Mechanical Circulatory Support-What is the future?

FARHA AHMED PAYYANIL KARLATH, MD

**I.INTRODUCTION**

End-stage heart failure is a devastating as well as ever growing disease. Median survival of patients with end stage heart failure is only 6 months on ionotropic support alone. The only option available for these patients for years was heart transplantation. Later, left ventricular assist device (LVAD) emerged as a bridge to transplantation.

The widespread acceptance of implantation of LVAD in the treatment of heart failure has ignited a revolution in the way of treatment of end stage heart failure. LVADs have improved the survival in heart failure patients since their approval by the US FDA. This was also accompanied by better biocompatibility , longer device life and decreased perioperative morbidity over first-generation assist devices. LVADs will undoubtedly remain to play a vital role as a therapeutic option for those patients with heart failure.

**II. HISTORY OF LVADs**

The initial use of the intra-aortic balloon pump was the beginning of surgical intervention for heart failure. Given the poor outcomes of transplantation initially, there arose a need for long lasting support for the heart. Better understanding of biocompatibility combined with improvements in technology and led to growth in the field of left ventricular assist devices after the 1970s. The real use of mechanical circulatory support (MCS) devices for the first time was from the REMATCH trial that compared optimal medical therapy with the first generation of implantable, pulsatile and permanent LVADs . There has been an exponential growth in the device implantations. Appropriate patient selection has led to more than 10,000 implants with durable as well as implantable MCS devices in the INTERMACS registry.

Despite these advancements; however, there are LVAD-specific as well as generalized issues that prevent circulatory devices from becoming uniformly adopted. Device inconvenience, short battery life, the need for lifestyle modification, a lack of understanding of the technology, need for a transcutaneous driveline, need for frequent medical follow-up ,lack of proper timing and access to technology and device-specific complications have been barriers to a wider utility of these devices. Most common cause of mortality with these devices within the initial four years after implant are infections, right heart failure, bleeding, neurological, multi-system organ failure and device malfunction. A sound understanding of these issues related to the shortcomings and benefits of MCS technology determines the future of MCS .

**III. FUTURE OF MECHANICAL CIRCULATORY SUPPORT**

1. **PATIENT SELECTION**

Appropriate selection of candidates and timing of LVAD implantation are critical for better outcomes of assist devices. Those patients with advanced heart failure, who are referred for mechanical support before the onset of major complications have the best chance of achieving excellent 1-year survival with assist devices.

The establishment of the INTERMACS database along with a better understanding of the patient profile that was found to derive the most predictable benefit from the technology has been a huge accomplishment over the past decade. A number of risk scores for heart failure and implantation of LVAD have been developed and validated to help in selection of patients. However, selection bias has been an issue with tendency to select healthy patients resulting in sick patients skewing outcomes despite the risk scores.

The ROADMAP trial is enrolled with two hundred patients compared between optimal medical management versus circulatory support. This might make it possible to answer not only the question on survival benefit of devices in heart failure, but also gain insight into quality of life and freedom from rehospitalization. It is unfortunate that `REVIVE-IT` (Randomized Evaluation of VAD Intervention before Inotropic Therapy), a study that looks at optimal medical therapy versus LVAD, was cancelled recently due to concern over equipoise in the presence of an increased risk of thrombosis of device.

1. **RIGHT VENTRICULAR SUPPORT DEVICES**

It is to be noted that the function of right heart is also of considerable importance. There are ample descriptions in literature regarding the risk factors involved and the management strategies to limit right ventricular failure following LVAD implantation. Prediction of the RV failure prior to the implementation of LVADs remains a diagnostic enigma.

Failure of RV failure after LVAD implantation is of profound importance. Real long term isolated right sided MCS does not exist till date. Even though prolonged RV support by off-label use of HVAD is being used by many, the only real long term device that is FDA approved is the total artificial heart. Since the introduction of SynCardia for bridge to transplant into clinical trials, this technology has continued to be miniaturized. Meanwhile, the need for bridging peri-operative mechanical support for the right ventricle has led to the advancement of percutaneous strategies. This includes the Impella RP and Protek Duo in addition to the support offered by the ABIOMED BVS 5000™ and CentriMag.

1. **TYPES OF MECHANICAL SUPPORT**

In addition to comparisons between univentricular and biventricular MCS, the idea of partial as opposed to total circulatory support is intriguing. The usage of partial mechanical support is evidenced by the successful experience of bridging patients with axillary intra-aortic balloon pumps . A more permanent form of partial support solution is the CircuLite Synergy assist device. The flowrate of this micro-pump can be up to 3 litres/minute and has had mixed reviews regarding its ability to offer long term support for patients with chronic advanced heart failure. With the growth of literature, undoubtedly, a clear definition of the patient population that can derive the most benefit from the partial and less invasive support devices can be availed.

The more central question in the setting of acute decompensated chronic heart failure is immediate permanent device in opposition to temporary device as a bridge to either permanent or recovery device. The double bridge strategy is being increasingly employed in assessing long term benefits of implantation of permanent device and patient viability. The strategy must be to rescue patients in acute onset cardiogenic shock with either ECMO(extra-corporeal membrane oxygenator) used for biventricular support or with CentriMag that can be used for univentricular device until the achievement of a more definitive assessment. This can include assessment of even psychosocial barriers for successful long term outcomes.

**D. MAINTENANCE OF PATIENTS**

A consensus across centres on how to take care of the patients with support devices will be an important barrier in the reduction of complications in the future. There are no strict guidelines for the management of such patients at present and there exists significant variability amongst various centres in various aspects of care. The PREVENT trial highlights the need for an organised and systematic approach to these patients .

A real time communication between caregivers and patients dealing with possible problems can be executed by remote monitoring of hemodynamics and pump parameters. Devices like the CardioMEMS™ heart sensor for pressure monitoring of pulmonary artery and remote facilities offered by the HeartAssist-5 ventricular assist device will improve immediate individualized care. In addition to these hemodynamic parameters, the role of surveillance echocardiograms is being noticed. The assessment of left and right ventricular remodelling after implantation of LVAD will allow appropriate changes to not only optimize pump settings but also to adjust the patient’s medical regimen.

Self-empowerment of patients via internet and social media are equally important and will continue to grow in the future. Websites, like [www.mylvad.com](http://www.mylvad.com) have made possible a culture of education for patients and caregivers. Various usable forms, checklists and ability to interact with other patients will further drive LVAD patient-centered care forward.

Giving untethered energy to LVAD through a totally transcutaneous energy source or transcutaneous energy transfer can be revolutionary and is yet, out of current reach. This will be solved in the coming years, thus abolishing driveline infections but introducing a new sort of device-related complications.

**IV. CONCLUSION**

Left Ventricular Assist Devices have undoubtedly revolutionised the landscape of heart failure treatment and will continue to do so in the future. With the expansion of the patient population that can benefit from this as well as the knowledge on morbidity of implantation, significant steps in the treatment of advanced heart failure are to be taken. We have gained considerable achievements in the therapy over the past several years and the future is bright for mechanical circulatory support.

**REFERENCES**

1.Kantrowitz A, Tjonneland S, Freed PS, et al. Initial clinical experience with intraaortic balloon pumping in cardiogenic shock. *JAMA* 1968;203:113-8. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/5694059)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=JAMA&title=Initial+clinical+experience+with+intraaortic+balloon+pumping+in+cardiogenic+shock.&author=A+Kantrowitz&author=S+Tjonneland&author=PS+Freed&volume=203&publication_year=1968&pages=113-8&pmid=5694059&)]

2. Kilic A, Ailawadi G. Left ventricular assist devices in heart failure. *Expert Rev Cardiovasc Ther* 2012;10:649-56. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/22651840)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=Expert+Rev+Cardiovasc+Ther&title=Left+ventricular+assist+devices+in+heart+failure.&author=A+Kilic&author=G.+Ailawadi&volume=10&publication_year=2012&pages=649-56&pmid=22651840&)]

3.Barnard CN. The operation. A human cardiac transplant: An interim report of a successful operation performed at Groote Schuur Hospital, Cape Town. *S Afr Med J* 1967;41:1271-4. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/4170370)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=S+Afr+Med+J&title=The+operation.+A+human+cardiac+transplant:+An+interim+report+of+a+successful+operation+performed+at+Groote+Schuur+Hospital,+Cape+Town.&author=CN+Barnard&volume=41&publication_year=1967&pages=1271-4&pmid=4170370&)]

4. Rose EA, Gelijns AC, Moskowitz AJ, et al. Long-term use of a left ventricular assist device for end-stage heart failure. *N Engl J Med* 2001;345:1435-43. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/11794191)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=N+Engl+J+Med&title=Long-term+use+of+a+left+ventricular+assist+device+for+end-stage+heart+failure.&author=EA+Rose&author=AC+Gelijns&author=AJ+Moskowitz&volume=345&publication_year=2001&pages=1435-43&pmid=11794191&)]

5. Kirklin JK, Naftel DC, Pagani FD, et al. Sixth INTERMACS annual report: A 10,000-patient database. *J Heart Lung Transplant* 2014;33:555-64. [[PubMed](https://pubmed.ncbi.nlm.nih.gov/24856259)] [[Google Scholar](https://scholar.google.com/scholar_lookup?journal=J+Heart+Lung+Transplant&title=Sixth+INTERMACS+annual+report:+A+10,000-patient+database.&author=JK+Kirklin&author=DC+Naftel&author=FD+Pagani&volume=33&publication_year=2014&pages=555-64&pmid=24856259&)]