SOLACI SOCIME'25
MEXICO CITY

USO DE PROTESIS BALON EXPANDIBLE MYVAL EN PACIENTES DE MUNDO REAL EN DOS CENTROS DE ECUADOR

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INTRODUCTION

Innovation in this field has led to the development of the Myval balloon-expandable prosthesis (Meril Life Sciences Pvt. Ltd., India). The device was awarded the European Community (CE) mark following the Myval-16 study, conducted in 30 patients at intermediate-to-high risk. It demonstrated its efficacy and safety, with no paravalvular leak, significant aortic regurgitation, or the need for a permanent pacemaker after implantation, and a 12-month survival rate of 86.67%. One of the main novelties is that its sizes, based on valve diameter, include 20, 23, 26, and 29 mm, like the SAPIEN 3 system, but also 21.5, 24.5, and 27.5 mm, which limits the degree of overexpansion of the aortic annulus and reduces the risk of rupture, one of the main concerns when implanting balloon-expandable prostheses. It also adds 30.5 and 32 mm sizes, covering a wider range of sizes. Furthermore, the system is inserted through an expandable 14 Fr introducer, resulting in a shorter entry profile compared to other devices.
This study includes the use of the device in real-world patients and its long-term efficacy, safety, and benefit.

OBJECTIVES

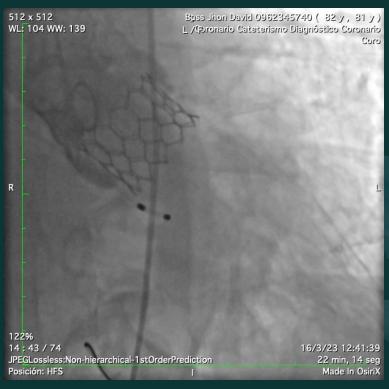
165 patients were included from December 18, 2020, to May 27, 2025, in a single high-complexity center. Baseline characteristics, procedural data, and one-year clinical follow-up were analyzed retrospectively.

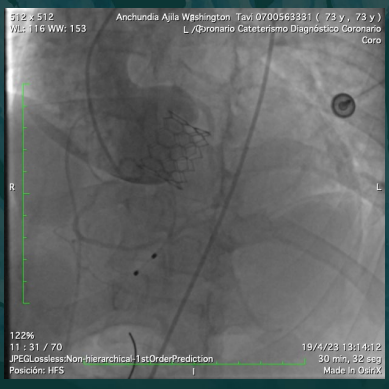
RESULTS

Of the patients undergoing TAVI, 62% were implanted with the Myval aortic prosthesis; 60% were male; the mean age was 75 years; 92% had hypertension; 55% had DM; 20% had PLD; 13% had prior AMI; 6% had CABG; and 5% had valve replacement. The most common clinical presentation of patients was dyspnea in 65%; cases of aortic stenosis and regurgitation, tricuspid, and bicuspid valves were included. In this cohort, procedural success was 93% with Myval in 103 patients who underwent implantation. Immediate cardiac death occurred in 3 patients (2%) and 14 patients (13%) postoperatively, at one month, and at one year. The pacemaker rate was 15% at one year in 16 patients.

CONCLUSIONS:

This registry suggests the efficacy and safety of MyVal in the percutaneous treatment of severe, high-risk aortic valve disease. Following successful implantation, MyVal demonstrated adequate functional parameters, which persisted over the medium term and at one-year follow-up.





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