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EDITORIAL
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When expansion outpaces certainty: Transcatheter Aortic Valve Replacement in patients younger than 65 years

Cuando la expansión supera la certeza: reemplazo valvular aórtico transcatéter en pacientes menores de 65 años

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Keywords: aortic stenosis, federal drug administration, low surgical risk, transcatheter aortic valve replacement, surgical aortic valve replacement.

Palabras clave: *estenosis aórtica, administración federal de medicamentos, bajo riesgo quirúrgico, reemplazo valvular aórtico transcatéter, reemplazo valvular aórtico quirúrgico.*

Abbreviations:
TAVR = Transcatheter Aortic Valve Replacement
STS = Society of Thoracic Surgeons
ACC = American College of Cardiology
FDA = Food and Drug Administration

The contemporary evolution of Transcatheter Aortic Valve Replacement (TAVR) into progressively younger populations represents one of the most consequential shifts in structural heart disease over the past decade. In their national analysis from the STS/ACC TVT Registry, Alabbadi et al. document not merely an epidemiologic trend, but a conceptual transformation in the management of patients younger than 65 years with aortic stenosis.[1]

TAVR was originally reserved for individuals at prohibitive or extreme surgical risk. Following regulatory expansion by the U.S. Food and Drug Administration (FDA) in 2019,[2] TAVR entered the low-risk arena, supported by pivotal randomized trials such as PARTNER 3[3] and Evolut Low Risk.[4] These studies demonstrated non-inferiority, and in some cases, superiority, relative to surgery within carefully defined populations and limited follow-up horizons. Regulatory approval followed. Clinical adoption accelerated. What the present registry analysis reveals is the magnitude of that acceleration.

Between 2012 and 2024, the number of hospitals performing TAVR in patients younger than 65 years increased from 161 to 726. The median STS predicted risk of mortality declined from 3.0 to 1.8%. Most notably, the proportion of low-risk individuals in this age group increased from about 2.7 to 35.7% after the FDA approved the indication expansion in 2019.[2] Concurrently, bicuspid valve morphology (historically underrepresented in pivotal trials) approached one quarter of cases. The phenotype has shifted from highly comorbid, anatomically complex patients toward individuals with longer life expectancy and fewer conventional surgical contraindications. This change is not incremental, it is structural.

Yet the findings demand restraint in interpretation. Within the cohort younger than 65 years, an adjusted inverse

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relationship between age and one-year mortality emerged: *for every five-year increase in age, mortality decreased by approximately 10%.* In other words, the "very young" experienced higher adjusted mortality than those approaching 65. This non-linear association, absent in older age strata where mortality predictably rises with age, challenges intuitive assumptions about biological advantage. Although residual confounding and phenotypic heterogeneity may explain part of this signal, the observation remains clinically disquieting: youth alone does not confer protection in transcatheter therapy.

Equally important is the temporal limitation of available evidence. FDA approval for TAVR in low risk in August 16, 2019 was based upon trials with outcomes restricted to one year.[3,4] Structural valve degeneration, durability beyond a decade, lifetime reintervention strategies, and the biomechanical implications of bicuspid anatomy remain incompletely defined. For patients in their 50s or early 60s, a 12-month horizon represents only the prologue of a therapeutic narrative that may span in the neighborhood of three decades.

Current guidelines from the American College of Cardiology and the American Heart Association for Valvular Heart Disease continue to favor surgical aortic valve replacement in many patients younger than 65 years, largely because long-term durability data for transcatheter valves remain limited.[5] This divergence between guideline conservatism and clinical expansion reflects a familiar dynamic in cardiovascular innovation: regulatory permissibility establishes access, and practice patterns progressively redefine normality.

Approval, however, is not synonymous with equivalence across the lifespan.

The U.S. Food and Drug Administration regulates medical products, not medical judgment. Its central function in clinical medicine is to determine whether a drug or device may be legally marketed in the United States on the basis of demonstrated safety and efficacy under specified conditions. That is the extent of its mandate. Yet regulatory approval is frequently misconstrued as an endorsement of clinical supremacy. To be "FDA-approved" means that a product satisfies defined regulatory standards, is supported by sufficient evidence for commercialization, and may be used within particular indications. It does not mean that it is superior to all prior therapies, optimal for every subgroup, prudent in younger patients, or proven durable beyond the duration of studied follow-up. The FDA does not certify definitive clinical truth; it certifies conformity with regulatory thresholds. It determines whether a product may be sold. Medicine must determine whether it ought to be used. *In that distinction lies the true locus of professional responsibility.*

None of this diminishes the transformative impact of TAVR. Its procedural safety, reduced early morbidity, and rapid recovery have reshaped the therapeutic landscape of aortic stenosis. But when intervention extends into populations with extended life expectancy, durability becomes destiny. Thirty-day safety and one-year outcomes are necessary conditions for adoption; they are not sufficient conditions for generational replacement of surgery.

The expansion of TAVR into younger, lower-risk patients illustrates a broader principle: the evidentiary threshold for market entry differs from the evidentiary threshold required for lifetime therapeutic strategy. Until long-term randomized data clarify durability, valve performance in bicuspid anatomy, and optimal sequencing of reinterventions, shared decision-making must explicitly acknowledge uncertainty rather than assume resolution.

In structural heart disease, innovation defines progress.

Durability defines legacy.

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ORIGINAL ARTICLE

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Care of congenital heart disease in an adult cardiac surgery service

Atención de las cardiopatías congénitas en un servicio de cirugía cardíaca de adultos

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ABSTRACT

Introduction: congenital heart diseases (CHD) constitute the primary malformation at birth, and their diagnosis and treatment are regarded as one of the most significant triumphs of contemporary medicine. Pediatric cardiology has undergone substantial evolution, not only in diagnostic modalities but also in therapeutic approaches, thereby enabling a considerable proportion of patients to survive into adulthood. **Objective:** to ascertain the demographic and clinical characteristics, as well as the management, of adult patients with CHD who necessitated surgical repair at our institution. **Material:** we conducted a descriptive, cross-sectional study encompassing the period from 2008 to 2023, inclusive of all patients with a diagnosis of congenital heart disease who required surgical repair by our department. **Results:** a total of 128 patients were enrolled, with a slight predominance of males (53.2%). The most prevalent cardiac anomaly encountered was bicuspid aorta, accounting for 40.6% of cases, followed by atrial septal defect (18.75%). The mean age at diagnosis was 21 years, with only 1.5% of patients having a history of prior pediatric intervention. The overall mortality rate was 9.3%. **Conclusions:** the data garnered from this study indicate that delayed diagnosis of CHD remains a persistent issue, thereby underscoring the need for modifications to national public healthcare policies to ensure optimal management.

Keywords: congenital heart disease, cardiac surgery, adult.

RESUMEN

Introducción: *las cardiopatías congénitas (CC) constituyen la principal malformación presente al nacimiento, y su diagnóstico y tratamiento se consideran uno de los logros más significativos de la medicina contemporánea. La cardiología pediátrica ha experimentado una evolución sustancial, no solo en las modalidades diagnósticas, sino también en los enfoques terapéuticos, lo que ha permitido que una proporción considerable de pacientes sobreviva hasta la edad adulta.* ***Objetivo:*** *determinar las características demográficas y clínicas, así como el manejo, de los pacientes adultos con CC que requirieron reparación quirúrgica en nuestra institución.* ***Material:*** *realizamos un estudio descriptivo, transversal, que abarca el periodo comprendido entre 2008 y 2023, e incluye a todos los pacientes con diagnóstico de cardiopatía congénita que necesitaron reparación quirúrgica por parte de nuestro servicio.* ***Resultados:*** *se inscribió un total de 128 pacientes, con un ligero predominio del género masculino (53.2%). La anomalía cardíaca más prevalente fue la aorta bicúspide, que representó el 40.6% de los casos, seguida de la comunicación interatrial (18.8%). La edad media al diagnóstico fue de 21 años, y solo el 1.5% de los pacientes tenía antecedentes de intervención pediátrica previa. La tasa de mortalidad global fue del 9.3%.* ***Conclusiones:*** *los datos obtenidos en este estudio indican que persiste el problema del diagnóstico tardío de las CC, lo que subraya la necesidad de modificar las políticas nacionales de salud pública para garantizar un manejo óptimo.*

Palabras clave: *cardiopatía congénita, cirugía cardiaca, adulto.*

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Congenital heart disease (CHD) constitutes the most prevalent congenital malformation detected at birth. Historically, in the 1950s, the survival rate of children born with a cardiac anomaly was a mere 15%. However, contemporary advances have enabled over 90% of these individuals to survive into adulthood.[1] The global estimated incidence of CHD stands at 4-5 per 1,000 live births, although this metric remains undetermined in our country.[2] Among adult populations, the prevalence of CHD is approximately 0.35%, with 85-90% of these cases having a documented history of palliative surgery, corrective interventions, or other procedural measures undertaken during the pediatric stage.[3] Notwithstanding expert pediatric care, it is projected that roughly 20% of patients will necessitate surgical intervention during the initial 15 years of adulthood, with nearly half of this cohort requiring reoperation.

Advances in surgical techniques, perfusion methodologies, and perioperative care have culminated in a contemporary 45-year survival rate of 85%.[4] This substantial augmentation in survival rates, coupled with the altered natural history of the condition, has enabled patients with CHD to attain adulthood, thereby transcending the exclusive purview of pediatric care. This transitional phase, however, poses novel challenges pertaining to follow-up and management. Consequently, numerous countries have instituted transition clinics, which entail multidisciplinary specialist teams and facilitate comprehensive, longitudinal care for this patient cohort.[2,5] Regrettably, in our country, such specialized clinics are scarce, being confined to a limited number of centers, thereby resulting in a dearth of CHD care provision for adult patients.

MATERIAL

Our hospital's cardiovascular surgery service was established circa the 1990s; however, the decision to implement a dedicated database was only undertaken in 2008, hence the rationale for selecting this study period. We undertook a prospective, observational study encompassing all adult patients with CHD –defined as individuals over 15 years of age– who necessitated surgical repair between 2008 and 2023. The study protocol received approval from the hospital's ethics committee. Given that the variables under scrutiny were derived from routine clinical care data, the requirement for informed consent was waived.

Variables

Routinely collected data encompassed demographic characteristics, anatomical diagnoses, previous surgical histories, surgical procedure specifics, complications, and early mortality rates.

Statistical analysis

The primary objective was to ascertain the demographic, clinical, and management characteristics of adult patients with CHD requiring surgical repair at our institution. Statistical analyses were conducted utilizing IBM SPSS Statistics version 25. Continuous variables were expressed as means or medians, whereas categorical variables were represented as percentages, accompanied by minimum values where pertinent.

RESULTS

Demographic clinical and characteristics

A total of 128 surgeries for congenital heart disease were performed in adult patients with a slight male predominance 53.2% with a mean age of 35 years. The most common rhythm on admission was sinus rhythm in 97.2% followed by atrial fibrillation in 2.8%. The mean left ventricular ejection fraction was 62% (range, 48-73%), pulmonary artery systolic pressure was 31 mmHg (range, 28-62 mmHg) and right ventricle end diastolic volume was 101 ml/m^2 (range, 70-165 ml/m^2) *(Table 1)*.

The most common heart disease was bicuspid aortic valve (40.6%) followed by atrial septal defect (18.75%). Only two patients (1.56%) had a history of cardiac surgery

Table 1: Demographic characteristics and clinical presentation.

Variable	Value
Age (years), mean [range]	35 [16-75]
Weight (kg), mean [range]	69 [41-87]
Height (cm), mean [range]	161 [156-172]
Gender, n (%)	
Male	68 (53.19)
Female	60 (46.87)
Rhythm on admission, %	
Sinus	97.2
Atrial fibrillation	2.8
Echocardiographic findings, mean [range]	
Left ventricular ejection fraction (%)	62 [48-73]
Atrial fibrillation (%)	41 [34-52]
Right ventricular end diastolic volume (ml/m^2)	101 [70-165]
Pulmonary systolic arterial pressure (mmHg)	31 [28-62]
Associated comorbidities, n (%)	
Diabetes mellitus type 2 (DM2)	12 (9.3)
Hypertension (HAS)	24 (18.75)
DM2 and HAS	16 (12.5)
DM2, HAS, and Obesity	5 (3.9)
None	71 (55.0)

Table 2: Clinical description.

Variable	n (%)
Type of heart disease	
Bicuspid aortic valve	52 (40.6)
Atrial septal defect	24 (18.8)
Ventricular septal defect	20 (15.6)
Atrial and ventricular septal defects	6 (4.6)
Coarctation of the aorta	4 (3.1)
Partial anomalous pulmonary venous connection	4 (3.1)
Subvalvular aortic stenosis	4 (3.1)
Ventricular septal defect and patent ductus arteriosus	4 (3.1)
Unicuspid aortic valve	1 (0.7)
Patent ductus arteriosus	3 (2.3)
Tetralogy of Fallot	2 (1.5)
Ebstein's anomaly	2 (1.5)
Pulmonary insufficiency	2 (1.5)
History of previous heart disease	2 (1.5)
Age at diagnosis (years), mean [range]	21 [1-63]
Age at surgery (years), mean [range]	35 [16-75]
Complications	15 (11.7)
Bleeding	12 (9.3)
Severe paravalvular leak	2 (1.5)
Ischemia	1 (0.7)

in their pediatric population. *Table 2* describes the diagnosis, associated anomalies, type of previous surgical procedure, age at diagnosis and age at surgery.

Characteristics of the surgical procedures, complications and hospital stay

The mean duration of cardiopulmonary bypass time and aortic cross-clamping time were 155 minutes and 122 minutes, respectively. The most commonly used cardioplegia solution was Custodiol in 98% of cases. The mean estimated blood loss was 231 ml. Ninety six percent of patients required aminergic support with dobutamine being the primary treatment in 73%, followed by adrenaline in 18% and levosimendan in 9%.

Regarding the type of surgical procedure, 6.25% underwent minimally invasive cardiac surgery, out of which five correspondents to mechanical valve replacement in the aortic position and three patients with closure of interatrial communication.

Among the postoperative complications, the most common was bleeding in 9.3% of cases, followed by severe valvular leak in 1.56%. The mean hospital stay was seven days. In hospital survival was 90.6%. The main causes were cardiogenic shock in 6 cases, followed by hypovolemic and septic shock in three cases each. *Table 3* shows the surgical characteristics of the performed procedures.

DISCUSSION

Cardiac surgery for CHD in adult populations is becoming increasingly prevalent, with our center performing approximately eight such cases annually. The two predominant cardiac conditions treated within our cohort were bicuspid aortic valve and atrial septal defect. This aligns with existing literature, wherein bicuspid aortic valve, treated in 40.6% of cases at our institution, is recognized as the most common CHD in the general population.[6] Given its extreme heterogeneity across the clinical spectrum, bicuspid aortic valve can manifest as a subclinical entity throughout life or, at the more severe end of the spectrum, present with severe valvular dysfunction.[7] Amidst this interindividual clinical dispersion, it is well-established that complications during mid-adult life are common, conferring a substantially higher morbidity burden compared to another CHD.[6,8] It is therefore anticipated that this entity would constitute the most prevalent condition within our cohort. With regard to atrial septal defect, which accounted for 18.75% of cases, some literature posits this as the primary cardiac condition encountered in adult populations, affecting 40% of adults with CHD.[9] Analogous to bicuspid aorta, the clinical presentation of atrial septal defect is characterized by extreme variability, contingent upon factors such as defect size, vascular resistance, and comorbidities. In many instances, atrial septal defect can remain asymptomatic until adulthood, manifesting with nonspecific symptoms such as recurrent respiratory tract infections or cardiac arrhythmias, the latter being a common feature in our series. Notably,

Table 3: Characteristics of surgical procedures.

Variable	n (%)
Cardiopulmonary bypass time (minutes), mean [range]	155 [45-307]
Aortic cross clamping time (minutes), mean [range]	122 [29-180]
Cardioplegia type, %	
Custodiol	98
Del Nido	2
Surgical bleeding (ml), mean [range]	231 [30-1,370]
Excessive bleeding, %	11.7
Valve position	60 (100.0)
Mitral	3 (2.3)
Aortic	53 (41.4)
Tricuspid	2 (1.5)
Pulmonary	2 (1.5)
Type of prosthetic valve	
Mechanical	45 (75.0)
Biological	15 (25.0)
Reintervention first 24 hours postsurgical	7 (5.4)
Mortality	12 (9.3)

cyanotic pathologies were also treated within our cohort, specifically two patients presenting with Tetralogy of Fallot and Ebstein's anomaly. These conditions are predominantly observed in pediatric populations, with the majority of cases necessitating reoperation. Tetralogy of Fallot represents the most frequent cyanotic CHD in pediatric population, typically presenting within the first year of life. Survival into adulthood without corrective surgery or with palliative measures alone is exceptional.[10] In the case of our patients, neither had a history of prior corrective or palliative surgery; however, their ages at presentation were 16 and 22 years, respectively. Ebstein's anomaly, a rare condition accounting for less than 1% of all CHD cases,[11] was also encountered. The severity of this anomaly is determined by the degree of atrialization and tricuspid regurgitation, which, in turn, dictates the type of surgical intervention, symptomatology, and other clinical parameters. The optimal timing for surgical intervention remains a subject of controversy, generally being guided by a combination of factors including diminished functional class, paradoxical embolism, progressive cardiomegaly on chest radiography, and progressive right ventricular dilatation.[11,12] Within our series, these patients underwent surgery at the ages of 17 and 19 years, respectively.

In terms of complexity, approximately 50% of CHD in adult populations are classified as simple, 30-40% as moderate, and fewer than 15% as severe.[13] Notably, less than 10% of CHD cases are diagnosed after the age of 18 years.[14] The mean age at which surgical intervention was undertaken in our cohort was 21 years, with some patients having been diagnosed as early as one year of age. One of the primary challenges confronting pediatric cardiology is the phenomenon of loss to follow-up among adolescent patients, as highlighted by Liu et al.,[15] who identified four distinct domains that pose barriers to consistent follow-up care. The transition from pediatric to adult care is fraught with multiple challenges, including the absence of a seamless handoff process, the establishment of a trusting relationship, and the fostering of an appropriate balance between patient autonomy and understanding of their condition. Additional logistical challenges, such as time constraints, geographical distance, cost considerations, and the availability of specialized care, are further compounded by psychosocial factors and the inherent heterogeneity of cardiac abnormalities affecting our patient population. Patients with CHD constitute a diverse cohort with disparate priorities and needs, suggesting that a more individualized approach may be necessary to ensure adequate follow-up care. However, it can be generally stated that many of these factors are applicable to our population and may contribute to the lack of follow-up care during the pediatric stage, thereby explaining why these patients received care in adulthood. Cardiac surgery for adult patients with CHD, when performed in a referral hospital with a multidisciplinary team, is associated with low mortality rates and improved functional class. Surgical indications are primarily guided by the onset of symptoms and prognostic considerations. A thorough understanding of the patient's anatomical characteristics, previous surgical interventions, structural interventions, and their sequelae is essential for optimal patient care.[3,16] The overall mortality rate at our institution stands at 9.4%, which is comparable to rates reported in the existing literature, such as the studies by Garcia Cruz et al.[3] and Horer et al.,[17] which documented mortality rates of 12.3 and 10%, respectively. It is noteworthy that the former study exclusively encompassed complex pathologies, excluding patients with previous surgical interventions, given that prior sternotomy represents a high risk for bleeding and other surgical complications. In the study by Horer et al.,[17] the specific types of heart disease were not delineated. Within our series, we observed a predominance of patients requiring aortic valve replacement, which, as previously mentioned, constituted the primary type of CHD treated.

CONCLUSIONS

The decision to undertake cardiac surgery in adult patients with CHD represents a paradigm shift for both the clinical and surgical teams. A thorough clinical and functional assessment, coupled with the identification of comorbidities, is imperative in determining the optimal surgical approach for each individual case. In conclusion, it can be stated that late diagnosis is frequently the primary factor underlying the presentation of CHD in adult populations, thereby underscoring the necessity for physicians who are adequately trained to provide timely and effective care for these patients. The establishment of an early care system, facilitating surgical interventions during the earliest stages of life, is crucial.

Study limitations

It is acknowledged that this is a single-center study, which may have inherent limitations in terms of generalizability.

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VA-ECMO post-cardiotomy: mortality and outcomes. A 10-year cohort

ECMO-VA post-cardiotomía: mortalidad y desenlaces. Cohorte de 10 años

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ABSTRACT

Objective: Veno-Arterial (VA) Extracorporeal Membrane Oxygenation (ECMO) for refractory postcardiotomy cardiogenic shock carries high mortality. The objective was to describe the frequency of mortality and complications in adult patients who required this support after cardiac surgery, as well as the associated factors. **Material and methods:** an observational, descriptive, retrospective study. Records of 30 patients undergoing cardiac surgery requiring VA ECMO support at the "Dr. Gaudencio González Garza" General Hospital between January 1, 2013, and December 31, 2023, were analyzed. Demographic, surgical and complication variables were compared between survivors and non-survivors using t-Student and χ^2 tests. **Results:** thirty patients were included, with a mean age of 44.8 years; 80% were cardiac transplants. Overall mortality was 63.3% (n = 19). The most frequent complications were acute kidney injury (66.7%) and bleeding (60%). No significant differences were found in age (p = 0.14) or support duration (5.73 vs 5.78 days, p = 0.97). Pre-support Left Ventricular Ejection Fraction (LVEF) was the only variable with statistical significance, being paradoxically higher in the deceased group (mean 34.4%) compared to survivors (mean 27.4%) (p = 0.031). **Conclusions:** mortality for post-cardiotomy VA ECMO in our cohort (63.3%) is high, consistent with international reports. Renal failure and bleeding were the predominant complications. Pre-support LVEF was not a predictor

RESUMEN

Objetivo: *el choque cardiogénico refractario postcardiotomía tratado con oxigenación por membrana extracorpórea (ECMO, por sus siglas en inglés) veno-arterial (VA) presenta una elevada mortalidad. El objetivo fue describir la frecuencia de mortalidad y complicaciones en pacientes adultos que requirieron este soporte después de una cirugía cardíaca, así como los factores asociados.* ***Material y métodos:*** *estudio observacional, descriptivo y retrospectivo. Se analizaron los expedientes de 30 pacientes sometidos a cirugía cardíaca que requirieron soporte con ECMO VA en nuestra institución entre el 1 de enero de 2013 y el 31 de diciembre de 2023. Se compararon variables demográficas, quirúrgicas y complicaciones entre sobrevivientes y fallecidos usando pruebas t-Student y* χ^2. ***Resultados:*** *se incluyeron 30 pacientes, con edad media de 44.8 años, 80% fueron trasplantes cardíacos. La mortalidad global fue de 63.3% (n = 19). Las complicaciones más frecuentes fueron insuficiencia renal aguda (66.7%) y sangrado (60%). No se encontraron diferencias significativas en edad (p = 0.14) ni duración del soporte (5.73 vs 5.78 días, p = 0.97). La fracción de eyección del ventrículo izquierdo (FEVI) presoporte fue la única variable con significancia estadística, siendo paradójicamente mayor en el grupo de fallecidos (media 34.4%) comparada con los sobrevivientes (media 27.4%) (p = 0.031).* ***Conclusiones:*** *la mortalidad de pacientes en ECMO VA postcardiotomía en nuestra cohorte (63.3%) es elevada, en concordancia con reportes internacionales. La falla renal y el sangrado fueron las complicaciones predominan-*

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of survival; its paradoxical association with mortality suggests that other perioperative factors are more determinant.

Keywords: extracorporeal membrane oxygenation, cardiac surgery, cardiogenic shock, mortality, heart transplantation.

tes. La FEVI presoporte no fue un predictor de supervivencia; su asociación paradójica con la mortalidad sugiere que otros factores perioperatorios son más determinantes.

Palabras clave: *oxigenación por membrana extracorpórea, cirugía cardíaca, choque cardiogénico, mortalidad, trasplante cardíaco.*

Abbreviations:
AKI = Acute Kidney Injury
ECMO = Extracorporeal Membrane Oxygenation
LVEF = Left Ventricular Ejection Fraction
VA = Veno-Arterial

Veno-Arterial (VA) Extracorporeal Membrane Oxygenation (ECMO) represents a sophisticated life support modality, frequently deployed in the cardiothoracic arena as a hemodynamic adjunct for post-cardiotomy patients precipitating into refractory cardiac failure, thereby necessitating a strategic bridge to recovery, decision-making, or transplantation.[1] VA ECMO provides a temporary reprieve, which facilitates diagnostic elucidation and therapeutic intervention. Ultimately, this fosters the potential for myocardial recovery.[2,3]

Notwithstanding its therapeutic utility, VA ECMO support is not devoid of complications. International literature cites substantial hospital mortality rates associated with VA ECMO support. A 2017 meta-analysis revealed survival-to-discharge rates ranging from 24.8 to 40% in patients presenting with refractory post-cardiotomy cardiogenic shock, underscoring the gravity of this clinical scenario.[4]

Hemorrhagic complications resulting from induced anticoagulation and a proinflammatory state, which can lead to renal failure, are frequent challenges that significantly contribute to morbidity and mortality.[5,6] Although descriptions exist in the literature, it is fundamental to analyze outcomes in national reference centers to develop strategies to decrease mortality.

The present study aims to describe the mortality frequency, predominant complications, and scrutinize associated factors within a 10-year cohort of adult patients necessitating VA ECMO support during the postoperative period following cardiac surgery at our institution.

MATERIAL AND METHODS

A retrospective, descriptive, and observational study was undertaken, encompassing a thorough review of medical records from patients who underwent cardiac surgery and necessitated VA ECMO support at our institution spanning January 1, 2013, to December 31, 2023.

Inclusion criteria comprised records of patients aged 18-75 years, of either gender, requiring VA ECMO therapy post-cardiac surgery. Exclusion criteria included concomitant use of other ventricular assist devices during ECMO therapy. Records with incomplete data were eliminated.

Data retrieval was conducted retrospectively from clinical records, utilizing SPSS statistical software for analysis. Descriptive statistics, including measures of central tendency (mean) and dispersion (standard deviation), as well as frequencies, were employed to characterize variables of interest.

Comparative analyses between surviving and deceased patients utilized Student's T-test for quantitative variables and Pearson's χ^2 test for categorical variables, with $p < 0.05$ deemed statistically significant.

The study received approval from the institutional Ethics and Research Committee, classified as risk-free due to its retrospective and observational nature, warranting a waiver of written informed consent. Patient data confidentiality was ensured throughout.

RESULTS

The study cohort comprised 30 patients requiring VA ECMO support following cardiac surgery. The mean age was 44.8 years, with an average weight of 69 kg. Males accounted for 57% (n = 17) of the population. The most prevalent comorbidities were Type II Diabetes Mellitus (30%) and Systemic Arterial Hypertension (20%). Regarding the surgical procedure, 80% (n = 24) were heart transplants. Central cannulation was the predominant configuration, used in 87% of cases.

Overall mortality for the cohort was 63.3% (n = 19) *(Fig. 1)*. Acute Kidney Injury (AKI) was the most frequent complication, affecting 66.7% (n = 20) of patients, followed by bleeding in 60% (n = 18). Other documented complications included limb ischemia (23.3%), thrombosis (10%), and cerebrovascular events (6.7%) *(Fig. 2)*.

Bivariate analysis of quantitative variables *(Table 1)* revealed no statistically significant differences between survivors and non-survivors regarding age (49.7 vs 41.9 years; p = 0.14), weight (p = 0.63), aortic cross-clamp time (p = 0.18), or duration of ECMO support (5.73 vs. 5.78 days; p = 0.97).

Notably, the pre-support Left Ventricular Ejection Fraction (LVEF) was the sole quantitative variable demonstrating statistical significance. Paradoxically, LVEF was higher in the deceased group (mean 34.4%) compared to the survivor group (mean 27.4%) (p = 0.031) *(Fig. 3)*.

Regarding categorical variables *(Table 2)*, no significant association with mortality was found for sex (p = 0.33),

comorbidities (diabetes mellitus, p = 0.87; hypertension, p = 1.00), or cannulation type (p = 0.25). Similarly, the incidence of complications, including AKI (p = 0.50), bleeding (p = 0.39), and thrombosis (p = 0.61), did not differ significantly between groups. *Fig. 4* illustrates the distribution of surgical procedures stratified by outcome.

DISCUSSION

This study delineates the outcomes of a decade-long cohort of patients necessitating post-cardiotomy VA ECMO support at a national referral center. The observed mortality rate stood at 63.3%, corroborating our alternative hypothesis (H1 > 40%) and aligning with international registry reports, which cite hospital mortality rates ranging from 50% to 70% for this high-acuity population.[4,7]

Notably, 80% of our cohort comprised post-heart transplant patients, a subgroup characterized by severe ventricular dysfunction linked to ischemia time, contributing to the elevated mortality. A striking finding was the paradoxical association between LVEF and mortality. Patients who succumbed exhibited a significantly higher mean LVEF (34.4%) compared to survivors (27.4%) (p = 0.031), countering the conventional assumption that lower LVEF implies poorer prognosis. This may be attributed to overestimation of LVEF in the context of maximal inotropic support or the influence of perioperative factors and extracardiac complications on outcomes.

The predominant complications in our cohort were acute kidney injury (66.7%) and bleeding (60%), mirroring reports in other series and highlighting key clinical challenges in VA ECMO management. The necessity for systemic anticoagulation, compounded by the circuit-induced

Table 1: Comparison of quantitative variables and complications between survivors and deceased patients.

Variable	Deceased (Mean)	Survivors (Mean)	Student's T-test	p
Age	41.9	49.7	−1.52	0.14
Weight (kg)	69.7	67.7	0.49	0.63
Height (m)	1.62	1.63	−0.15	0.88
Aortic clamping time (min)	93.8	83.1	1.37	0.18
Cardiopulmonary bypass time (min)	204.2	178.2	1.64	0.11
LVEF (%)	34.4	27.4	2.28	0.031
ECMO Duration (days)	5.78	5.73	0.04	0.97

ECMO = Extracorporeal Membrane Oxygenation. LVEF = Left Ventricular Ejection Fraction.

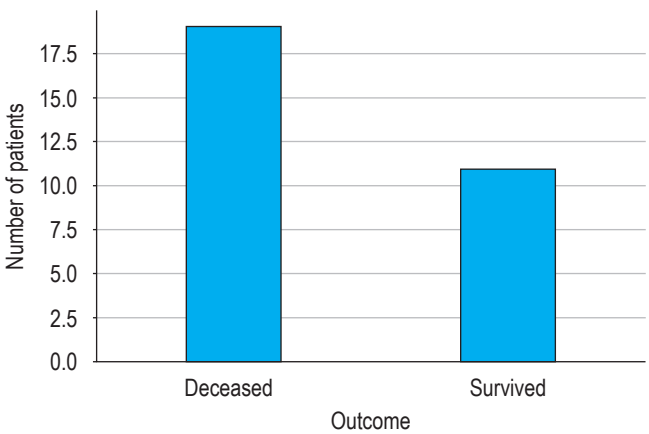

Figure 1: Frequency of global mortality in the cohort of 30 patients, 63.3% (n = 19) of the patients died (yes), while 36.7% (n = 11) survived (no).

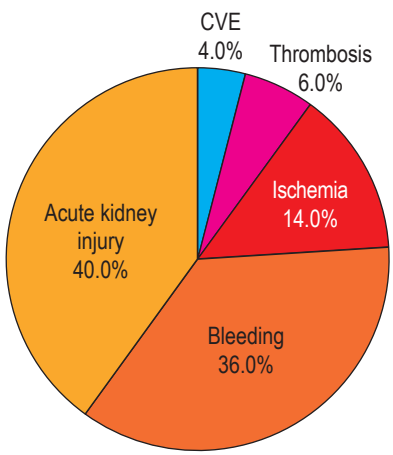

Figure 2:

Distribution of the main complications in the total cohort (n = 30).
CVE = Cerebrovascular Event.

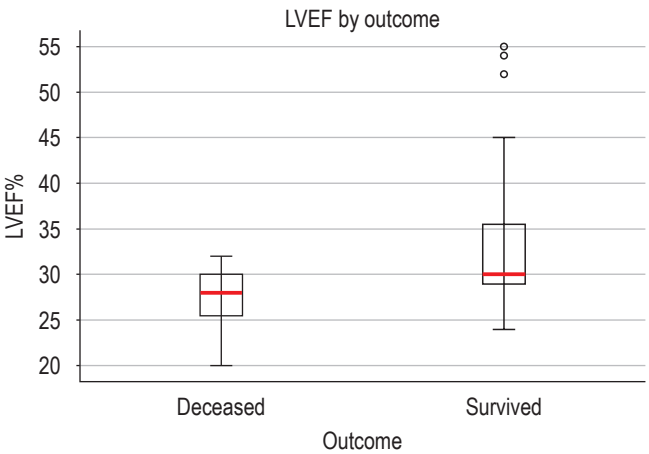

Figure 3: Boxplot comparing Left Ventricular Ejection Fraction (LVEF) by outcome. A significantly higher median and mean LVEF is observed in the deceased group (yes) compared to survivors (no) (p = 0.031).

proinflammatory state, creates a precarious balance impacting morbidity and mortality.[6,8]

This study is limited by its retrospective, single-center design and reduced sample size (N = 30), constraining multivariate analysis. Nonetheless, it serves as a valuable local reference for clinical outcomes.

CONCLUSIONS

The mortality rate in patients receiving VA ECMO following cardiac surgery in our cohort was 63.3%, reflecting the severity of this population and consistent with data from international centers.

The only variable demonstrating a statistically significant relationship with mortality was LVEF, which was unexpectedly higher in the non-survivor group.

No significant differences in mortality were identified when analyzing other demographic variables, comorbidities, or cannulation type.

The use of VA ECMO in this context was associated with a considerable risk of complications, especially acute kidney injury (66.7%) and bleeding events (60%), which represented the main clinical challenges.

There is a need to implement institutional protocols for the early detection of candidates and the preventive management of complications, especially those related to renal protection and bleeding control.

Table 2: Comparison of categorical variables and complications between survivors and deceased patients.

Variable	Survived N = 11 n (%)	Deceased N = 19 n (%)	χ^2	p
Type II diabetes mellitus	4 (36)	5 (26)	0.03	0.87
Systemic arterial hypertension	2 (18)	4 (21)	0.00	1.00
Chronic kidney disease	1 (9)	1 (5)	0.00	1.00
Cannulation Type	8 (73)	18 (95)	1.33	0.25
Acute kidney injury	6 (55)	14 (74)	0.45	0.50
Cerebrovascular event on ECMO	0 (0)	2 (11)	0.13	0.72
Ischemic events on ECMO	5 (45)	2 (11)	3.00	0.08
Bleeding during ECMO therapy	5 (45)	13 (68)	0.72	0.39
Thrombosis during ECMO therapy	2 (18)	1 (5)	0.26	0.61

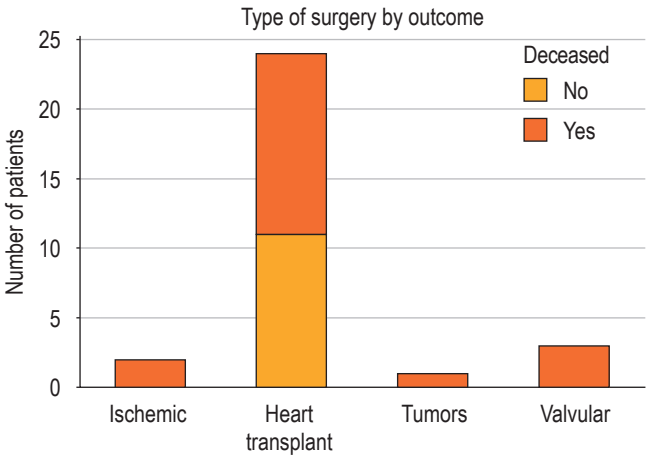

Figure 4: Stacked bar chart showing the distribution of surgery types (ischemic, transplant, tumor, valvular) according to outcome (deceased [yes] vs survivor [no]), in number of patients.

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PARTNER 3 at 7 years: temporal heterogeneity, endpoint architecture, and the limits of long-term equivalence

PARTNER 3 a 7 años: heterogeneidad temporal, arquitectura de los puntos finales y los límites de la equivalencia a largo plazo

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ABSTRACT

The 7-year follow-up of the PARTNER 3 trial provides the most robust randomized evidence comparing balloon-expandable transcatheter aortic valve implantation (TAVI) with surgical aortic valve replacement (SAVR) in patients with severe aortic stenosis at low surgical risk. Although early analyses demonstrated noninferiority of TAVI, longer-term data reveal temporal heterogeneity of treatment effects, nonproportional hazards, and interpretative dependence on composite endpoint structure. While the primary non-hierarchical composite endpoint shows no statistically significant difference at seven years, all-cause mortality is numerically higher in the TAVI group (19.5 vs. 16.8%). Hazard ratios converge and appear to invert beyond the first year, and restricted mean survival time analyses integrate early benefit with late-phase attenuation. This Point of View examines the methodological and temporal architecture of the 7-year analysis and discusses its implications for durability assessment and long-term decision-making in low-risk patients with extended life expectancy.

Keywords: aortic valve stenosis, clinical trials, TAVI, SAVR, evidence-based medicine.

RESUMEN

El seguimiento a siete años del ensayo PARTNER 3 proporciona la evidencia aleatorizada más robusta que compara la implantación de válvula aórtica transcatéter (TAVI, por sus siglas en inglés) con expansión de balón con la sustitución quirúrgica de la válvula aórtica (SAVR, por sus siglas en inglés) en pacientes con estenosis aórtica grave con bajo riesgo quirúrgico. Aunque los análisis iniciales demostraron no inferioridad de TAVI, los datos a más largo plazo revelan heterogeneidad temporal de los efectos del tratamiento, riesgos no proporcionales y dependencia interpretativa de la estructura del criterio de valoración compuesto. Si bien el criterio de valoración compuesto primario no jerárquico no muestra una diferencia estadísticamente significativa a los siete años, la mortalidad por todas las causas es numéricamente mayor en el grupo TAVI (19.5 frente a 16.8%). Las razones de riesgo convergen y parecen invertirse más allá del primer año, y los análisis de tiempo de supervivencia medio restringido integran el beneficio temprano con la atenuación en la fase tardía. Este punto de vista examina la arquitectura metodológica y temporal del análisis a siete años y discute sus implicaciones para la evaluación de la durabilidad y la toma de decisiones a largo plazo en pacientes de bajo riesgo con esperanza de vida prolongada.

Palabras clave: *estenosis de la válvula aórtica, ensayos clínicos, implante de válvula aórtica transcatéter, reemplazo quirúrgico de válvula aórtica, medicina basada en evidencia.*

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The PARTNER 3 trial (safety and effectiveness of the SAPIEN 3 transcatheter heart valve in low-risk patients with aortic stenosis; NCT02675114) constitutes the most robust randomized study available to date comparing transcatheter aortic valve implantation (TAVI) with conventional surgical aortic valve replacement (SAVR) in patients with severe symptomatic aortic stenosis and low surgical risk.[1]

This was a prospective, multicenter, randomized clinical trial that enrolled 1,000 patients assigned in a 1:1 ratio to TAVI with a balloon-expandable valve (n = 503) or to surgery with a conventional biological prosthetic valve (n = 497). Low risk was primarily defined by an STS-PROM score < 4%, accompanied by anatomical and clinical criteria that excluded patients with significant surgical complexity. The mean age was approximately 73 years, representing a cohort with extended life expectancy within the context of degenerative valvular disease.

The primary endpoint was a non-hierarchical composite of all-cause mortality, disabling stroke, and valve-related or heart failure-related rehospitalization. In addition, a hierarchical analysis was performed using the win ratio method. Secondary outcomes included individual mortality, stroke, valve reintervention, echocardiographic parameters of function and durability, as well as complications such as atrial fibrillation, valve thrombosis, and paravalvular leak.

The results demonstrated noninferiority of TAVI compared with SAVR. The 7-year follow-up represents the longest available time horizon in this low-risk population and has been widely interpreted as evidence of sustained equivalence.[2] However, a careful examination of endpoint architecture, the temporal evolution of risk, and late mortality necessitates a more nuanced reading of this trial.

ENDPOINT ARCHITECTURE, ANALYTICAL FRAMING, AND THE LIMITS OF STATISTICAL NEUTRALITY

The 7-year evaluation rests on two complementary analytical strategies constructed from overlapping clinical events. The first employs a conventional non-hierarchical composite –death, any stroke, or valve- or heart failure-related rehospitalization– analyzed through time-to-first-event methods (Kaplan-Meier estimates and Cox proportional hazards models). The second applies a hierarchical composite assessed by the win ratio, which orders outcomes according to clinical priority: death, disabling stroke, nondisabling stroke, and cumulative days of rehospitalization.

While the clinical components are largely shared, the inferential architecture differs. Time-to-first-event analysis treats all first occurrences equivalently from a statistical standpoint, regardless of severity. The win ratio, in contrast, ranks patient pairs according to predefined clinical gravity, thereby incorporating an explicit value hierarchy into the comparison. Both approaches are methodologically sound and increasingly utilized in contemporary cardiovascular trials. However, they shed light on distinct dimensions of treatment effect –event incidence versus comparative clinical ranking– and neither, by itself, resolves questions extending beyond the observed follow-up.

At seven years, the non-hierarchical composite occurred in 36.3% of patients undergoing TAVI and 34.5% of those undergoing SAVR (HR ≈ 1.05; 95%CI 0.90-1.22). The range of this interval encompasses both a modest relative reduction in risk and a potentially meaningful excess hazard. Statistically, the null hypothesis cannot be rejected. Yet statistical non-significance is not synonymous with equivalence, particularly in a study not designed or powered to establish noninferiority at this temporal horizon. As follow-up continues and the accumulation of events stabilizes, diminished power heightens susceptibility to type II error;[3,4] neutrality under such conditions means indeterminacy rather than interchangeability.

Interpretation is further complicated by the structure of composite endpoints.[5] Even when hierarchically ordered, the aggregation of outcomes with different prognostic and ethical weight generates conceptual conflicts. Death, disabling stroke, nondisabling stroke, and rehospitalization differ fundamentally in their implications for survival, autonomy, and long-term quality of life. Statistical frameworks can reorder or group these events, but they cannot erase their qualitative asymmetry.

For younger patients with low operative risk and substantial life expectancy, the pivotal issue is not merely the absence of demonstrable difference, but whether the available evidence justifies declaring two distinct interventions therapeutically interchangeable over the long term. The 7-year findings do not provide that level of certainty. Rather, they delineate a rigorously analyzed yet intrinsically uncertain space in which methodological sophistication coexists with unresolved clinical doubt.

TEMPORAL HETEROGENEITY, NONPROPORTIONAL HAZARDS, AND THE LIMITS OF INTEGRATED METRICS

The 7-year analysis explicitly acknowledges evidence of nonproportional hazards for key mortality-related outcomes, indicating that the assumption of a constant hazard ratio over time is not fully sustained. This is a critical interpretative issue, not a minor statistical detail. When proportional hazards are violated, a single Cox-derived hazard ratio no longer represents a stable treatment effect; instead, it becomes a time-averaged summary across different risk phases.

In the context of PARTNER 3, the risk pattern likely includes an early procedural phase favoring TAVI, an intermediate period where risks converge, and a later phase where the relative hazard may decrease or even reverse. The survival curves support this pattern: they separate early, then converge, with hazard ratios beyond the first year appearing less favorable to TAVI and diverging over time. This time-dependent pattern is plausible in structural valve interventions, possibly due to differences in valve durability, leaflet integrity, hemodynamic performance, patient-prosthesis interaction, and device-related issues that accumulate over time.

Methodologically, the investigators respond appropriately to this temporal heterogeneity. It is well established that the two principal approaches developed to address departures from the proportional hazards assumption are weighted log-rank procedures and analyses based on restricted mean survival time (RMST).[6,7] By incorporating RMST for both the primary composite end point and all-cause mortality, the authors adopt a framework that does not rely on proportional hazards and instead estimates the average event-free survival up to a prespecified time horizon (2,555 days) by integrating the area under the survival curve. There is therefore no statistical inconsistency in presenting hazard ratios alongside RMST estimates; the latter serves as a robustness measure when treatment effects vary over time.

However, RMST, by design, integrates early benefit and later attenuation into a single cumulative metric. In this analysis, the primary composite endpoint modestly favors TAVI, with approximately 134 additional event-free days, whereas the difference for all-cause mortality is small (approximately −15 days) and not statistically significant. While RMST provides a stable and assumption-free average measure, it does not describe the directional evolution of hazard beyond the restriction horizon, nor does it distinguish between front-loaded procedural advantage and late-phase risk convergence. In interventions where durability is a concern, this integration may hide emerging late differences. As a result, when hazards are not proportional, long-term equivalence cannot be assumed based on overall, time-averaged data alone. The clinical question shifts from whether average survival differs to how risk unfolds across time—a distinction that is not statistical nuance, but a determinant of durable therapeutic inference.

LATE MORTALITY: A SIGNAL THAT WARRANTS ATTENTION

At seven years, all-cause mortality was 19.5% in the TAVI group compared with 16.8% in the SAVR group. The difference was not statistically significant, yet it remains numerically higher. As in PARTNER 3 trial, in a cohort with a mean age of 73 years and a potential life expectancy exceeding a decade, modest late divergences may carry greater strategic relevance than early procedural advantages. Over extended horizons, small absolute differences can translate into clinically meaningful trajectories.

The manuscript narrative suggests that early benefits may be counterbalanced by later events. However, the underlying mechanisms that could account for such attenuation – structural durability, persistent paravalvular leak, subclinical valve thrombosis, or prolonged hemodynamic interaction– are not causally explored.

Statistical non-significance does not exempt from the obligation of continuous clinical monitoring.

GUIDELINE-DEFINED LOW RISK VERSUS TRIAL-SELECTED LOW RISK: ALIGNMENT AND TENSION

Although PARTNER 3 formally aligns with the 2020 ACC/AHA definition of low surgical risk –requiring a low STS-PROM score, absence of frailty, no major end-organ dysfunction, and no procedure-specific impediments– the trial applies this definition in an exceptionally stringent manner.[8] The enrolled population represents not merely "low risk" in the pragmatic clinical sense, but a carefully selected group optimized for dual eligibility: anatomically suitable for transfemoral TAVI, free of bicuspid morphology, devoid of complex coronary disease, and largely spared significant renal, pulmonary, neurologic, or hepatic dysfunction. In doing so, the trial achieves high internal validity and methodological clarity.

However, this rigor simultaneously narrows its external applicability. In routine practice, many patients considered low surgical risk under guideline frameworks present with gradations of comorbidity, coronary complexity, or anatomical variation that were systematically excluded from PARTNER 3.

Thus, the study does not so much misclassify risk as idealize it. Importantly, even within this optimized and physiologically favorable cohort, long-term equivalence remains statistically neutral and clinically nuanced, with late mortality numerically favoring surgery and evidence of non-proportional hazards over time. If uncertainty persists under idealized conditions, extrapolation to broader, more heterogeneous low-risk populations warrants measured restraint rather than conceptual substitution of one therapy for the other.

Therefore, the critical issue is not patient selection per se, but extrapolation. The concern emerges when an ultra-selected experimental phenotype is implicitly transformed into a mandate for broad clinical expansion. Guidelines may define "low surgical risk" using structured and stringent criteria; however, in real-world practice, that designation often

shifts in meaning over time. The term expands to encompass patients with increasing anatomical complexity, incremental comorbidity, or longer life expectancy than those represented in the trial population.

At that point, the basis of the evidence as evidentiary foundation becomes less directly transferable. What was demonstrated under tightly controlled, idealized conditions risks being generalized to a wider and more heterogeneous population in whom the balance between early procedural advantage and long-term durability may differ substantially. The distinction between internal validity and clinical universality is subtle but decisive – and it is exactly here that caution becomes not about being overly careful, but about being methodologically responsible.

If uncertainty persists under idealized experimental conditions, its extrapolation to broader and more heterogeneous low-risk populations demands prudence.

DURABILITY AND CONCEPTUAL REDEFINITION

Durability assessment is grounded in VARC-3 criteria.[9] Under these standardized definitions, TAVI and SAVR appear broadly comparable. However, several considerations complicate this apparent symmetry:

1. Clinically significant valve thrombosis is more frequent following TAVI (2.8 vs. 0.5%; HR 5.7; 95%CI 1.29-25.25).
2. Paravalvular leak persists in a non-negligible proportion of TAVI recipients (17.7 vs. 2.2%).
3. A 7-year horizon does not approximate the biological lifespan of a patient aged 65-70 years.

Durability cannot be reduced to the absence of reintervention:[10] it entails sustained physiological integration over time.

DURATION OF FOLLOW-UP AND CONDITIONAL LIFE EXPECTANCY

According to the National Center for Health Statistics, life expectancy at birth in the United States in 2025 is 78.4 years overall (75.8 years for men and 81.1 years for women).[11,12] However, this metric is not the relevant parameter when analyzing a cohort with a mean age of 73 years, as in PARTNER 3. At that age, the appropriate reference is conditional life expectancy: a 73-year-old man has an average additional life expectancy of 10.95 years, and a woman 13.28 years; even at age 65, the additional expectancy is 16.06 and 19.06 years, respectively.[13] These figures imply that a substantial proportion of patients enrolled in the trial –carefully selected, low surgical risk, and without significant frailty– are likely to survive well beyond the first decade following valve implantation.

Given that structural valve degeneration in biological prosthetic aortic valves typically becomes clinically meaningful after 8-10 years and may accelerate thereafter, follow-up at one, five, or even seven years primarily captures procedural performance and intermediate outcomes rather than true long-term durability. In this context, 7-year data cannot reasonably be regarded as definitive for informing therapeutic decisions in low-risk patients whose conditional life expectancy substantially exceeds that time horizon.

WHAT THE STUDY DOES WELL

Critical appraisal does not entail dismissing methodological rigor. PARTNER 3 stands as one of the most robustly designed trials in TAVI: randomized, multicenter, supported by independent event adjudication, and grounded in the rigorous application of VARC-3 definitions. It has demonstrated that expansion into low-risk populations has not resulted in early clinical failure.

However, the absence of early collapse is not synonymous with superiority, nor does it establish full therapeutic interchangeability with SAVR.

FINAL COMMENTARY

The 7-year follow-up of PARTNER 3 illustrates how temporal dynamics and endpoint architecture shape long-term interpretation.

Key observations include:

1. Violation of proportional hazards assumptions.
2. Numerical late-phase mortality divergence.
3. Dependence of composite outcomes on rehospitalization components.
4. Analytical reliance on hierarchical win ratio and RMST integration.

These findings underscore the necessity of cautious extrapolation when translating early procedural benefits into long-term therapeutic preference.

In structural heart disease, time is not merely a covariate; it is the decisive variable. In patients with substantial life expectancy, as in low-risk patients, the essential question is not whether the statistical average appears neutral, but in which direction risk ultimately evolves.

At seven years, that answer remains unsettled.

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CASE REPORT

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Comprehensive approach of patients with cardiac perforation and management of difficult airway: case report

Abordaje integral del paciente con perforación cardíaca y manejo de la vía aérea difícil: reporte de caso

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ABSTRACT

Myocardial perforation related to cardiac pacemakers is a rare but potentially fatal complication. Risk factors such as active fixation electrodes, steroid use, advanced age, female sex, comorbidities, and apical electrode placement confer a higher risk. We report the case of an 83-year-old woman who experienced cardiac perforation two years after pacemaker implantation, caused by electrode migration. Her advanced age and non-septal electrode placement were identified as risk factors. The patient underwent successful surgical repair via anterior thoracotomy, with hybrid intubation employed due to a predicted difficult airway. She exhibited favorable clinical progress and was discharged after a one-week hospital stay. The hybrid intubation technique, although more commonly used in pediatrics, proved useful in this adult patient with predictors of a difficult airway.

Keywords: cardiac pacemaker, difficult airway, electrode migration, hybrid intubation, thoracotomy, ventricular perforation.

RESUMEN

La perforación miocárdica relacionada con marcapasos cardíacos es una complicación rara pero potencialmente mortal. Factores de riesgo como electrodos de fijación activa, uso de esteroides, edad avanzada, sexo femenino, comorbilidades y colocación apical de electrodos confieren un mayor riesgo. Reportamos el caso de una mujer de 83 años que experimentó perforación cardíaca dos años después de la implantación de un marcapasos, causada por la migración de electrodos. Su edad avanzada y la colocación no septal de electrodos se identificaron como factores de riesgo. La paciente se sometió a una reparación quirúrgica exitosa mediante toracotomía anterior, con intubación híbrida empleada debido a una vía aérea difícil prevista. Presentó una evolución clínica favorable y fue dada de alta después de una semana de hospitalización. La técnica de intubación híbrida, aunque más comúnmente utilizada en pediatría, resultó útil en esta paciente adulta con predictores de una vía aérea difícil.

Palabras clave: *marcapasos cardíaco, vía aérea difícil, migración de electrodos, intubación híbrida, toracotomía, perforación ventricular.*

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Abbreviations:
AV = atrioventricular
DA = difficult airways
VCI = video classification of intubation
WHO = World Health Organization

At the Ignacio Chávez National Cardiology Institute in Mexico, a substantial cohort of over 2,000 pacemakers has been implanted between 2018 and 2021.[1] The predominant indications for permanent pacemaker implantation are sinus node dysfunction, notably symptomatic sinus bradycardia, and high-grade atrioventricular (AV) block, encompassing second-degree Mobitz II AV block and complete AV block, as corroborated by existing literature.[2,3] Concomitant with any invasive procedure, there exists an inherent risk of complications, which tend to manifest predominantly within the initial six-month post-procedural period. The primary complication is electrode migration, while other notable adverse sequelae include hematoma formation, infection, pericardial effusion, cardiac tamponade, pneumothorax, and cardiac perforation.[2,4]

Myocardial perforation related to cardiac pacemaker electrodes is a rare but potentially fatal complication.[5] Perforation is more commonly seen in the atria than in the ventricles,[6] due to the thinner wall. However, if the perforation is in the ventricle, it usually affects the right ventricle more frequently and it is classified according to its presentation as: acute if it occurs within < 24 hours of pacemaker placement; subacute if it occurs between > 24 hours and one month after the procedure; and late if it occurs more than one month after implantation.[7] In addition, factors such as the use of temporary transvenous pacemakers, active fixation electrodes, use of steroids seven days prior to implantation, age over 80 years, female sex, the presence of comorbidities such as type II diabetes, electrodes at the apex of the right ventricle, and operator experience are associated with an increased risk of cardiac perforation[5,8,9] *(Table 1)*.

The clinical manifestations of cardiac perforation due to pacemaker electrode migration include sudden onset of severe stabbing chest pain. It is often accompanied by fatigue, exercise intolerance, and syncope. Hemodynamic instability may occur depending on the location of the electrode tip, which can migrate to the myocardium, pericardium, mediastinum, pleural space, lung, or even the abdomen.[10] Another important issue in the management of critically ill patients with myocardial perforation is the approach taken by the anesthesiology team. One of the main objectives of the anesthesiologist during surgery is airway management, which commences with a preoperative assessment, encompassing a comprehensive medical history and physical examination. This assessment serves to evaluate the patient's condition and provide insight into the potential complexity of airway management. A difficult airway is defined as a scenario wherein a trained anesthesiologist encounters difficulty or is unable to provide adequate ventilation during a procedure, attributable to the patient's anatomical characteristics or clinical circumstances.[11]

Recent studies report that between 1.5 and 8% of intubations in the surgical setting are classified as difficult. In emergency situations, this incidence can escalate to 15%.[11] To assess the airway, various scales are employed, including the Mallampati classification, Patil-Aldreti (thyromental distance), sternomental distance, and the Cormack-Lehane classification. Based on these scales, predictive indices for difficult intubation have been established[12,13] *(Table 2)*. Innovations in devices and technologies have significantly transformed the management of difficult airways (DA). The advent of video laryngoscopes has revolutionized the intubation process. The failure rate associated with video laryngoscopy is 2% when utilized as a primary technique and 8% when employed as a rescue technique.[14] The flexible fiberoptic bronchoscope is regarded as the gold standard for intubation in pediatric patients with difficult airways.[14,15]

CASE DESCRIPTION

An 83-year-old female patient with a history of systemic hypertension, hypothyroidism, and mild cognitive impairment, managed with medical treatment, underwent placement of a permanent dual-chamber pacemaker in DDDR mode in March 2023 for complete atrioventricular block. She was admitted to the hospital in July 2025 for scheduled replacement of the device due to suspected malfunction. The patient did not report severe chest pain, but had recently experienced episodes of fatigue, mild dyspnea, and palpitations. Upon device interrogation, an output voltage of 5V was detected, prompting adjustment of the pacemaker mode to DDD with an output voltage of 2V. A chest X-ray was performed,

Table 1: Risk factors for cardiac perforation by pacemaker electrodes.

Patient-related factors	Factors related to the implant or technique
• > 80 years of age • Female • BMI < 20 kg/m^2 (underweight) • Use of steroids • Comorbidities such as T2DM, HTN	• Electrode thickness and stiffness • Active fixation mode • Excessive electrode tension • Temporary transvenous pacemaker • Non-septal tip location • Operator experience

BMI = body mass index. HTN = hypertension.
T2DM = type 2 diabetes mellitus.

Table 2: Predictors of complexity for difficult intubation.[13,14]

Lower complexity	Greater complexity
• Mallampati score III or IV • BMI > 40 (morbid obesity) • Limited cervical mobility • Limited mandibular protrusion • Thyromental distance < 6 cm • Mento-sternal distance < 12 cm • Short, thick neck, dental deformities, macroglossia, facial hair • Male sex	• History of difficult intubation • Two or more predictors of lower complexity • Cervical immobility • Mouth opening < 3 cm • Airway tumors or masses • Craniofacial malformations • Airway manager inexperience

BMI = body mass index.

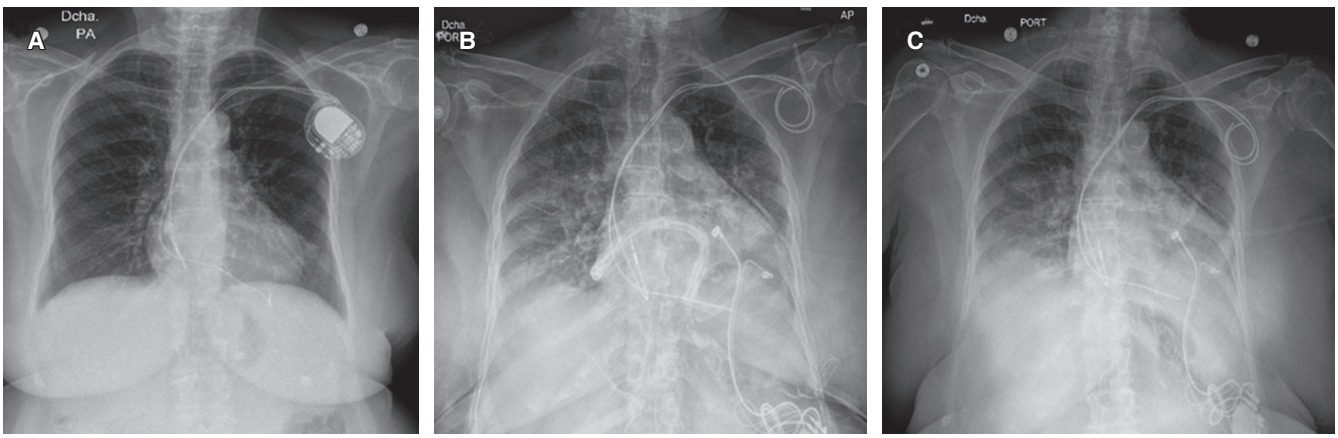

Figure 1: A) Anteroposterior chest X-ray upon admission to the service. A left dual-chamber pacemaker is observed, with one electrode located in the right atrium and another toward the free wall of the right ventricle with myocardial perforation and migration toward the mediastinum. **B)** Anteroposterior chest X-ray immediately after the pacemaker replacement procedure. Presence of mediastinal probe. Left metal electrodes without a pacemaker source, with the presence of a second functional pacemaker with epicardial leads in the left chambers. **C)** Anteroposterior chest X-ray at the time of hospital discharge. Leads from the previous dual-chamber pacemaker without a pacemaker source remain, with the presence of a second functional pacemaker with epicardial leads in the left chambers.

demonstrating a dual-chamber pacemaker with electrodes situated in the right chambers. However, the right ventricular electrode exhibited migration toward the mediastinal space *(Fig. 1A)*. Consultation with the thoracic surgery department was requested, leading to scheduling of surgical replacement of the dysfunctional pacemaker with epicardial leads. The pre-anesthetic assessment yielded the following parameters: mandibular protrusion: 1, Oral opening: II (2 cm), Mallampati: IV, Thyromental distance: II, Atlanto-occipital extension: II, and a body mass index of 30.36 (World Health Organization [WHO] grade I obesity), indicating clinical predictors of a difficult airway. Additionally, the patient reported a history of difficult airway in previous surgical procedures, as documented by anesthesiology. The patient was transferred to the operating room, where Point of Care Ultrasound (POCUS) screening and airway assessment using linear ultrasound were performed to measure the distance between the vocal cords, thereby predicting the endotracheal tube size, which was determined to be 0.45 cm *(Fig. 2)*. Following this measurement, type I monitoring and neuromonitoring were instituted, with induction achieved using fentanyl at 2 µg/kg, lidocaine 1 mg/kg, and rocuronium 50 milligrams. Hybrid intubation was then performed, utilizing a video laryngoscope with a McGrath #2 blade, which yielded a video classification of intubation (VCI): VCI M75D classification by the first operator. A second operator employed a pediatric fiberoptic bronchoscope to locate the carina, facilitating placement of a #5 endotracheal tube. The endotracheal tube was secured at 18 cm from the lip commissure. Anesthesia was maintained with desflurane at 1 minimum alveolar concentration after which the surgical procedure commenced. During the approach via anterior thoracotomy at the level of the fourth

left intercostal space, a pericardial window was created, confirming myocardial perforation of the anterior wall of the right ventricle secondary to migration of the pacemaker electrode *(Fig. 3)*. A mediastinal tube was left in place, and a control anteroposterior radiograph was obtained immediately post-procedure *(Fig. 1B)*. Following a one-week hospital stay characterized by adequate clinical progress, the patient was deemed suitable for discharge *(Fig. 1C)*.

COMMENT

We present the case of an 83-year-old female patient who developed cardiac perforation secondary to migration of a pacemaker electrode that had been placed two years prior. Ventricular wall perforation is a rare but potentially fatal complication if not identified and treated in a timely manner. The patient exhibited several risk factors for cardiac perforation, including age > 80 years, female sex, presence of comorbidities (hypertension), and a non-septal location of the ventricular electrode tip, specifically situated at the free wall. Given the characteristics of the injury and the patient's risk profile, a surgical approach via anterior thoracotomy was elected. Considering the patient's history of difficult airway, a decision was made to employ a hybrid intubation technique, which is a management strategy for difficult airways utilizing a dual-device approach, namely a video laryngoscope and a flexible fiberoptic bronchoscope. Video-laryngoscopy is associated with enhanced glottic visualization, a high success rate (92%), and a relatively rapid learning curve. Although the hybrid intubation technique is predominantly utilized in pediatric populations, it can be highly beneficial in adult patients presenting with difficult airways. The hybrid technique demonstrates a higher first-attempt intubation success rate in adults compared to the standard technique. Furthermore, it reduces the incidence of airway trauma, expedites the intubation process, minimizes episodes of desaturation, and obviates the need for alternative techniques to achieve successful tracheal intubation, relative to standard intubation methods.[14,15]

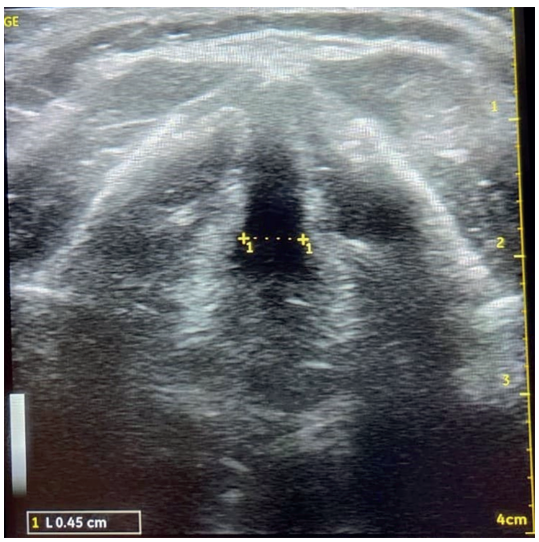

Figure 2: Ultrasound image of the glottis, distance between vocal cords 0.45 cm.

CONCLUSIONS

Although transvenous pacemakers with intraventricular electrodes are generally considered safe, they are associated with a risk of complications, including electrode malfunction and ventricular wall perforation. Device dysfunction should be promptly evaluated and identified, irrespective of the time

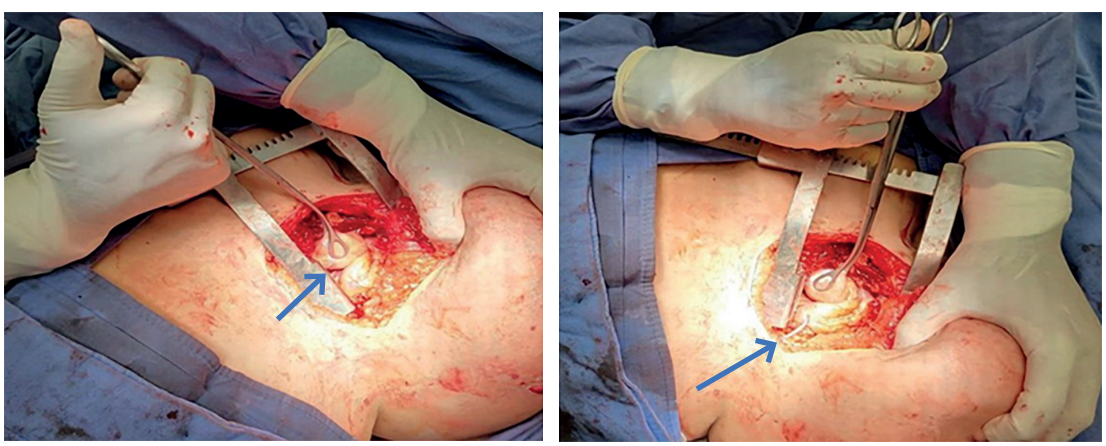

Figure 3: Surgical approach via anterior thoracotomy at the level of the fourth left intercostal space. The electrode originally located in the right ventricle can be seen, which has moved toward the mediastinum, perforating the anterior wall of the right ventricle.

elapsed since pacemaker placement. It is noteworthy that the majority of complications attributable to perforation tend to manifest clinically during the initial months following placement. With regard to airway management in patients with a documented history of difficult airway, as exemplified by the present case, the hybrid technique of flexible bronchoscopy assisted by video-laryngoscopy is of particular importance. Despite its widespread use in pediatric patients, this technique facilitates safe and successful tracheal intubation in these patients and can be employed electively or as a rescue measure.[14,16]

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CASE REPORT
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Double aortic arch due to a persistent left arch remnant: a tomographic finding in a patient with tetralogy of Fallot

Doble arco aórtico por remanente de arco izquierdo: hallazgo tomográfico en un paciente con tetralogía de Fallot

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ABSTRACT

The term vascular ring refers to a group of aortic arch anomalies that compress the trachea, esophagus, or both. These malformations represent approximately 1% of all congenital heart defects and are characterized by the formation of a complete ring around the trachea and esophagus, composed of structures derived from the primitive aortic arches. Within this group is the double aortic arch, a rare condition that can be associated with various congenital heart defects. We present the case of a double aortic arch secondary to a persistent remnant of the left aortic arch, identified incidentally on computed tomography in a patient with tetralogy of Fallot.

Keywords: aortic arch anomalies, computed tomography, congenital heart disease, double aortic arch, tetralogy of Fallot, vascular ring.

RESUMEN

El término anillo vascular se refiere a un grupo de anomalías del arco aórtico que producen compresión de la tráquea, el esófago o ambos. Estas malformaciones representan aproximadamente 1% de todas las cardiopatías congénitas y se caracterizan por la formación de un anillo completo alrededor de la tráquea y el esófago, constituido por estructuras derivadas de los arcos aórticos primitivos. Dentro de este grupo se encuentra el doble arco aórtico, una entidad poco frecuente que puede asociarse a diversas cardiopatías congénitas. Presentamos el caso de un doble arco aórtico secundario a un remanente persistente del arco izquierdo, identificado como hallazgo tomográfico en un paciente con tetralogía de Fallot.

Palabras clave: *anomalías del arco aórtico, tomografía computarizada, cardiopatías congénitas, doble arco aórtico, tetralogía de Fallot, anillo vascular.*

Abbreviations:
CT = Computed Tomography
DAA = Double Aortic Arch

Double Aortic Arch (DAA) results from the persistence of both primitive fourth aortic arches. In this condition, the subclavian and common carotid arteries typically arise independently from each arch. The larger arch is termed dominant, with the right arch being predominant in 75-81% of cases.[1]

As a vascular ring, DAA belongs to a group of cardiovascular and ligamentous anomalies originating from abnormal embryonic development, frequently causing

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symptomatic compression of the trachea or esophagus.[2] While DAA often occurs as an isolated lesion, it is associated with other congenital heart diseases in approximately 22% of cases.[3] Among these associations, ventricular septal defect and tetralogy of Fallot are the most prevalent, followed by transposition of the great arteries and truncus arteriosus.[4,5]

This report presents a case of double aortic arch identified as an incidental tomographic finding in a patient with tetralogy of Fallot.

CASE DESCRIPTION

A 7-year-old male presented with a heart murmur and dyspnea on moderate exertion. Echocardiography revealed Tetralogy of Fallot; however, the anatomy of the aortic arch could not be definitively visualized. Consequently, cardiac Computed Tomography (CT) angiography was performed, demonstrating a right aortic arch with mirror-image branching of the supra-aortic trunks and a remnant of the left aortic arch *(Fig. 1)*, consistent with a truncated double aortic arch. The left arch terminated caudally in a blind *cul-de-sac*, originating from the left brachiocephalic trunk *(Fig. 2) (Fig. 3)*.

Given the absence of obstructive symptoms characteristic of a vascular ring and no detectable pressure gradient on echocardiography, the medical team proceeded with the complete surgical repair of the tetralogy of Fallot while opting for conservative monitoring of the double aortic arch. To date, the patient's postoperative progress has been satisfactory.

COMMENTARY

Vascular rings are embryonic developmental anomalies of the aortic arch and great vessels resulting from the persistence of the fourth primitive aortic arches. These structures partially or completely encircle the trachea and esophagus, potentially causing compression and subsequent respiratory or gastrointestinal symptoms.[3,4] The term encompasses both complete rings and partial configurations, with or without fibrous ligamentous bands, that exert mass effect on the aerodigestive tract.[3] While the DAA is the most common complete vascular ring, the case presented here describes an incomplete or truncated variant.

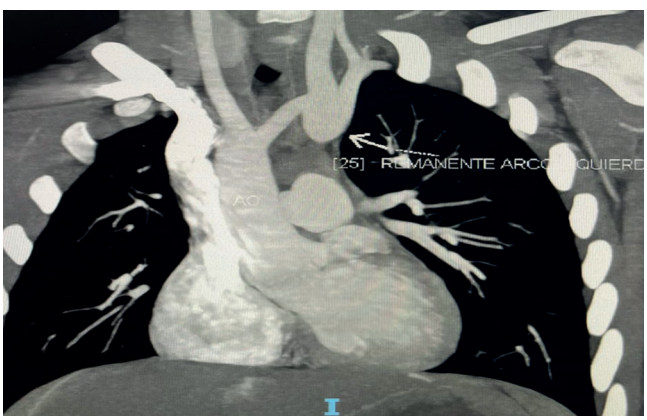

Figure 1: Sagittal section tomography of the heart showing the right aortic arch with a remnant of the left arch.

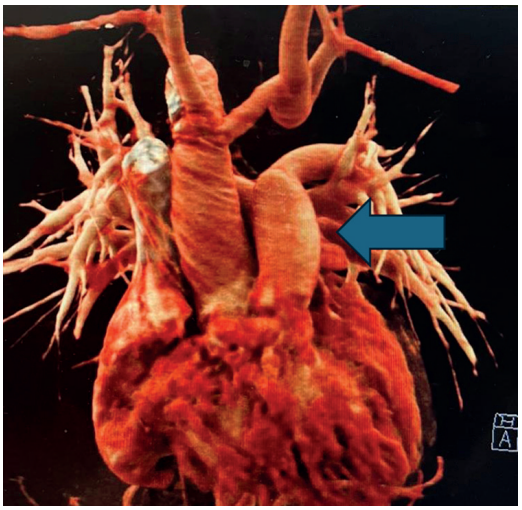

Figure 2: Reconstruction of angiotomography of the heart and large vessels where the arrow point to the remnant of the left arch.

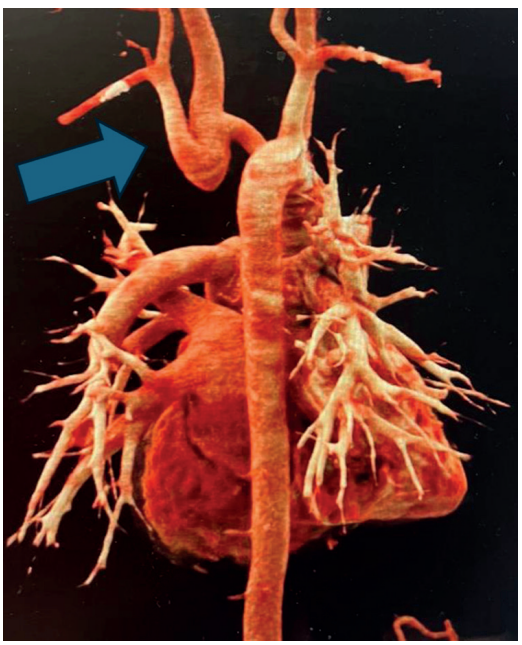

Figure 3: Reconstruction of angiotomography of the heart and large vessels with a posterior view where the remnant of the left arch can be seen ending in a blind *cul-de-sac* caudally.

During cardiac morphogenesis, five pairs of aortic arches connect the ventral and dorsal aortas. The persistence of both fourth aortic arches and both dorsal aortas give rise to a DAA.[3] Typically, these arches are asymmetrical, with right-sided dominance being the most frequent presentation,[5] as observed in our patient. This condition shows a slight male predominance and may occur in isolation; however, approximately 22% of cases are associated with other congenital heart defects, most notably ventricular septal defects and tetralogy of Fallot.[6] This aligns with our case of a male patient diagnosed with Tetralogy of Fallot.

Although symptoms from tracheal or esophageal compression are common, some cases remain asymptomatic and are discovered as incidental findings.[7] Among the various diagnostic modalities, non-invasive techniques such as CT angiography and magnetic resonance imaging are currently preferred. These tools provide detailed three-dimensional anatomical visualization, which is essential for accurate diagnosis and surgical planning.[8]

CONCLUSIONS

Vascular rings represent a rare group of pathologies that warrant exclusion in patients presenting with conotruncal heart defects. Non-invasive diagnostic modalities, particularly computed tomography angiography and magnetic resonance imaging, offer precise anatomical delineation, facilitating accurate diagnosis and management planning.

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CASE REPORT
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Ozaki procedure. Initial experience in a Mexican Pediatric Heart Center

Procedimiento de Ozaki. Experiencia inicial en un Centro Mexicano de Cardiología Pediátrica en México

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ABSTRACT

This article reviews the Ozaki procedure, its surgical indications, a description of our surgical technique, and the clinical outcome in a pediatric patient. The objective is to report the first case of the Ozaki procedure in a pediatric patient at our institution.

Keywords: aortic valve repair, Ozaki procedure, autologous pericardium, aortic valve neocuspidization (AVNeo).

RESUMEN

El presente artículo realiza una revisión del procedimiento de Ozaki, sus indicaciones operatorias, la descripción de nuestra técnica quirúrgica y el resultado clínico en un paciente pediátrico. El objetivo es reportar el primer caso del procedimiento de Ozaki en un paciente pediátrico en nuestra institución.

Palabras clave: *reparación de la válvula aórtica, procedimiento de Ozaki, pericardio autólogo, neocuspidización de la válvula aórtica (AVneo).*

Abbreviation:
AVNeo = aortic valve neocuspidization

INTRODUCTION

Aortic valve disease in the pediatric group presents several surgical challenges in order to preserve the valve as long as possible until adulthood. Techniques such as commissurotomy, annuloplasty, cusp free edge unfolding, and supra-aortic crest enhancement have yielded promising results in adult populations.[1] However, balloon valvuloplasty and the Ross procedure are well-established options for pediatric patients. The Ross procedure is criticized for converting single-valve disease into two-valve pathology and causing neo-aortic dilatation and technical complexity. Consequently, a reproducible procedure that maintains optimal hemodynamics without anticoagulation and mitigates the challenges associated with the Ross procedure is warranted.

In 2011, Shigeyuki Ozaki pioneered the aortic valve neocuspidization (AVNeo) procedure, initially describing its

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application in a cohort of adult patients with diverse etiologies, including aortic stenosis, infective endocarditis, prosthetic valve endocarditis, and annulo-aortic ectasia.[2] In contrast, pediatric aortic valve disease poses distinct challenges due to its often-congenital origin, necessitating consideration of the dynamic interplay between the developing aortic root and leaflets as the child grows. This ontogenetic factor critically influences the selection of an optimal procedure, tailored to the patient's age and aortic anatomy. Notably, the Ozaki procedure's utilization of autologous pericardium confers several advantages, including enhanced tissue durability, reduced immunogenicity, and a mitigated risk of calcification, thereby underscoring its potential benefits in pediatric patients.

These factors collectively contribute to the durability and resilience of the reconstructed valve, thereby enhancing its long-term functionality.[3] The standard technique can be tailored to accommodate diverse patient profiles, including those with prior aortic valve replacement, pediatric patients, and individuals with congenital aortic valve disease, encompassing a range of valve morphologies, such as unicuspid, bicuspid, and quadricuspid valves. Notably, the predominant pathology in older adults is typically acquired calcific aortic stenosis, often associated with bicuspid valves, whereas in young pediatric patients, congenital aortic valve stenosis with regurgitation secondary to balloon aortic valvuloplasty is more prevalent. Irrespective of the patient population, thorough excision of existing leaflets and fibrotic calcification or previously implanted valves enables the unrestricted application of the AVNeo procedure, unencumbered by native commissural architecture, cusp number, size, or position.[4] A crucial aspect of the procedure involves the utilization of glutaraldehyde, a potent aldehyde with fixative and preservative properties, which facilitates effective cross-linking of collagen, the primary structural component of valvular tissue, thereby conferring enhanced stability and durability.[5]

In an *ex-vivo* porcine model study conducted in Germany, researchers investigated the hydrodynamic performance and cusp kinematics of the Ozaki aortic valve in comparison to native and prosthetic aortic valves. The results demonstrated that both the Ozaki and native aortic valves exhibited comparable and significantly larger orifice areas than all prosthetic valves tested, particularly at high flow rates, with no discernible difference between the Ozaki and native valves. Moreover, the native aortic valve and Ozaki valve displayed a similar increase in effective orifice area in response to increasing flow rates, whereas prosthetic valves showed a notably weaker response. Cusp kinematics were also comparable between native and Ozaki valves, whereas prosthetic valves exhibited distinct differences. These findings led to the conclusion that the Ozaki valve exhibits physiological behavior in multiple aspects, which may potentially contribute to favorable clinical outcomes.[6]

CASE REPORT

We present the case of a 14-year-old female patient with Turner syndrome. She had a history of a heart murmur, detected at age seven. A diagnosis of aortic stenosis was made, and she underwent two balloon dilations via cardiac catheterization at ages 7 and 9. At follow-up, the patient presented with both stenosis and insufficiency. She was followed by endocrinology and was managed with somatropin. Clinically, she presented with dyspnea on heavy exertion. Her weight was 39.7 kg, height was 144 cm, and saturation was 96%. Physical examination revealed an expulsive systolic murmur in a IV/VI aortic foci. Chest X-ray showed a cardiothoracic ratio of 0.43. The electrocardiogram was in sinus rhythm, showing evidence of left ventricular hypertrophy. The echocardiogram reported bicommissural aortic valve with a mean gradient of 55 mm Hg, mild to moderate aortic regurgitation, aortic annulus 18.8 mm, and dilated coronary sinus *(Fig. 1)*. Surgical treatment was decided for aortic valve repair versus mechanical prosthesis implantation. A median sternotomy and central aortic and right atrial appendage cannulation were performed, cardiopulmonary bypass at 32 degrees Celsius, aortic cross-clamping was performed and cold blood cardioplegia was infused. An aortotomy was performed and a bileaflet aortic

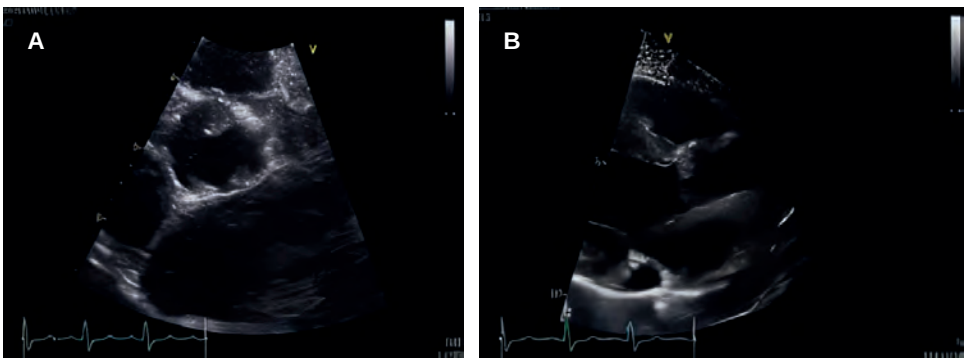

Figure 1:

A) Preoperative short axis echocardiogram of the aortic valve. B) Preoperative parasternal long axis of aortic valve.

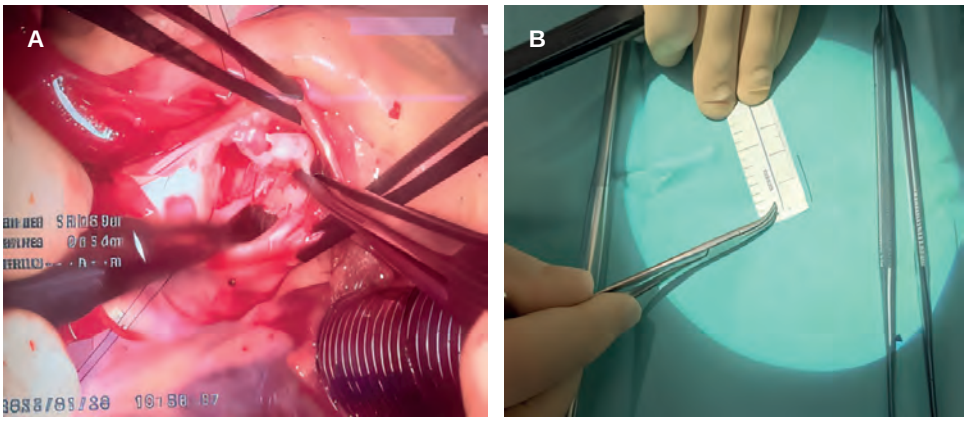

Figure 2:

A) Aortic valve stenosis with commissural fusion. B) Measuring cusps and commissures with silk.

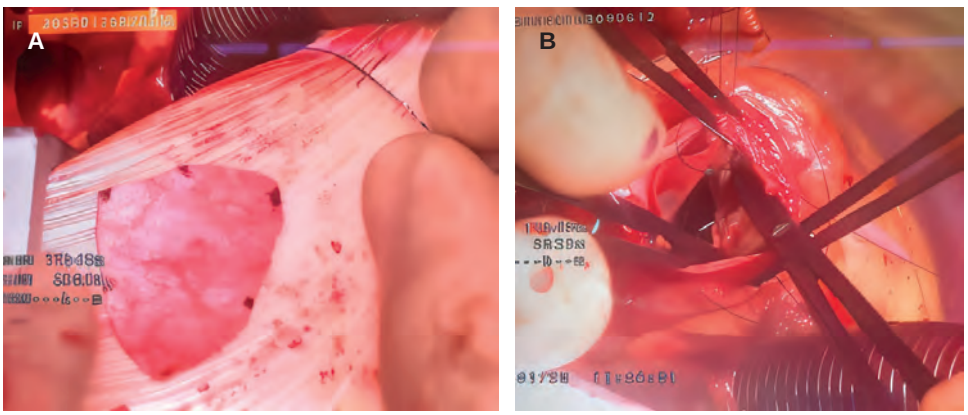

Figure 3:

A) Construction of neo-leaflet with autologous pericardium. B) Anastomosis of neo-leaflet to the aortic ring.

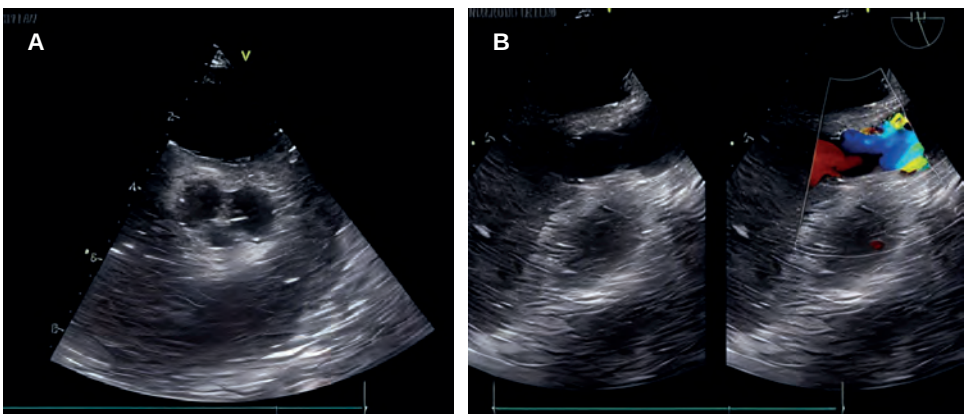

Figure 4:

A) Final result, short axis echocardiogram. B) Long axis without evidence of insufficiency on Doppler.

valve was observed, with fusion of the right coronary and non-coronary leaflets, finding a thick raphe between them. The edge of both leaflets was thickened with very little mobility *(Fig. 2A)*. A commissurotomy was performed, the edges were thinned, and the left coronary leaflet rupture site (caused by balloon dilation) was repaired with an autologous pericardial patch. The result was examined and found to be suboptimal.

The leaflets were resected, and the distance between the commissures, cusps, and nadir of the annulus was measured individually with 2-0 silk *(Fig. 2B)*. Subsequently, the cut points on the pericardium were marked, and each neo-leaflet was constructed with glutaraldehyde-treated pericardium *(Fig. 3A)*. A pericardial template was not available at our institution, and the neocusp was sutured to the aorta with 5/0

monofilament *(Fig. 3B)*. The postoperative echocardiogram showed preserved biventricular systolic function, without residual aortic stenosis or valvular regurgitation, and a velocity of 1.6 m/s *(Fig. 4)*. Cardiopulmonary bypass time was two hours 49 minutes. Aortic clamping time was two hours 14 minutes. Protamine was administered and the cannulas were removed, the sternum was closed, and atrial and ventricular pacemaker leads and mediastinal drainage were placed. The patient was transferred to intensive care and extubated within the first 24 hours without complications. The patient was discharged from the hospital on the 6th postoperative day.

COMMENT

The Ozaki procedure has yielded promising outcomes in pediatric patients to date. The AVNeo technique entails the complete excision of anomalous cusps and their individualized replacement with autologous pericardium. However, the long-term behavior of these neocusps in growing individuals remains uncertain, particularly with regard to the potential for progressive aortic regurgitation in patients with conotruncal anomalies who lack annular stabilization.[7] A meta-analysis conducted by Halder et al.[8] reported a notable absence of reoperation or moderate to severe aortic regurgitation in pediatric patients who underwent the Ozaki procedure. In contrast to the Ross procedure and other interventions for aortic valve disease, the Ozaki procedure appears to confer a lower risk of reoperation and mortality. Nonetheless, further longitudinal data are warranted to comprehensively assess the durability and efficacy of the Ozaki procedure in children.

CONCLUSIONS

The Ozaki procedure should be considered in the surgical treatment of aortic valve disease in children, as it offers very favorable hemodynamics with excellent postoperative results. Long-term results remain to be evaluated to determine the durability of the procedure.

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CASE REPORT

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Successful surgical closure of a ventricular septal rupture following an acute myocardial infarction. Case report

Cierre quirúrgico exitoso de ruptura del septum ventricular posterior a infarto agudo de miocardio. Informe de un caso

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ABSTRACT

Ventricular septal rupture is a rare yet severe complication of acute myocardial infarction. Delayed surgical closure is the treatment of choice in select cases. We present the case of a 71-year-old woman with anterior myocardial infarction who developed an apical ventricular septal rupture following late percutaneous coronary intervention. Echocardiography confirmed a 1.2 cm defect with a left-to-right shunt. The cardiology team recommended surgical closure, which was successfully performed on day 21 post-infarction. The patient experienced adequate recovery after a postoperative hemorrhagic complication and was discharged with clinical improvement. Delayed post-infarction closure may be beneficial in stable patients. This case supports an individualized and multidisciplinary approach.

Keywords: acute myocardial infarction, cardiogenic shock, heart failure, post–myocardial infarction, mechanical complication, ventricular septal rupture.

RESUMEN

La ruptura septal ventricular es una complicación poco frecuente pero grave del infarto agudo de miocardio. El cierre quirúrgico tardío es el tratamiento de elección en casos seleccionados. Presentamos el caso de una mujer de 71 años con infarto de miocardio anterior que desarrolló una ruptura del tabique ventricular apical después de una intervención coronaria percutánea tardía. La ecocardiografía confirmó un defecto de 1.2 cm con un cortocircuito de izquierda-derecha. El equipo de cardiología recomendó cierre quirúrgico, que se realizó con éxito el día 21 postinfarto. La paciente experimentó una recuperación adecuada después de una complicación hemorrágica postoperatoria y fue dada de alta con mejoría clínica. El cierre diferido postinfarto puede ser útil en pacientes estables. Este caso respalda un abordaje individualizado y multidisciplinario.

Palabras clave: *infarto agudo de miocardio, choque cardiogénico, insuficiencia cardíaca, infarto agudo de miocardio, complicación mecánica, ruptura del tabique interventricular.*

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Abbreviation:
VSR = ventricular septal rupture

The three main types of mechanical complications following acute myocardial infarction are: ventricular septal rupture (VSR), free wall rupture of the left ventricle, and severe acute mitral regurgitation secondary to papillary muscle rupture.[1] These complications typically occur early, within the first 48 hours after symptom onset, and are generally associated with occlusive coronary artery disease in the absence of collateral circulation.

In the case of VSR, onset typically occurs between the first 24 hours and days 3 to 5 following the onset of infarction symptoms.[2] VSR carries a high mortality rate, ranging from 50 to 80%, primarily attributed to ventricular failure secondary to large infarcts.[3]

CASE DESCRIPTION

We report the case of a 71-year-old female who presented with a 10-day history of anterior myocardial infarction. She received delayed reperfusion therapy via percutaneous coronary intervention to the left anterior descending artery on day 5, where acute thrombotic occlusion was identified and successfully treated with stent placement. The remaining coronary arteries showed no significant lesions.

While under observation, a holosystolic murmur was detected over the mid-precordium, raising suspicion of a mechanical complication. Transthoracic echocardiography confirmed the presence of an apical VSR, measuring 1.2 cm, with a left-to-right shunt and an interventricular gradient of 50 mmHg. Left ventricular ejection fraction was 48%, with regional akinesia involving the apex and apical segments of the lateral, anterior, and septal walls.

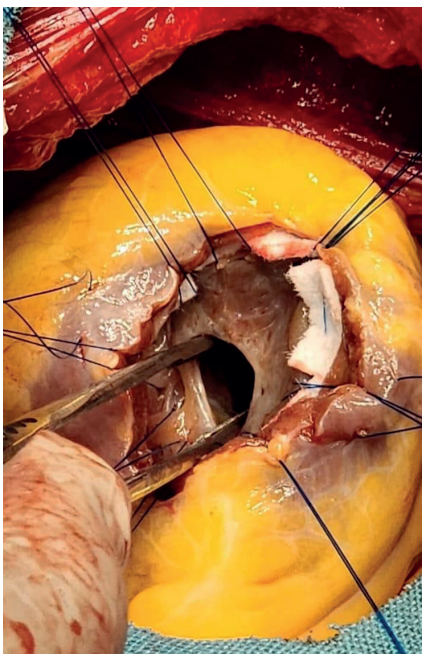

Figure 1:
Debridement of the necrotic muscle portion of the apical defect due to a 9-mm ventricular septal defect is observed, as well as placement of 3/0 polypropylene U-shaped sutures along the anterior edge of the defect.

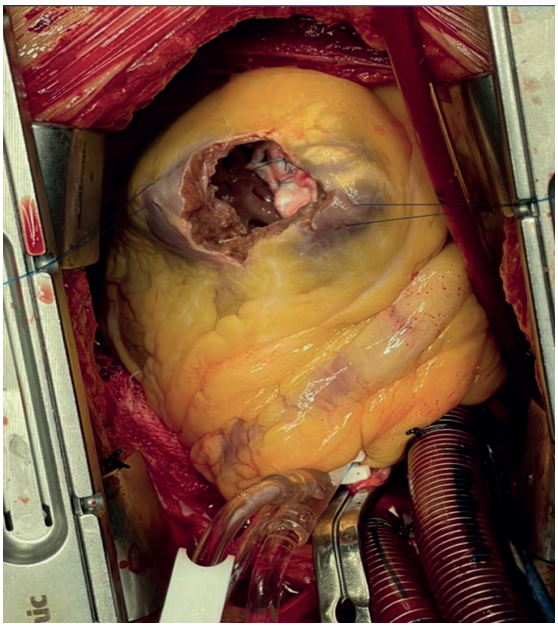

Figure 2: Left ventriculotomy in the infarcted inferior wall, lateral to the interventricular septum, identifying the ventricular septal defect.

The case was evaluated by the institution's heart team, which determined that due to the location of the defect, surgical closure was preferred. The patient remained under close observation in the coronary care unit, following literature-based recommendations that suggest delaying surgery to improve outcomes. Surgical intervention was performed on day 21 post-infarction. Intraoperatively, a 9-mm septal defect was identified *(Fig. 1) (Fig. 2)*, and successfully closed using a 15.2 × 15.2 cm polytetrafluoroethylene patch.

During the immediate postoperative period, the patient experienced higher-than-expected bleeding, prompting surgical re-exploration; however, no active bleeding was found, and no further intervention was required. The patient remained in the postoperative care unit, experienced early extubation, and progressed adequately. She developed acute kidney injury, which resolved within the first few days. After being transferred to the general ward, she began mobilization and ambulation, and was eventually discharged with clinical improvement.

COMMENTARY

According to international literature, the mortality rate for post-infarction mechanical complications exceeds 80%.

However, there is still ongoing debate regarding the optimal management approach and ideal timing for surgical repair.[4] Given the high mortality rate associated with post-infarction ventricular septal rupture, prompt recognition and timely intervention are crucial. Our case highlights the importance of a multidisciplinary approach and careful consideration of the optimal timing for surgical repair, which can significantly impact patient outcomes.

CONCLUSIONS

We report the case of a geriatric patient who underwent successful surgical intervention. Although there is no universally accepted guideline on the ideal timing for defect closure, it has been proposed that surgical repair performed after 18 days post-infarction yields better outcomes, as myocardial tissue is less friable. This was consistent with our patient's case, in which delayed intervention resulted in a favorable outcome.

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Two-stage surgery of the ascending aorta and aortic arch. An option for managing aortic pathology

Cirugía de aorta ascendente y arco aórtico en dos etapas. Una opción para el manejo en la patología aórtica

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ABSTRACT

Acute Stanford A aortic dissection is a condition with a high mortality rate that requires timely diagnosis and surgical treatment. We present the case of a 58-year-old patient with Stanford A aortic dissection, who initially underwent supracoronary aortic replacement with woven dacron. Nine days later, aortic arch replacement and revascularization of the supra-aortic trunks were completed in a second operation. The clinical outcome was favorable.

Keywords: aortic aneurysm, aortic dissection, ascending aorta, aortic arch, aortic surgery, surgical treatment.

RESUMEN

La disección aórtica aguda Stanford A es una patología con alta mortalidad que requiere un diagnóstico y tratamiento quirúrgico oportuno. Se presenta el caso de un paciente de 58 años con disección aórtica Stanford A, al cual se le realiza inicialmente una sustitución de aorta injerto de dacrón supracoronario. Nueve días después, se completó el reemplazo del arco aórtico y la revascularización de los troncos supraaórticos en una segunda operación. La evolución clínica fue favorable.

Palabras clave: *aneurisma aórtico, disección aórtica, aorta ascendente, arco aórtico, cirugía aórtica, tratamiento quirúrgico.*

Acute DeBakey type I aortic dissection is a critical and lethal pathology requiring urgent diagnosis and surgical treatment.[1,2] Despite continuous progress in surgical techniques, brain protection methods, and perioperative management, perioperative mortality remains high, with some reports indicating rates as high as 20%.[2] Surgical intervention for DeBakey type I aortic dissection is recognized as the gold standard and is often pivotal for patient survival.[3,4] This procedure usually involves the repair of the ascending aorta and, in many cases, the placement of a graft to restore aortic integrity.[4,5] However, the intricate nature of the surgery combined with the severe condition of the patients creates considerable challenges and a high probability of postoperative complications.

Given that the aortic dissection flap typically extends beyond the ascending aorta in the majority of patients, the ultimate fate of the residual dissected aorta holds increasing relevance for these survivors.[3] More than 10% of acute aortic dissection cases that undergo initial repair subsequently require one or more additional surgical interventions due to residual distal dissection.[1,4]

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In select instances, the intricate nature of the disease and the patient's precarious condition necessitate a stepwise, staged surgical approach.[2,3] This methodology facilitates a safer and more effective surgical intervention, meticulously tailored to the unique circumstances of each patient. This strategy is especially valuable for individuals with substantial comorbidities or those presenting with an unstable hemodynamic status, where immediate, single-stage surgery might confer a prohibitive risk of complications.[4,6] Through this deliberate approach, the objective is not only to effectively address the aortic dissection but also to optimize perioperative care and mitigate the potential for postoperative complications.

CASE DESCRIPTION

A 58-year-old male patient presented with a clinical presentation of oppressive chest pain, with sudden onset during aerobic physical activity, radiating to the interscapular region, associated with diaphoresis and dyspnea for 10 days. The patient had an 8-year history of systemic arterial hypertension and dyslipidemia, both under treatment.

The patient was evaluated in three hospital units for the clinical presentation described, with suspected acute coronary syndrome, and was discharged after the latter was ruled out.

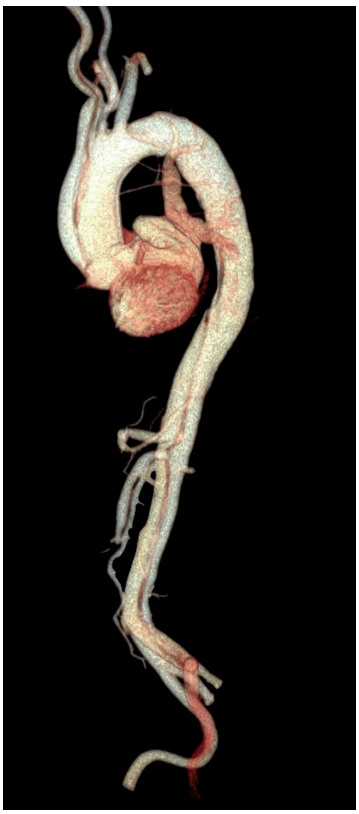

Figure 1:

Preoperative computed tomography reconstruction of the aortic dissection in the ascending and descending aorta.

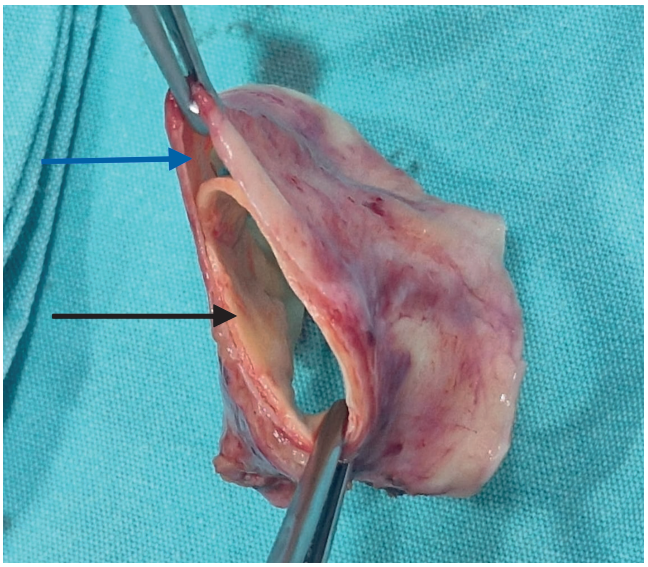

Figure 2: Resected ascending aorta showing true lumen (black arrow) and dissection flap with false lumen (blue arrow).

During a fourth evaluation, a thoracoabdominal CT angiography was performed, diagnosing a Stanford A, De Bakey type I aortic dissection, for which he was referred to our institution. The patient was admitted hemodynamically stable. CT findings showed a diameter of 37 mm at the level of the sinuses of Valsalva and 48 mm in the ascending aorta, with a dissection flap starting in the aortic root and extending to the supra-aortic trunks. Clinically, there was no cerebral malperfusion syndrome, limb or abdominal trunk involvement, and right renal hypoperfusion was a CT finding. Echocardiogram showed an ejection fraction of 65% and a trileaflet aortic valve with mild regurgitation *(Fig. 1)*.

The initial surgical procedure was performed on the patient's second day of admission. Cardiopulmonary bypass was achieved via femoral arterial cannulation and venous cannulation in the right atrium. The patient's temperature was lowered to 30 °C. The procedure involved resection and replacement of the ascending aorta in the supracoronary region and proximal to the brachiocephalic trunk *(Fig. 2)*. The aortic tissue was reinforced at the distal and proximal ends with intraluminal and extraluminal Teflon bands, and a 30-mm Dacron woven tube was used to replace the resected aorta. Direct examination of the aortic valve revealed no structural abnormalities. The aortic cross-clamping time was 133 minutes, and extracorporeal circulation was 168 minutes.

The postoperative course was favorable. During the postoperative period, the presence of systemic arterial hypertension refractory to medical treatment was noted. The postoperative control CT scan identified a dissection flap distal to the cranial end of the graft, which perpetuated

pressurization of the false lumen toward the supra-aortic and abdominal trunks. For this reason, it was decided to perform a second intervention to replace the aortic arch with stabilization of the dissection flap and debranching of the supra-aortic trunks.

The second intervention was performed nine days after the first surgery, in the context of surgery on a patient with clinical stability. Cannulation for cardiopulmonary bypass was performed via a central line due to the impossibility of passing guidewires for femoral cannulation. The arterial line was connected via a Dacron woven chimney anastomosed to the graft in the ascending aorta position, and the venous drainage line was introduced through the right atrium. Body temperature was reduced to deep hypothermia as a measure of cerebral and visceral protection. The aortic arch was resected, reinforcing the distal lumen with Teflon bands. An anastomosis was created with a 28-mm Dacron woven tube. Debranching revascularization was then performed to the left subclavian artery, left carotid artery, and brachiocephalic trunk. The procedure ended with a circulatory arrest time of 115 minutes, aortic cross-clamping of 218 minutes, and extracorporeal circulation of 291 minutes *(Fig. 3)*.

The patient's postoperative course was uneventful, with stabilization of the aortic lumen and no clinical changes suggestive of poor perfusion. To date, he has not required reintervention.

COMMENT

Aortic dissection with ascending aortic involvement requires timely diagnosis and treatment. Despite its characteristic clinical presentation, the spectrum of conditions that can be differentially diagnosed is broad. Therefore, a high level of suspicion and a comprehensive and exhaustive evaluation of the case, leading to appropriate decision-making in an optimal timeframe, have the potential to have a positive impact on the patient's outcome. The best chances of survival in most patients are associated, above all, with the time elapsed from the onset of symptoms to the time of surgical resolution.[3,6,7]

The surgery to be performed in patients with aortic dissection is strictly related to the patient's preoperative condition, prognosis, the structures involved, and the presence or absence of secondary clinical alterations. In the case of this particular patient, the indication for aortic valve preservation is evident, since there were no structural or hemodynamic alterations secondary to valve dysfunction, the main objective in the first intervention was to stabilize the lumen of the diseased aorta by replacing the supracoronary portion.[3-5]

The need for intervention beyond the brachiocephalic trunk in the setting of acute aortic syndromes, such as hemiarch and aortic arch replacement procedures, depends on three circumstances: the presence of primary reentry sites in the aortic arch or proximal descending aorta, the presence of cerebral or peripheral malperfusion syndrome, and the presence of aneurysmal dilatation or rupture of the aortic arch or descending aorta; these indications are presented with a class IIa recommendation and level B evidence in the 2021 American Association of Thoracic Surgery guidelines for the surgical management of acute type A aortic dissection, so the indication for surgical management limited to the ascending aorta in the patient complies with what is recommended according to the guidelines.[8]

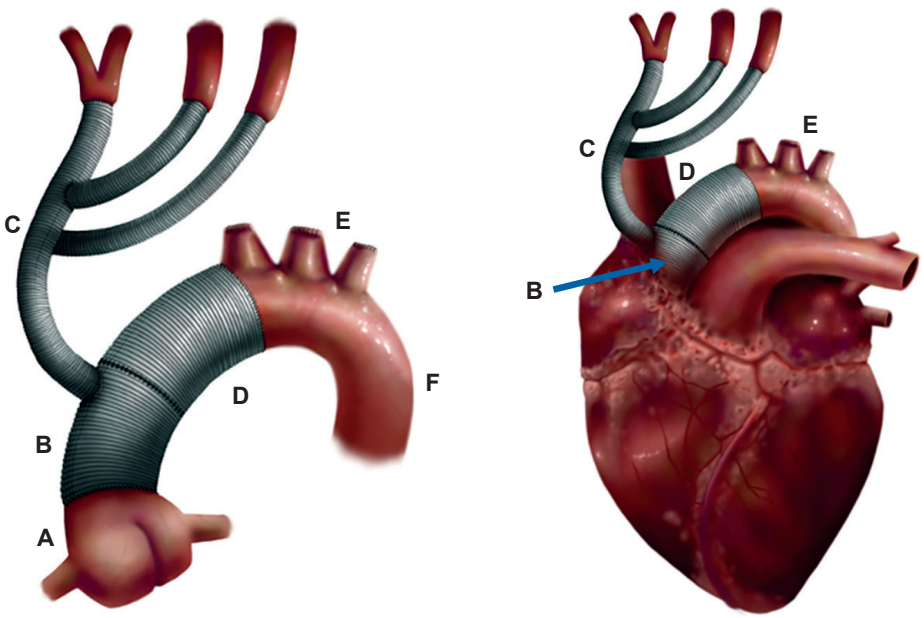

Figure 3:

Representation of the complete procedure performed. **A)** Aortic root. **B)** Dacron woven graft of the supracoronary aorta. **C)** Revascularization (debranching) of supra-aortic trunks from a proximal graft. **D)** Distal Dacron woven graft. **E)** Ligation of supra-aortic trunks. **F)** Descending aorta.

The discovery of a residual dissection flap distal to the site of the initial surgery is the primary indication for a second intervention, intended to restore flow to the true aortic lumen. The need for cerebral and visceral protection during the circulatory arrest required for aortic arch surgery requires meticulous preoperative analysis and planning. Although various strategies exist for such protection, in this case, the exclusive use of deep hypothermia during the circulatory arrest period proved effective.

Undoubtedly, the surgical management of patients with aortic dissection represents a challenge that goes beyond the technical skill required to perform the surgery. A favorable outcome is impossible without adequate analysis and functioning of Team Aorta from the moment of diagnosis to the patient's discharge.

CONCLUSIONS

Two-stage surgery represents a valid and safe strategy in patients with DeBakey type I aortic dissection, especially in cases of high anatomical and clinical complexity, optimizing surgical and clinical outcomes.

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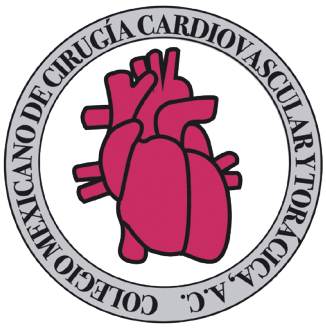
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