

## Long-Term Ventricular Assist Devices: Where are We in Brazil?

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The use of long-term ventricular assist devices (VADs) as a therapeutic option in patients with advanced heart failure (HF) refractory to drug therapy is well established worldwide. The latest update of the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) reported more than 27,000 VAD implants between 2010 and 2019, with approximately 3,000 implants annually in recent years. In addition, 12-month survival rates after implantation reached 82%, with significantly improved quality of life and functional capacity.<sup>1</sup>

The technological development of VADs in the last decade has dramatically changed the type of device used. Between 2010 and 2014, axial-flow devices accounted for most VAD implants. Since 2017, centrifugal-flow VADs with magnetic levitation have had a significant increase in the number of implants, accounting for 75% of implanted devices in 2019.<sup>1</sup>

This technological advancement, combined with increased expertise in the selection and care of patients with a VAD, has allowed gains in survival. Recent data show that the median survival of patients with a VAD is approaching 5 years.

Another trend in recent years, especially in the United States, has been the shift from VAD indication as a bridge to heart transplantation (HT) to destination therapy. This was encouraged by a change in the heart allocation policy by the United Network for Organ Sharing (UNOS) in 2018, which decreased the priority of patients on the HT waiting list with a previously implanted VAD, reducing their chance of transplantation compared with patients treated with intravenous inotropes or with percutaneous mechanical circulatory support.<sup>2</sup>

Until 2017, just under half of implants had destination therapy as a strategy. In 2019, more than 70% of VADs were implanted for this purpose.

Despite advances and promising results with the use of VADs, the rates of device-related events and the need for hospitalization after implantation remain high. More than 60% of patients undergoing a VAD implant are estimated to

develop relevant complications and require hospitalization in the first year after the procedure.<sup>1</sup>

These data further support the need for continuous development of new technologies and improvements in VADs. In the Momentum 3 study, which compared axial-flow devices vs centrifugal-flow devices with magnetic levitation, the rates of neurological events were significantly lower in patients with the newer devices.<sup>3</sup> Thus, with the increase in the number of patients receiving next-generation devices, the rates of complications, thromboembolic events, and hospitalizations are expected to gradually reduce.

In Brazil, the first VAD was approved by the Brazilian Health Regulatory Agency (*Agência Nacional de Vigilância Sanitária*, ANVISA) in 2000. Since then, few national studies have been published on the topic.<sup>4</sup> Data on the experience of national excellence centers are also limited.

Data provided by the companies that sell VADs in Brazil indicate that, since 2010, approximately 80 devices have been implanted in the country (one third of which are centrifugal-flow devices), mainly in the last 4 years. Resources for the few VAD implants in Brazil were obtained from health care providers and court decisions, philanthropic programs subsidized by the Brazilian Ministry of Health, private funding, or donations from manufacturers.

The following are major obstacles for a more widespread use of VADs in Brazilian patients with advanced HF:

- High cost of the devices marketed in Brazil.
- A lack of feasibility and cost-effectiveness studies of VADs in hospitalized patients on the HT waiting list in Brazil.
- Questionable interpretation of VAD coverage regulations in ANVISA's list of procedures, which allows health insurance companies to question VAD coverage.

Despite these barriers, Brazilian programs for VAD implantation in selected patients are being developed, although some aspects must be considered and discussed.

Centralizing VAD implant procedures and patient care in regional excellence centers, preferably with experience and capacity to support patients with advanced HF and HT, would be an important strategy to obtain positive results to support this therapy.

The high costs involved in VAD implantation and the high rates of associated complications require good clinical

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results to support this type of procedure. Thus, a rigorous selection of patients with low morbidity and mortality risk would be advisable when implementing a VAD program.

In addition, the scarcity of resources for VAD implantation in centers with well-established HT programs places patients with limitations for HT (such as the presence

of severe pulmonary hypertension and increased immune sensitization) high in the priority list to receive this therapy.

Finally, the creation of a Brazilian registry on the experience of VAD implantation would be a good strategy to understand the country's reality and difficulties and to propose solutions according to the best medical practices.

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