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Editorial

# Insights on the first report of the Spanish registry of durable mechanical support (REGALAD)

## Reflexiones sobre el primer informe del registro español de asistencia ventricular de larga duración (REGALAD)

Sharan Malkani and José Nativi-Nicolau*

*Division of Heart Failure and Transplant, Mayo Clinic, Jacksonville, Florida, United States*

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## INTRODUCTION

Given the scarcity of donors and contraindications for transplant, the use of durable mechanical circulatory support (MCS) devices for treating advanced heart failure (HF) has increased steadily over the last FEW decades. Their versatility provides new treatment avenues as a bridge to heart transplant and destination therapy. Their growing use has been due to engineering advances in electromagnetic hydraulics that allow for smaller durable pumps. Initially, in 2002 the REMATCH trial introduced the first generation of pulsatile implantable left ventricular assist devices, the HeartMate I (Abbott, United States), after showing improved survival.[1] It was followed by the second-generation, axial flow nonpulsatile devices, the HeartMate II, after studies by Miller et al.[2] in 2007 and Slaughter et al.[3] in 2009 showed their use as a bridge to transplant and destination therapy, respectively. Then, third-generation devices were introduced. Initially, the HeartWare Ventricular Assist Device ([HVAD] Medtronic, United States), a centrifugal flow device in 2012, and later in 2019, the MOMENTUM 3 trial[4] established the contemporary HeartMate 3. This fully magnetically levitated central flow pump device significantly improved survival and reduced major adverse event rates. All of the studies showed a continuum of improved survival and fewer adverse effects that changed the boundaries of MCS therapy, allowing the evolution of clinical practice in managing patients with advanced HF. Despite the convincing efficacy and safety demonstrated in clinical trials, these studies do not describe the challenges of practices and patients beyond the umbrella of a clinical trial. Registries can provide complementary information on "real-world" outcomes and temporal trends that can be used by providers, patients, industry, and governments to guide therapeutic goals and strategies.

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* Corresponding author.
*E-mail address:* nativinicolau.jose@mayo.edu (J. Nativi-Nicolau).

## THE REGALAD FIRST REPORT

The Spanish registry of durable assist devices (REGALAD), recently published in *Revista Española de Cardiología*, the first report of 263 patients with durable ventricular assist devices (dVADs) implanted from 2007 to 2020.[5] This is a comprehensive collaboration among the 22 implanting centers in Spain. Their data includes 263 implanted dVADs, including 69% continuous flow devices, 30% pulsatile flow devices, and 1% with total artificial hearts. Overall, there is a continuous growth in implants per year, starting with 1 implant in 2007 and then peaking at 41 implants in 2019.

### Survival

In REGALAD, patients supported with continuous flow devices achieved a remarkable survival of 80.0% at 12 months. These results approximate the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) survival of 81.9% at 12 months[6] and is higher than that described by the European registry for patients with Mechanical Circulatory Support (EUROMACS) of 69% at 12 months.[7] Survival analysis using INTERMACS and EUROMACS as points of reference enables more clarity and perspective on the Spanish registry. Furthermore, their results further consolidate the Spanish standard of care and reflect how dVADs have been firmly established in Spain as a valuable tool in managing advanced HF patients.

### Temporal trends

The REGALAD registry includes patients over a 13-year period. This extensive registration period displays the evolution and adoption of the newest trends in MCS patient care. The data were divided into 3 cohorts, 2007-2020, 2011-2015, and 2016-2022. Regarding management indications, the REGALAD registry showed an increase in destination therapy from 0%, 25%, and up to 30% for each cohort. This trend suggests more confidence in the durability of newer devices with fewer adverse effects to support older adults for longer years. Although destination therapy is trending upward, the proportion remains significantly lower than the INTERMACS

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**Table 1**
Utility of clinical registries[8]

| | |
|---|---|
| Evaluating patient outcomes | Outcome results can be generalizable to a wider range of patients |
| Evaluates care provided | Reported outcomes reported are more representative of what is achieved in real-world practice |
| Describes natural history of disease | Includes characteristics, management, and outcomes with and/or without treatment |
| Determining effectiveness | Determine clinical effectiveness and cost-effectiveness in real- world clinical practice |
| Measuring or monitoring safety and harm | Quantifying risk and attributing it properly. Works as a surveillance system for the occurrence of unexpected events |
| Measuring quality of care | Allows quantifying the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge |

registry, which reached 78% in 2020, dramatically increasing from 49.5% in 2017. This increase might represent the 2018 United Network for Organ Sharing heart allocation policy changes in the United States that triggered a shift to prioritize patients on temporary MCS compared with patients on dVADs.

Additionally, the Spanish registry shows the percentage of patients implanted according to their risk profile using the INTERMACS risk classification. Their data revealed a lower trend for high-risk INTERMACS 1-2, decreasing from 36%, 28%, and 18% for each cohort. Notably, the stable patients with symptoms at rest INTERMACS 4, increased from 18%, 25%, and 28%. This trend could be explained by the approach to providing upfront temporary MCS to move the patient from a high-risk INTERMACS 1-2 in cardiogenic shock to a lower-risk INTERMACS 3-4 before a dVAD is implanted. This practice is described and encouraged in the last HF guidelines of the European Society of Cardiology and is based on the better survival observed in lower risks INTERMACS 3-4. However, compared with REGALAD, the INTERMACS registry has a higher proportion of high-risk INTERMACS 1-2, up to 52%. The difference could be related to the scarcity of available donors, with longer waiting times in the United States requiring dVADs as a bridge to transplant for those who cannot wait for long periods on temporary MCS.

## CLINICAL USEFULNESS OF REGISTRIES

The ability to compare the delivery of medical practice in different parts of the world raises the importance of a clinical registry. These have been fundamental in self-evaluating and emphasizing measurement and improvement in the quality and efficiency of medical care. By measuring performance, registries are designed to understand the care provided and its outcomes. The organized system of observational data has allowed the evaluation of specific outcomes that provide a view of current clinical practice, patient outcomes, and safety. Table 1 summarizes the uses of clinical registries proposed by Gliklich, Dreyer, and Leavy.[8]

In the case of MCS, it has allowed the comparison of survival, treatment indications, and adverse events.[9] VAD registries show each phase of MCS care, from candidate selection to perioperative and longitudinal clinical management. In addition, registries surpass data from any clinical trial in national coverage, extended follow-up, and comparison of different pumps and their indications, essentially showing the entire landscape of the MCS device experience.

The REGALAD registry[5] has shown the capabilities of MCS programs in Spain. Their results are comparable to those of international practice as their quality metrics reveal positive outcomes. Registries in cardiovascular care remain an active area for innovation and continued evaluation. Maintaining data documentation will continue to be fruitful in the evolving standard of practice. MCS registries will continue to lay the foundation of decision-making influenced by factors beyond survival alone. They will refine the understanding of HF and its relationship with MCS to keep deciphering new management strategies for advanced HF therapies.

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## CONFLICTS OF INTEREST

None for this topic.

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