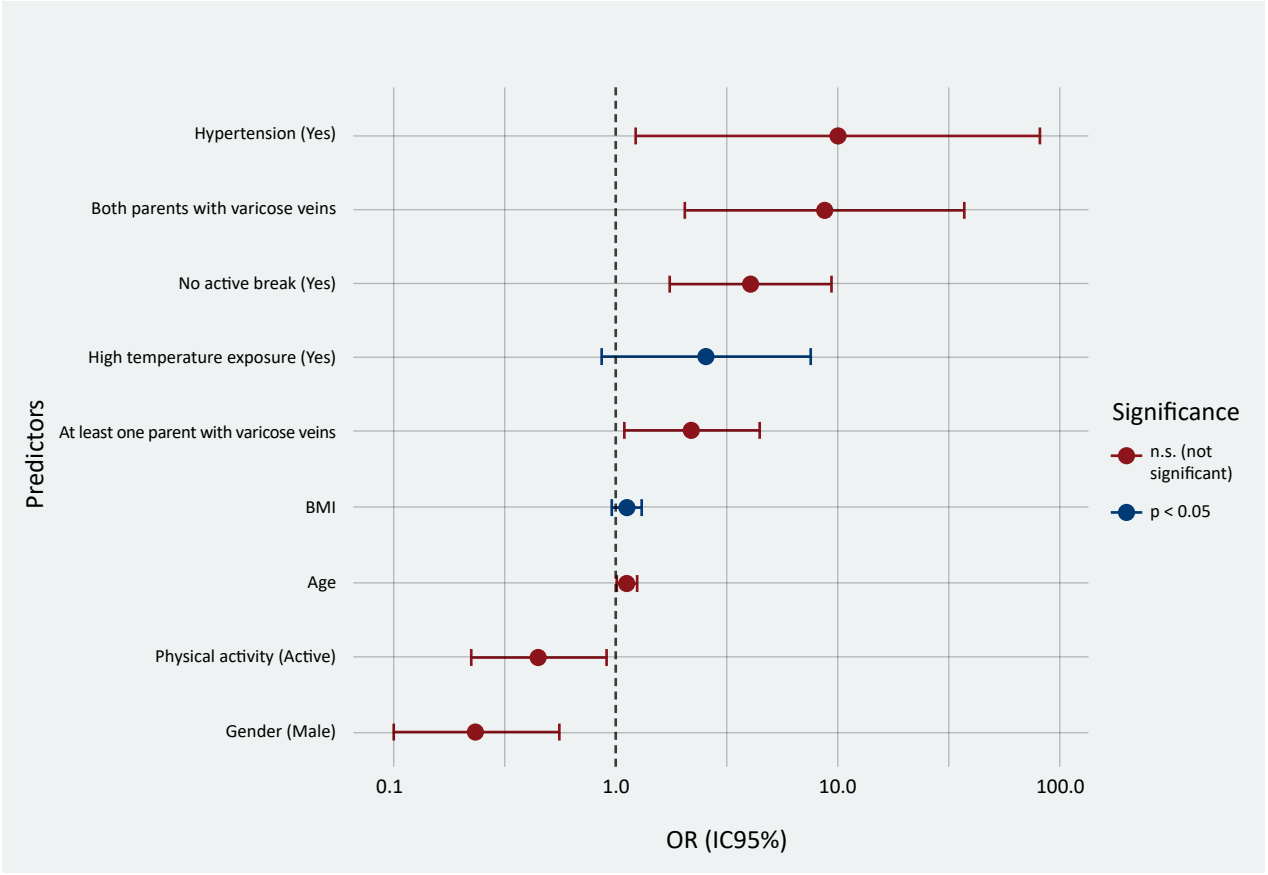
TABLE 3. Univariate regressions in both sexes (n = 239) and in women (n = 176)

	Both sexes			Women		
Predictor	**OR**	**CI95%**	***P***	**OR**	**CI95%**	***P***
Age	1.05	1.01-1.08	**0.001**	1.07	1.02-1.13	**0.005**
Active break = No	3.49	1.87-6.56	**<0.001**	3.5	1.58-7.83	**0.002**
High temperature exposure	2.08	0.96-5.03	0.080	5.19	1.47-33.0	**0.029**
Body mass index	1.08	1.01-1.15	**0.023**	1.10	1.02-1.21	**0.025**
One parent with varicose veins	2.76	1.11-3.39	**0.019**	2.34	1.04-5.30	**0.039**
Both parents with varicose veins	8.92	2.89-39.2	**<0.001**	12.9	2.41-239	**0.016**
Physical activity = Active	0.56	0.31-1.02	0.074	0.71	0.33-1.55	0.390
Hypertension = Yes	8.14	2.39-51.0	0.033	8.50	1.71-154	**0.039**
Job seniority (years)	1.06	1.00-1.13	0.050	1.09	1.01-1.19	**0.032**
Pregnancies (≥2 versus 0 to 1)	–	–	–	1.13	0.52-2.45	0.747
Oral contraceptives = Yes	–	–	–	0.64	0.28-1.49	0.280
Gender = Male	0.30	0.16-0.56	**<0.001**	–	–	–

CI95%: confidence Interval, OR: odds ratio.
Source: Own elaboration.

The multivariate model in both sexes (*Figure 2*) showed that being male was a protective factor (OR = 0.23; p <0.001), while having at least one parent with varicose veins (OR = 2.33; p = 0.028) and having hypertension (OR = 10.08; p = 0.032) were significantly associated with a higher risk. The model explained 39.6% of the variability of the phenomenon (Cragg-Uhler Pseudo-R^2 = 0.396).

FIGURE 2. Chronic venous insufficiency in both sexes (n = 233)



Source: Own elaboration
Note: Predictors with *p* <0.05 are shown in red. Bars represent 95% CI. n.s. = not significant.

DISCUSSION

Chronic venous insufficiency (CVI) among healthcare workers represents a priority field for occupational medicine. Evidence in Argentina remains limited, despite international studies reporting high prevalence in this group. The World Health Organization estimates that nearly 60% of nursing personnel present with CVI of the lower limbs.[10]

According to Benn et al. (2023), the mean prevalence of CVI among healthcare workers is 58.5%, higher than in the general population. In their review of 15 cross-sectional studies, the main associated factors were prolonged standing, female sex, age, obesity, and the nursing profession.[11] In our study, prevalence was even higher (75.3%), possibly due to the symptom-based approach applied. More than 80% of women and over 50% of men reported being symptomatic.

The Edinburgh Vein Study reported a higher age-adjusted prevalence in men (39.7%) than in women (32.2%).[12] Family history was strongly associated with the presence of varicose veins. Despite apparent contradictions with other studies, it has been noted that variables such as context, diet, and ethnicity influence the sex-related differences observed.[13]

In Germany, Kirsten et al. (2021) reported a prevalence of 3.6% in the working population, although differences were observed depending on occupational exposure. Significant factors included age, BMI, family history, physical exertion, and prolonged standing.[14]

In Italy, Rosati et al. (2019) found a high prevalence among nurses (37%) and women, with associated factors similar to those identified in our study: family history and prolonged standing.[15] In Mexico, Silva-Magaña et al. (2023) identified nurses and surgical technologists as particularly vulnerable groups due to their working conditions.[10] In Chile, a previous study noted heat exposure in kitchen areas as an additional risk factor for the development of CVI.[16]

Despite the high prevalence of symptoms, the use of preventive measures remains low. Only 2.7% of healthcare staff reported daily use of compression stockings, despite their proven efficacy.[17]

Our results are consistent with prior literature and provide representative evidence for Argentina. The

association between occupation and CVI risk revealed relevant trends: "janitorial services" appeared to confer possible protection, whereas "kitchen staff," "nursing," and "medicine" showed elevated odds ratios, although not statistically significant. This highlights the need for more targeted studies that consider the workplace environment.

The strengths of this study include the representativeness of the sample and its comprehensive approach to working conditions and risk factors. Limitations include the absence of clinical diagnosis and imaging, as well as the potential underrepresentation of certain occupational groups.

In Argentina, Decree 49/2014 recognizes bilateral varicose veins as an occupational disease when working conditions involve prolonged standing.[18] From a historical perspective, Ramón Carrillo had already emphasized the impact of working conditions as determinants of morbidity.

Considering these findings, implementing preventive programs in hospitals has become crucial. Institutional policies that incorporate education, active breaks, risk factor screening, and provision of physical measures could reduce the burden of venous disease among healthcare workers.

Declarations

The authors declare no conflict of interest.

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SCIENTIFIC LETTER

QUADRICUSPID AORTIC VALVE WITH SEVERE TYPE II AORTIC REGURGITATION

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ABSTRACT

Heart valve diseases are multifactorial conditions with a significant genetic and/or hereditary component. In such cases, structural alterations of the aortic valve are often observed, including a supernumerary cusp that forms a quadricuspid valve. This anomaly is closely associated with the onset and progression of aortic regurgitation, even under optimal medical management. In a small proportion of patients, the quadricuspid valve may also be associated with aortic stenosis.

A quadricuspid aortic valve is usually discovered incidentally, most often in the sixth decade of life.

We report the case of a female patient with a quadricuspid valve associated with severe type II aortic regurgitation who underwent successful surgical replacement with a biological aortic prosthesis.

Keywords: *quadricuspid aortic valve, aortic regurgitation, congenital cardiac malformation.*

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INTRODUCTION

Quadricuspid aortic valve (QAV) is a rare congenital and hereditary anatomical defect characterized by the presence of a supernumerary cusp. It is strongly associated with the onset and progression of aortic regurgitation, even with optimal medical management, and may occur in various positions relative to the coronary ostia.[1]

It is an uncommon anomaly, with a prevalence of less than 0.005%, according to a study conducted between 1982 and 1988 that identified only 8 cases in a cohort of 60,000 patients.[1] In 2001, a prevalence of 0.0059% was reported in a population of 357,228 participants, and in 2014, a prevalence of 0.0065% was found in a sample of 431,505 individuals. The mean age of patients with this condition is 43.5 years.[1] Cadaveric studies have reported incidences of 0.008%, and among patients undergoing aortic valve surgery, a prevalence ranging from 0.55% to 1.46% has been observed.[2]

The diagnosis of QAV is usually made as an incidental finding, generally by transthoracic echocardiography. However, when this anomaly is identified, transesophageal echocardiography may be indicated for further evaluation, as it provides a more accurate characterization of valve morphology and allows for a more detailed classification of the type of quadricuspid valve.[3,4] This condition is commonly associated with moderate to severe regurgitation, although a small group of patients may present with stenotic valves.[5] Other diagnostic methods, such as computed tomography and magnetic resonance imaging, are also used in preoperative planning.[6]

This anomaly presents in different variants depending on cusp size and position. Two central classification systems are used: Hurwitz and Roberts (*Table 1*) and Nakamura (*Table 2*).[3,6] Several studies report a higher prevalence of types A and B in the Hurwitz and Roberts' classification, which account for up to 32% of cases.[1]

Type	Description
A	Four equal cusps.
B	Three equal cusps and one smaller cusp.
C	Two larger equal cusps and two smaller equal cusps.
D	One large cusp, two intermediate cusps, and one small cusp.
E	Three equal cusps and one larger cusp.
F	Two larger equal cusps and two unequal smaller cusps.
G	Four unequal cusps.

TABLE 1. Hurwitz and Roberts' classification

Type	Description
I	Accessory cusp between the left and right coronary cusps.
II	Accessory cusp between the right coronary and non-coronary cusps.
III	Accessory cusp between the left coronary and non-coronary cusps.
IV	Indistinguishable accessory cusp due to the non-coronary cusp being divided into two equal parts.

TABLAE 2. Nakamura classification

Although the association between QAV and aortic dilatation is not strong, up to 29% of patients may present some degree of aneurysmal dilatation. Of these, 36% showed dilatation of the aortic root, another 36% of the ascending aorta, and 29% of both segments.[7]

The predominant problem in QAV is aortic regurgitation, which often requires surgery during the fifth or sixth decade of life.[8] Pure stenotic QAV is very rare, occurring in approximately 0.7% of cases.[9] Surgical intervention is indicated in severe regurgitation or stenosis, especially when left ventricular function is compromised (LVEF <50%). While surgical treatment is typically necessary in symptomatic patients, some remain asymptomatic until later stages of life, underscoring the importance of careful follow-up and individualized treatment plans.

QAV can coexist with other congenital defects, such as coronary anomalies or septal defects, complicating surgical decision-making. Reviews report associated congenital heart disease in 18-32% of patients.[10]

Although QAV usually presents as an isolated condition, in one non-surgical cohort, 19% had mitral valve prolapse; 2%, tricuspid valve prolapse; 2%, atrial septal defect (ASD); and 5%, ventricular septal defect (VSD). In the surgical cohort, 13% presented myxomatous mitral valve changes and 10% had coronary anomalies due to ostial malformations and dysplasia, more frequently with left ostial obstruction by the accessory cusp.[8,9] Reports also mention the possible presence of hypertrophic cardiomyopathy, bundle branch blocks, and complete atrioventricular blocks.[10, 11]

Decision-making regarding patient selection and surgical strategy is crucial, as not all patients with QAV necessarily require surgery.[12] Approximately one-fifth of patients ultimately undergo surgical intervention, highlighting the importance of a multidisciplinary approach.

CLINICAL CASE REPORT

A 63-year-old woman with a history of hypothyroidism, hypertension, and type 2 diabetes mellitus was followed by the cardiovascular surgery service due to progressive functional deterioration (NYHA class III/IV). An external echocardiogram of a tricuspid aortic valve showed severe insufficiency and preserved LVEF as evidenced by transthoracic echocardiography; admission was decided for scheduled open aortic valve replacement surgery.

Intraoperative transesophageal echocardiography revealed a quadricuspid aortic valve (*Figures 1* and *2*). Coronary angiography showed normal epicardial arteries. The patient underwent aortic valve replacement with a Medtronic Hancock II™ biological prosthesis No. 23 (SN: J140961) and annular enlargement, without complications.

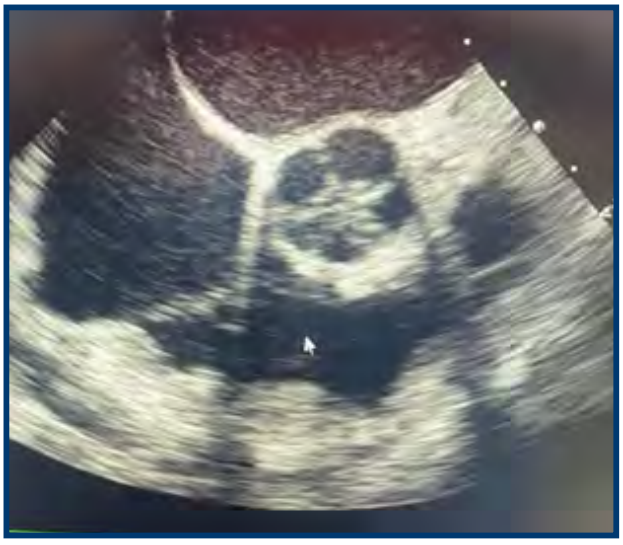

FIGURE 1. Intraoperative transesophageal echocardiogram. Mid-esophageal short-axis view of the aortic valve showing an "x"-shaped or cross-like appearance during diastole.

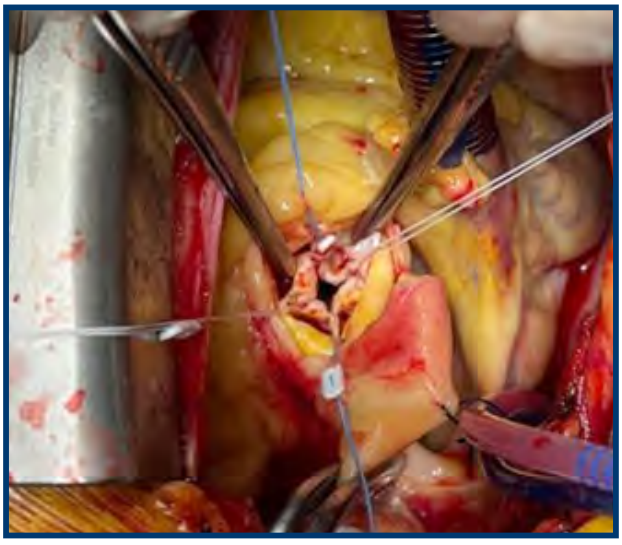

FIGURE 2. Intraoperative finding: native valve with four cusps.

At her one-month postoperative follow-up, the patient showed clear improvement in symptoms and functional class, with no wound complications or signs of infection.

Surgical techniques

The optimal surgical approach for patients with QAV and severe aortic stenosis or regurgitation may involve open surgical or transcatheter techniques,

depending on the patient´s specific condition and surgical risk. Recent studies have highlighted the efficacy of transcatheter aortic valve implantation (TAVI) and surgical repair techniques as alternative options to traditional valve replacement.[7,8]

Aortic valve replacement: Traditional surgical replacement remains a common approach, particularly in patients with significant comorbidities or those unsuitable for repair or TAVI, as in the present case.[13]

Tricuspidization and annular banding: The choice of technique depends on cusp flexibility and the presence of ascending aortic dilatation.[13] This approach involves reconstruction of the aortic root, correction of severe regurgitation, and replacement of the dilated ascending aorta.

Transcatheter aortic valve implantation (TAVI): This has shown promise for patients at high risk for traditional surgery. For example, an 83-year-old patient with severe aortic stenosis underwent successful TAVI with a self-expanding valve, demonstrating significant hemodynamic improvement.[14,15] Device choice (e.g., Evolut R™ or SAPIEN 3™) is critical, as specific designs minimize paravalvular leak and adapt to the unique anatomy of QAV.[16]

DISCUSSION

First described by Balinton in 1862, the quadricuspid aortic valve is a rare congenital anomaly with an incidence of less than 0.005% in the general population.[1,4] The mean age of presentation is 45-60 years, with a higher prevalence in men.[4] According to the Hurwitz and Roberts classification, type A is the most frequent, associated with aortic regurgitation in up to 75% of cases.[17] QAV generally presents as an isolated anomaly without associated congenital defects.[3,11]

We present the case of a female patient slightly older than the mean reported age. She had a type A QAV according to Hurwitz and Roberts, associated with severe type II aortic regurgitation, consistent with published data.[16,17] No other structural congenital heart anomalies were observed at diagnosis or during surgery. Her chronic symptoms mainly reflected functional limitation, an uncommon presentation given the absence of syncope or chest pain, as frequently described in the literature.[18-20]

Determining the optimal surgical approach for QAV requires careful consideration of valve function, associated anomalies, and the patient's overall health. Decision-making is a complex process that demands a comprehensive evaluation of these factors.

Although TAVI offers a less invasive alternative with favorable outcomes for high-risk patients, surgical repair may still be preferable when anatomy allows effective reconstruction. Ultimately, the choice depends on individual patient characteristics, the surgical team's expertise, and the use of advanced imaging modalities such as transesophageal echocardiography to assess valve morphology and associated anomalies.

In conclusion, quadricuspid aortic valve disease is a hereditary condition that, according to the current literature, typically manifests between the fifth and seventh decades of life and is strongly associated with mechanisms of aortic regurgitation. However, further statistical data are required to clarify its associations with sex, comorbidities, progression of regurgitation and/or stenosis, as well as morbidity and mortality in patients treated surgically versus those managed with optimal medical therapy.

ETHICAL CONSIDERATIONS

This study complies with the principles of respect for human dignity, confidentiality, beneficence, non-maleficence, and justice. The results will be used exclusively for scientific and academic purposes, in accordance with principles of good clinical research practice.

Declarations

The authors declare no conflict of interest.

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SCIENTIFIC LETTER

GREAT SAPHENOUS VEIN ANEURYSMS: A CASE SERIES AND SURGICAL APPROACH

ABSTRACT

Great saphenous vein aneurysms (GSVA) are an uncommon condition that presents a diagnostic challenge, often mistaken for other inguinal masses. Given their low prevalence and the potential risk of serious complications such as local thrombosis and pulmonary embolism, their correct identification and management are crucial. This article presents a series of three cases of GSVA in patients with chronic venous insufficiency, diagnosed using color Doppler ultrasound. In all cases, a proactive surgical approach was employed, resulting in favorable postoperative outcomes. This work highlights the importance of including GSVA in the differential diagnosis. It advocates that early detection and definitive surgical treatment are the preferred strategy to mitigate the risk of complications and ensure a favorable long-term prognosis.

Keywords: *venous aneurysm, venous insufficiency, pulmonary embolism.*

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INTRODUCTION

Venous aneurysms (VA) are defined as localized, abnormal, and permanent dilations of a vein segment, characterized by the presence of all three histological layers of the venous wall.[1] Unlike their arterial counterparts, venous aneurysms are considerably rare and often underdiagnosed. They may occur in any vein of the body. Still, their presence in the superficial venous system—particularly in the great or small saphenous vein—is of special clinical interest, as they may mimic other inguinal or crural conditions, such as inguinal hernias or soft tissue tumors.

Although Osler first described this entity in autopsies in 1915, the first documented symptomatic venous aneurysm leading to pulmonary embolism was reported by Dahl et al.,[2] involving a popliteal vein aneurysm.

The etiology of venous aneurysms is multifactorial and not always clear. Abbot et al.[3] proposed a classification that distinguishes between primary aneurysms (congenital or degenerative due to venous wall weakness) and secondary aneurysms (resulting from trauma, infections, arteriovenous fistulas, or states of chronic venous hyperflow). In the context of the great saphenous vein (GSV), its association with chronic venous insufficiency (CVI) is an important area of study, as both conditions may coexist and promote the development of these dilations.

Despite their rarity, the correct identification and management of GSV aneurysms are crucial due to the potential risk of severe complications, including local thrombosis (leading to pain, swelling, and induration of the mass), rupture (although rare, it can cause severe bleeding), and pulmonary embolism from thrombus migration within the aneurysmal sac.

The advent of non-invasive imaging techniques, such as color Doppler ultrasonography, has revolutionized the diagnosis of these lesions, allowing a detailed assessment of venous flow and confirmation of their vascular nature. This diagnostic tool is fundamental in differentiating venous aneurysms from other masses and in guiding appropriate treatment.

This article presents three cases of patients with CVI who consulted for lower limb masses, managed at our institution, highlighting the diagnostic challenges and surgical outcomes.

This review aims to enhance the understanding of this rare but clinically significant vascular pathology, contributing to early diagnosis and the implementation of treatment strategies that minimize complications and improve patient outcomes.

CASE REPORTS

Case 1

A 62-year-old male, with no relevant medical history, presented with persistent lower limb pain in the context of chronic venous insufficiency.

Physical examination revealed varicose collaterals in the inner aspect of the left leg.

Color Doppler ultrasonography of the lower limbs showed incompetence and dilation of the great saphenous vein (8 mm), with a saphenofemoral junction of 12 mm.

A left saphenectomy with resection of varicose collaterals was performed.

Left internal saphenectomy and resection of varicose collaterals were scheduled (*Figures 1A and B*).

Histopathology confirmed two saccular dilatations (0.8 cm) of the GSV, consistent with venous aneurysms, with intimal thickening replaced by fibrous connective tissue.

Case 2

A 68-year-old female patient, with no relevant medical history, presented with a mass in the right lower limb associated with pain. She brought an ultrasound of the skin and soft tissues of the inguinal region, which suggested a probable aneurysm of the great saphenous vein.

FIGURE 1. A: Preoperative surgical marking. Note the tumor marked with an oval on the inner aspect of the right thigh.

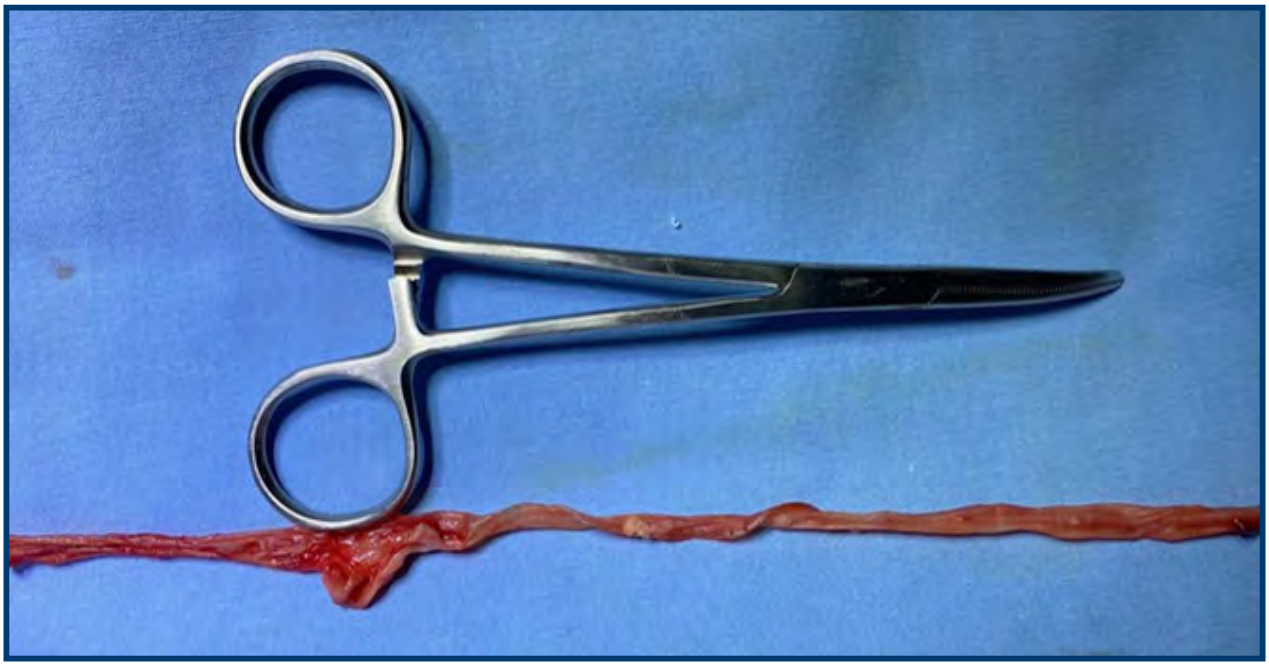

FIGURE 1. B: Surgical specimen showing aneurysmal dilatation of the great saphenous vein.

On physical examination, the right great saphenous vein was palpable along its entire course, appearing enlarged and associated with a mass in the inguinal region.

Venous Doppler ultrasound revealed a 14 mm right great saphenous vein junction with incompetence and dilatation along its course, as well as a 25 mm aneurysmal dilatation in the mid-thigh (Bush II). A dilated perforating vein with incompetence was also observed 18 cm from the plantar margin on the medial side. In addition, incompetence of the small saphenous vein (SSV) measuring 3 cm was identified, together with incompetence along the entire length of the left great saphenous vein, with a 3 mm junction.

A right great saphenectomy and resection of varicose collaterals were scheduled.

Pathological anatomy reported findings consistent with the great saphenous vein showing ectasia and luminal dilatation.

Case 3

A 70-year-old female patient presented with a mass in the left inguinal region, without any specific associated symptoms. A soft tissue ultrasound of the left crural region revealed a dilated vascular structure with aneurysmal characteristics, measuring approximately 30 × 15 mm. Additional evaluation with a Doppler study was recommended, and the patient was referred to the phlebology department for further assessment.

On examination, an inguinal mass of firm–to–elastic consistency was noted, non-reducible, with changes in size depending on the patient's position.

Venous Doppler ultrasound of the lower limbs reported the following:

Right side: Saphenofemoral junction: 7 mm, incompetent, great saphenous vein: 6 mm, incompetent, with collaterals in the thigh and leg re-entering via a perforating vein 34 cm from the sole. Small saphenous vein: 2 mm, competent. Deep venous system: competent.

Left side: Saphenofemoral junction: 10 mm, incompetent. Great saphenous vein: aneurysmal at 14 cm from the saphenofemoral junction, measuring 34 × 23 mm (**Bush Ia**) (*Figures 2A and B*), incompetent from the saphenofemoral junction down to the infrapatellar level. Epifascial collateral vein arising from the upper thigh, running along the medial thigh and leg. Incompetent perforating vein on the medial thigh, 54 cm from the sole, draining into the great saphenous vein at that level. At the medial aspect of the knee, the great saphenous vein is dilated (12 mm), incompetent, with collaterals in the thigh and leg. One collateral drains into the small saphenous vein 30 cm from the sole, which becomes incompetent from this point. Re-entry perforating vein in the posterior aspect of the leg, 28 cm from the sole. Additional re-entry perforating veins on the medial aspect at 32, 24, and 15 cm from the sole. Small saphenous vein: 2 mm, competent until it receives the collateral mentioned above (30 mm). Deep venous system: competent.

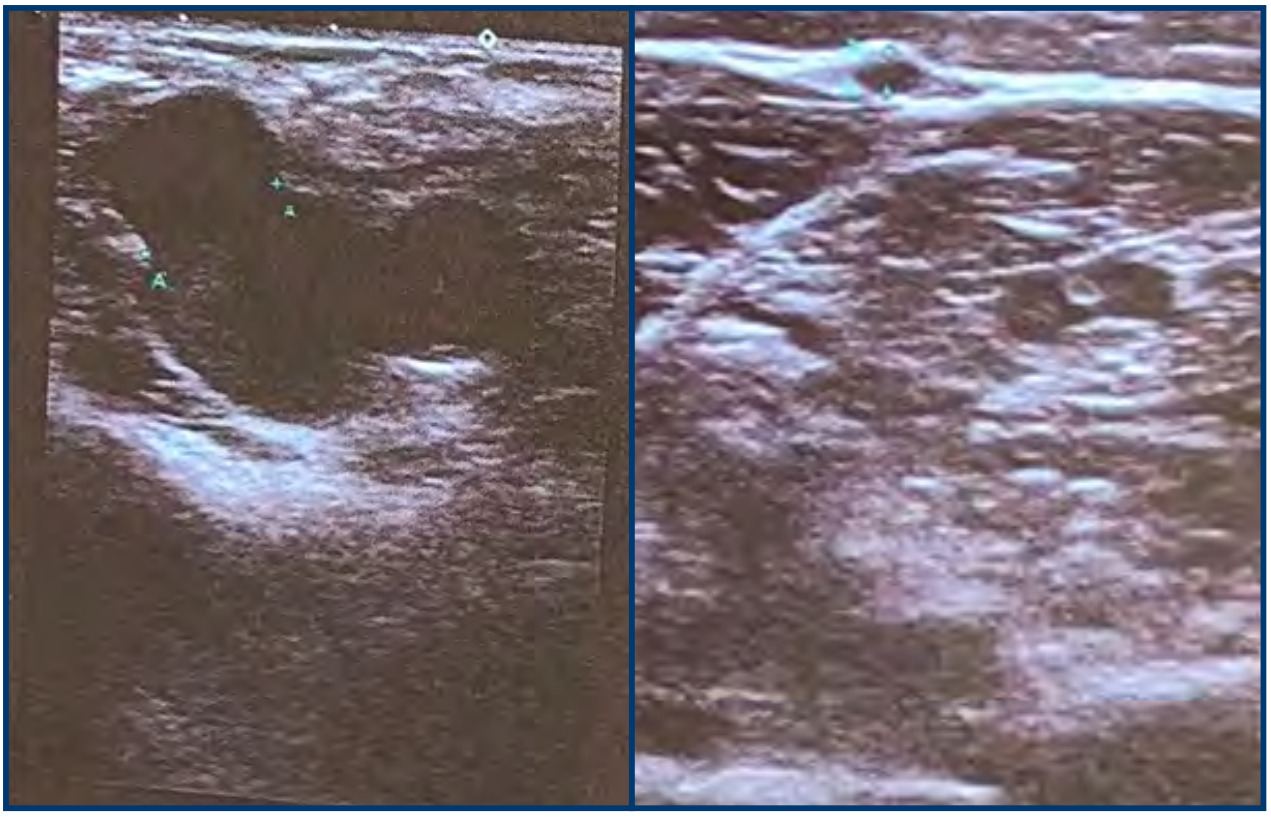

FIGURE 2. A: Axial view of the saphenofemoral junction, showing aneurysmal dilatation on the right side. **B:** Longitudinal view demonstrating venous wall dilatation consistent with an aneurysm.

Scheduled for left great saphenous vein stripping and resection of varicose tributaries (*Figures 3A and B*).

DISCUSSION

Venous aneurysms, particularly those affecting the superficial venous system, such as great saphenous vein aneurysms, are a rare entity that often poses a diagnostic challenge. Although the popliteal vein is the most common site, lesions in the superficial venous system are estimated to account for only 0.1% of cases.[4] Due to their low prevalence, these conditions are frequently underdiagnosed and misinterpreted as hernia-related masses; in some cases, they may even present as solitary masses without associated venous insufficiency. The variable presentations observed in Cases 1, 2, and 3 highlight the importance of timely identification and surgical management to achieve favorable postoperative outcomes.

A valuable tool for characterizing these lesions is the classification proposed by Bush et al.,[5] which groups superficial venous system aneurysms into six categories (Table 1). The cases reported in this study describe true dilatations corresponding to groups Ia (saphenofemoral junction) and II (mid or distal segment of the great saphenous vein), consistent with the predominant distribution of cases reported in the literature. The etiology of these dilatations is considered multifactorial. Irwin et al.[6] evaluated 8 patients with venous aneurysms to determine matrix metalloproteinase expression and suggested a potential causal role in the pathogenesis of these conditions. Their findings concluded that overexpression increases elastic fiber degradation, thereby promoting aneurysmal dilatation of the vessel wall.

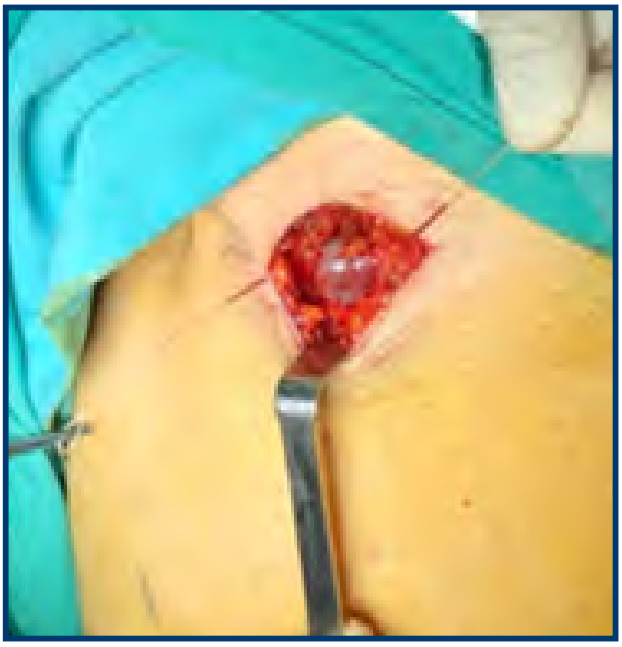

FIGURE 3. A: In-situ great saphenous vein aneurysm.

FIGURE 3. B: Surgical specimen following internal saphenectomy and aneurysmectomy.

TABLE 1. Classification of superficial venous aneurysms

Classification	Description
Ia	Involving the saphenofemoral junction
Ib	Distal to the subterminal valve
II	Involving the mid or distal segment of the great saphenous vein
IIIa	Various degrees of involvement of the saphenofemoral junction
IIIb	
IVa	Involving the saphenopopliteal junction
IVb	Lesions located more distally than the saphenopopliteal junction
Va	Involving the proximal anterior accessory saphenous vein
Vb	Involving the distal anterior accessory saphenous vein
VI	Not grouped within any of the other categories

Source: Adapted from Bush and Bush, 2014.

The diagnosis of great saphenous vein aneurysms fundamentally depends on clinical suspicion, detailed physical examination, and imaging techniques. Duplex color Doppler ultrasound of the lower limbs remains the gold standard among complementary tests, as it provides information regarding aneurysm size, flow characteristics, and its relationship with the deep venous system. In our cases, although ultrasound enabled the initial characterization of the lesions, it was during the physical examination that a venous aneurysm of the great saphenous vein emerged as a differential diagnosis. Computed tomography angiography (CTA) or magnetic resonance venography (MRV) may also be helpful, as suggested by Sessa et al.,[7] to confirm diagnosis and plan surgical management, particularly in relation to the saphenofemoral junction.

From a histopathological standpoint, findings can be highly variable, ranging from normal tissue to disorganization of the medial layers with or without inflammation, wall hypertrophy (preceding increased flow), and ultimately aneurysmal dilatation with sclerosis or calcification.[8]

Although several treatment options exist, no clear consensus has been established in the literature due to the low prevalence of this condition. Friedman et al.[9] described procedures such as aneurysmectomy with end-to-end anastomosis or venorrhaphy. However, in our patients with concomitant chronic venous insufficiency, complete aneurysm resection combined with internal saphenectomy was chosen. This decision is supported by evidence from Sessa et al.,[7] who suggested that aneurysmal dilatation may be associated with a state of chronic hyperflow and underlying venous ectasia. Furthermore, in 2022, Patel et al.[10] concluded that aneurysms occupying more than 25% of the venous lumen carry a high risk of thromboembolic complications, making surgical intervention particularly necessary in this group.

CONCLUSION

Great saphenous vein aneurysms are a rare condition (0.1%) that must be considered in the differential diagnosis of inguinal masses. Our case series demonstrates that, despite variable

clinical presentation, early diagnosis by Doppler ultrasonography is fundamental. Due to the potential risk of severe complications such as thrombosis and pulmonary embolism, proactive surgical management —consisting of aneurysm resection with concomitant saphenectomy in cases with chronic venous insufficiency—remains the treatment of choice to ensure a favorable prognosis and improved patient quality of life.

Declarations

The authors declare no conflict of interest.

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OPINION ARTICLE

RE-EVALUATING THE MATTERHORN TRIAL: A CRITICAL ANALYSIS OF ITS METHODOLOGICAL AND CLINICAL IMPLICATIONS

ABSTRACT

The MATTERHORN trial, the sole randomized controlled trial to date comparing mitral valve surgery with transcatheter edge-to-edge repair for functional mitral regurgitation in symptomatic patients ineligible for coronary artery bypass grafting, presents significant limitations. The exclusion of coronary artery bypass grafting is a critical omission, as it is the primary intervention for improving survival in these patients, with isolated mitral valve surgery predominantly addressing symptoms and quality of life. Moreover, numerous methodological deficiencies and inherent flaws compromise the trial's internal validity and its broader applicability in clinical practice. Therefore, a comprehensive re-evaluation, highlighting these biases, methodological shortcomings, and constraints, is essential, particularly as new clinical guidelines are anticipated.

Keywords: *mitral valve; mitral valve surgery; functional mitral regurgitation; randomized controlled trial; secondary mitral regurgitation; transcatheter edge-to-edge repair.*

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Introduction

The majestic Matterhorn, a towering peak of unparalleled prominence in the Alps, lends its name to a recent clinical trial, the MATTERHORN study, whose findings warrant meticulous examination within the cardiology community. This perspective piece undertakes a critical appraisal of the data presented by Baldus et al.,[1] emanating from the MATTERHORN trial (NCT02371512), a randomized controlled trial (RCT) sponsored by Abbott Vascular.[2]

The MATTERHORN trial set out to assess the comparative efficacy and safety between transcatheter edge-to-edge repair (TEER) and surgical mitral valve (MV) repair or replacement in patients suffering from heart failure (HF) and functional mitral regurgitation (FMR) who remained symptomatic despite receiving guideline-directed medical therapy (GDMT). The primary efficacy endpoint was a composite of clinical events at one year, while the primary safety endpoint tracked major adverse events within 30 days. Specifically, the one-year efficacy composite included death, HF rehospitalization, MV reintervention, left ventricular (LV) assist device implantation, or stroke. The trial's key finding asserted the non-inferiority of TEER to MV surgery regarding this composite endpoint at one year.[1]

Considering that the MATTERHORN is the only RCT directly comparing these two treatment modalities for FMR, a detailed critical appraisal of its reported outcomes is imperative. This analysis will highlight the methodological caveats and clinical implications that may impact the study's reliability and generalizability, thereby influencing future clinical practice.

Inconsistencies in the reporting: discordance between registry data and published results

To begin with, the official registry for the MATTERHORN trial reveals a discordance between the anticipated study timeline and the actual reporting of results. Initiated in 2015, the trial was slated for completion by 2019; however, the last reported data update occurred in 2017, with a conspicuous absence of subsequent registry updates. According to established protocols, a registry that remains inactive for an extended period (>2 years) without reported updates is deemed closed, thereby warranting an "unknown status" designation.[2] This anomaly is particularly pronounced in juxtaposition with the assertion by Baldus et al.[1] that patient randomization in MATTERHORN spanned from February 2015 to December 2022, encompassing a total of 210 patients. The purportedly prolonged enrollment period starkly contrasts with the publicly available registry data,[2] underscoring a notable disparity between the two sources.

In addition, given the considerable temporal gap between the initiation of enrollment in 2015 and the publication of the study (9 years), it is striking that the follow-up period is limited to a single year. One should expect a more protracted follow-up duration, extending to five years or beyond, to provide a more comprehensive understanding of the outcomes.

Methodological concerns: the mirage of non-inferiority

The methodological design of the MATTERHORN trial reveals several significant concerns, particularly in its reliance on the intention-to-treat (ITT) principle. While ITT analysis ensures that all randomized patients are included regardless of protocol adherence or withdrawal, including even those who are deceased, it provides a pragmatic assessment. However, this approach can also dilute actual treatment effects, especially in non-inferiority designs. Baldus et al.[1] reported 19 events (18.2%) in the TEER group (out of 104 patients) and 26 events (25%) in the MV surgery group (out of 104 patients) for the primary efficacy endpoint at one year. This translated to a non-significant p-value of 0.234, with a 6.8% difference (95% confidence interval [95% CI]: -4.42% to 17.84%).

A crucial aspect of non-inferiority trials is the statistical threshold. The use of a one-sided *p*-value of 0.025, as opposed to the more common two-sided 0.05, is often employed given the directional hypothesis.[3] However, our analysis, with a *p*-value of 0.234, suggests the observed differences between TEER and MV surgery are more likely due to random variation than a statistically meaningful effect.

Furthermore, interpreting non-inferiority studies demands a careful balance between statistical significance (*p*-value) and clinical relevance (effect size and confidence interval). The non-inferiority margin itself is central to this interpretation, and its derivation warrants meticulous scrutiny. The authors assumed an average 35% incidence of adverse events for their primary endpoint, resulting int a non-inferiority margin of 0.175.[1] The lack of clarity regarding the evidence or database supporting this 35% event rate is concerning. A higher assumed event rate can artificially broaden the non-inferiority margin, potentially skewing results towards non-inferiority. This is a notable dilemma in the MATTERHORN trial. The reported Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) of 2.2%[1] indicates a low-

risk cohort. Current data, such as that from Newell et al.,[4] suggest that patients undergoing MV repair with an STS-PROM ≤2% exhibit a composite mortality and morbidity rate of 8.03%, substantially lower than the 19.24% observed in those with STS-PROM >2%. Even assuming the MATTERHORN cohort had an STS-PROM >2%, their expected event rate would still not exceed 19.24%, falling considerably short of the 35% threshold proposed by the investigators.

The inclusion of soft endpoints can inflate event rates and, consequently, widen the non-inferiority margin, potentially benefiting the trial's outcome. In MATTERHORN, the one-year primary efficacy composite endpoint was driven mainly by reintervention [7.6% for TEER versus 18.5% for MV surgery; difference in proportions = -0.12 (-0.23; -0.01)] and rehospitalization for any cause.[1] Closer examination of reintervention rates reveals inconsistencies between 30-day and one-year reporting: the MV surgery group had more reinterventions at 30 days (10 cases) than TEER (7 cases), but at one year, the pattern shifted, with only 2 cases in MV surgery versus 5 in the TEER group. The lack of specific causes for early reinterventions further diminishes confidence in the accuracy of this outcome.

Furthermore, while rehospitalization for any cause demonstrated statistical significance between TEER and MV surgery [24.7% versus 39%; difference in proportions = -0.14 (-0.28; -0.004)], a deeper dive into specific causes reveals that only "other causes" (unrelated to HF or cardiovascular issues) reached statistical significance [13.9% versus 15.9%; difference in proportions = -0.02 (-0.13; 0.09)].[1] This raises questions about the appropriateness of including such non-specific events in a primary efficacy composite. The dilution of specificity, turning HF rehospitalization (3% versus 6.9%, $p = 0.1969$ at one year) into the broader "rehospitalization for any cause" underscores the critical importance of rigorous endpoint selection and definition, particularly for non-inferiority assessments. Adding to this complexity, the disparate implications of the non-inferiority margin for MV repair versus replacement procedures make their amalgamation potentially problematic, especially given that 28% of cases required MV prostheses.[1] By the same token, the broad variability in surgical MV repair techniques further reported in this RCT introduces confounding variables that could compromise the study's internal validity.

It is widely recognized that ITT analyses, when not complemented by per-protocol analyses, can obscure genuine differences between treatment arms due to protocol deviations.[3] Non-inferiority trials typically demand consistent conclusions from both ITT and per-protocol analyses. However, the MATTERHORN trial relied solely on an ITT analysis to declare non-inferiority, a methodological choice that may compromise the study's overall validity and credibility.

Limitations in functional mitral regurgitation phenotyping

A critical limitation of this study lies in its undifferentiated inclusion criteria concerning FMR. The current criteria, encompassing echocardiographic quantitative parameters [effective regurgitant orifice area (EROA), regurgitant volume, vena contracta, and regurgitant fraction], a history of recurrent HF hospitalizations, left ventricular ejection fraction (LVEF) ≥20%, Heart Team adjudicated high surgical risk, and New York Heart Association Class II-IV symptoms despite optimal GDMT, do not adequately distinguish between atrial-type FMR and ventricular-type FMR.

The lack of precise phenotyping is significant because atrial-type and ventricular-type FMR represent distinct pathophysiological entities with divergent prognoses, especially after MV intervention, regardless of TEER or surgical MV repair/replacement. Patients diagnosed with ventricular-type FMR demonstrate significantly poorer clinical outcomes compared to those with atrial-type FMR. Specifically, ventricular-type FMR is associated with a higher incidence of all-cause mortality [adjusted hazard ratio (HR) = 1.73, 95% confidence interval (CI 95%): 1.54-1.94, $p < 0.001$], and HF hospitalization (adjusted HR = 1.23, 95% CI: 1.15-1.32, $p < 0.001$).[5] The echocardiographic assessment utilized in this RCT does not facilitate this crucial differentiation, potentially obscuring the actual impact of interventions on specific FMR subtypes.

The patient demographic of the MATTERHORN trial is complex. While 43.7% had ischemic heart disease not requiring coronary artery bypass grafting (CABG), suggesting ischemic dilated cardiomyopathy, the extent of non-ischemic dilated cardiomyopathy remains unclear. Mitral regurgitation mechanisms were split: 46.9% exhibited LV tethering (Carpentier type IIIb), while 53.1% had annular dilation (Carpentier type I).[1] The latter group likely overlaps with 51% with a history of atrial fibrillation, indicating atrial-type FMR. This distinction is vital, as atrial-type FMR typically carries a more favorable prognosis than ventricular-type FMR, especially

post-intervention. Therefore, the high proportion (53.1%) of presumptive atrial-type FMR cases detected in the MATTERHORN trial, representing a lower-risk population, likely favored a non-inferiority finding, thereby limiting and essentially precluding the applicability of its results to the more common ventricular-type FMR secondary to ischemic heart disease requiring CABG.

High surgical risk: misused as a treatment rationale

It is important to note that while high surgical risk, as determined by the Heart Team, is an inclusion criterion for MATTERHORN, it does not guide the selection of specific treatments for FMR. Indeed, neither the American Heart Association (AHA) and American College of Cardiology (ACC) 2020 guidelines (AHA/ACC 2020) for the management of patients with valvular heart disease (VHD)[6] nor the European Society of Cardiology (ESC) and European Association for Cardio-Thoracic Surgery (EACTS) 2021 guidelines (ESC/EACTS 2021) for the management of VHD[7] base FMR treatment decisions on surgical risk.

Constraints on clinical applicability: a trial detached from real-world practice

The MATTERHORN trial's singular position as the only RCT comparing MV surgery with TEER for FMR prompts inquiry into its underlying rationale. The limited indications for isolated MV surgery in FMR in the absence of concomitant CABG —the specific patient population of this trial— likely explain this gap in evidence.[8]

Current clinical guidelines from both the 2020 ACC/AHA[6] and 2021 ESC/EACTS[7] for VHD clearly differentiate the management of severe FMR based on the presence of concomitant CABG. MV surgery receives a Class I indication with CABG, while TEER, which does not involve CABG, is a class IIa indication. Conversely, isolated MV surgery without CABG is merely a class IIb indication.[6,7] Astonishingly, the MATTERHORN trial enrolled no patients who underwent CABG, and those who had CABG within a month of enrollment were explicitly excluded. Essentially, the investigators sought to establish non-inferiority of a Class IIa indication (TEER) against a Class IIb indication (MV surgery without CABG) —a comparison that appears both questionable and clinically unnecessary.

Further complicating the surgical arm, Chikwe et al.[9] and García-Villarreal et al.[10] observed that while 72% of the surgical cohort underwent MV repair and 28% underwent MV replacement, no further details were provided regarding the specific prosthesis type (mechanical or biological) in 53.6 % of the series.[1] The surgeon's discretion governed the choice of surgical technique, an unstandardized and arguably lax approach for a multicenter trial where methodological consistency is paramount. The ultimate event count could be skewed by the ratio of repair to replacement procedures. Reoperation rates are expected to be higher in MV repair than in MV replacement (34% at one year, 59% at two years).[11,12] This disparity disproportionately impacts the primary composite outcome, potentially conferring an inherent advantage to TEER.

Lancellotti et al.[13] emphasized the importance of stringent echocardiographic criteria for successful MV repair in FMR. However, the MATTERHORN trial did not specify criteria for MV repair type. This is particularly critical when CABG is not part of the treatment plan, and the risk of recurrent mitral regurgitation (MR) is elevated. While LV remodeling dictates MV repair techniques (annular or subvalvular, with or without chordal/papillary muscle intervention),[8] the MATTERHORN trial provided no such details. Similarly, although the specific annuloplasty ring type may not be decisive, a strong consensus favors complete rings, especially given FMR's characteristic MV anteroposterior deformation. Etiology-specific rings have shown promise in achieving long-term freedom from MR.[14-18] Of note, the MATTERHORN trial again offered no information in this regard.

Questionable inclusion and severity criteria of MR

A further concern revolves around the inclusion criterion of EROA ≥20 mm^2.[1] Both the 2020 ACC/AHA[6] and 2021 ESC/EACTS[7] guidelines for VHD specify that only patients with severe FMR, defined by EROA ≥40 mm^2, regurgitant volume ≥60 mL, and regurgitant fraction ≥50%, are candidates for interventional treatment. In the MATTERHORN, the baseline median EROA was 20 ± 10 mm^2, ranging from 17 to 28 mm^2, indicating mild (1+) or mild-to-moderate (2+) MR. Critically, specific results coming from different MR subgroups [mild (<20 mm^2), mild-to-moderate (21-29 mm^2), moderate-to-severe (30-39 mm^2), and severe (≥40 mm^2) MR], according to Lancellotti et al.[13] and Zoghbi et al.,[19] were not provided in this RCT. At baseline, 59.8% had moderate-to-severe (3+) MR (30-39 mm^2), and only 37.3% had severe (4+) MR (≥40 mm^2).[1] Wang et al.[20] also noted that approximately 60% of MATTERHORN patients had non-severe FMR. This implies that only about one-third of the MATTERHORN participants would meet current guideline criteria for MV intervention,[6,7] thus

raising significant doubts about the trial's actual applicability to patients needing more than medical therapy.

Methodological shortcomings and missing information

Chikwe et al.[9] highlighted additional methodological shortcomings, including substantial patient dropout (11.9%) and significant missing data (e.g., 16.3% for 30-day mortality in the surgical group). Similarly, Baldus et al.[1] reported in the supplementary appendix considerable missing echocardiographic data at one year for parameters like vena contracta (62.5% for 2-chamber, 64.4% for 3-chamber), systolic pulmonary artery pressure (53.8%), LV end systolic diameter (43.2%), LV end diastolic diameter (43.2%), LVEF (43.2%), and LV end diastolic volume (44.2%). Such extensive data loss at follow-up severely compromises the study's reliability and generalizability.

Deficiencies in guideline-directed medical therapy adherence

Furthermore, the reported treatment adherence in MATTERHORN appears suboptimal. Concomitant ablation was performed in only 35.4% of patients with preoperative atrial fibrillation, and 10.5% of surgical patients received triple HF therapy.[9] The 2022 AHA, ACC and Heart Failure Society of America (HFSA) guidelines for the management of patients with HF with reduced ejection fraction (HFrEF), prevalent in more than 50% of patients with FMR, advocate for GDMT encompassing four cornerstone medication classes: mineralocorticoid receptor antagonist (MRA), beta blocker (BB), angiotensin receptor-neprilysin inhibitor (ARNi), and sodium-glucose cotransporter 2 inhibitor (SGLT2i), all with class IA recommendations.[21] Fonarow et al.[22] demonstrated that delaying or omitting GDMT in HFrEF significantly increases adverse outcomes, with omissions of SGLT2i, ARNi, and MRA linked to increased all-cause mortality and HF hospitalization. Baldus et al.[1] showed that only 19.3% of the total cohort received triple GDMT at discharge (27.5% in TEER versus 10.5% in MV surgery). MRA were prescribed in only 26.4%, ARNi proportions remain unknown, and SGLT2 inhibitors were absent,[1] despite their approval for HFrEF since May 2020[23] and the trial's enrollment extending to December 2022, according to MATTERHORN authors.[1] Furthermore, the post-procedural success of both surgical MV repair or replacement and TEER is heavily contingent upon the uptitration, continuation, and high quality of GDMT.[24]

Critical omissions, unaddressed metrics in outcome assessment

The MATTERHORN trial also failed to assess crucial post-procedural outcomes, such as residual MR or trans-mitral gradients, as primary efficacy endpoints. Optimal TEER outcomes depend on achieving specific hemodynamic targets, including residual MR ≤1+, MV area >2.0 cm^2, mean trans-mitral gradient < 5 mmHg, and pressure half-time <100 milliseconds post-procedure.[25] The absence of data on post-TEER trans-mitral gradients or MV area in the MATTERHORN study is a significant oversight.

Finally, structural failure rates of MV repair, regardless of whether the approach is surgical or percutaneous, have emerged as a more robust quality metric than reoperation rates, which are influenced by numerous patient and clinician variables.[26] The omission of structural failure rate as a hard endpoint in the MATTERHORN's primary composite outcome for efficacy is highly questionable.

Conclusion: a trial that falls short of its aspirations

While evocatively named after a mountain of great altitude, the MATTERHORN trial ultimately fails to reach equivalent scientific heights. In sum, for patients with FMR, particularly given that ischemic ventricular-type FMR is the overwhelmingly predominant phenotype encountered in clinical practice, the benefits of isolated MV surgery are largely palliative, addressing symptoms and improving quality of life. Conversely, CABG remains the primary driver of survival benefits in this population.[8] The trial excludes CABG, misclassifies MR severity, differentiates FMR phenotypes inadequately, underutilizes GDMT, and neglects critical endpoints; consequently, it offers limited guidance for real-world practice. Its methodology is undermined by significant limitations that preclude meaningful changes in clinical paradigms for managing FMR. Thus, the comparison between the majestic Matterhorn peak and the eponymous RCT appears tenuous, bearing little resemblance to the complex realities of clinical practice.

Declarations

The author declares no conflict of interest.

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DR. ENIO BUFFOLO (1941-2025)

Today, we pay tribute to a giant of cardiovascular surgery: Dr. Enio Buffolo, whose passing leaves a profound void in Brazilian medicine and in all of us who followed his remarkable career.

Born on December 9, 1941, in São Paulo, Brazil, he entered the *Escola Paulista de Medicina* (EPM) in 1960 and graduated in 1965 among the top students of his class. He completed his residency in cardiovascular surgery, pursued advanced training abroad (at the Cleveland Clinic), and perfected coronary revascularization techniques.

Over time, Enio became one of the foremost leaders of heart surgery in Brazil. He developed pioneering techniques in off-pump myocardial revascularization ("heartbeat surgery") and in the endovascular treatment of aortic aneurysms. His group operated on thousands of patients, trained generations of cardiovascular surgeons, and solidified Brazilian cardiac surgery on the international stage.

A Full Professor in the discipline of Cardiovascular Surgery at UNIFESP, he published more than 100 scientific articles —over 100 of them indexed in PubMed— and served as President of the Sociedade Brasileira de Cirurgia Cardiovascular and of the Sociedade de Cirurgia Cardiovascular do Estado de São Paulo, in addition to holding the position of Vice President of the Sociedade Brasileira de Cardiologia.

Enio, a close friend of our Argentine College of Cardiovascular Surgeons, participated in countless lectures and panels at our congresses and cardiovascular meetings, demonstrating not only his forward-thinking vision but also the character of a man deeply committed to his patients, teaching, and community.

Through his active participation in the equestrian world, this true *turf tifoso* also revealed another facet of his life beyond the operating room.

Dr. Enio Buffolo passed away on October 6, 2025, at the age of 83. His departure was announced by numerous medical and sporting institutions, which recognized him not only as a master of surgery but also as an exemplary citizen. Those of us who had the opportunity to know his work and draw inspiration from it understand that the greatest tribute we can offer is to continue along his path: to work with excellence, humanity, and innovation, always seeing the patient as a whole person. In doing so, Dr. Enio Buffolo will remain alive in the heart of cardiovascular surgery.

Editorial Committee

Dr. Enio Buffolo, an international leader in cardiac surgery, visited Mar del Plata in 1998 for the Hispanic-Luso-American Meeting of Cardiovascular Surgeons.

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