HEALTHY HEART

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As we know that heart failure is becoming a number one global health issue now a days. The optimal treatment for advanced heart failure (HF) patients with regards to mortality is till not clear. Heart transplantation (HTx) and left ventricular assist devices (LVAD) used either as a bridge to transplant (BTT) or destination therapy (DT) have been emerged as last resources for these patients. The growth in the number of patients with end-stage HF creates and increasing demand for reliable treatments to improve survival, reduce hospi-talizations, and improve functional capacity. This momentum has led to significant progress in both heart transplantation and use of LVADs, which offer progressively improved outcomes and reduced complications.

VENTRICULAR ASSIST DEVICES & HEART TRANSPLANTATION FOR ADVANCED HEART FAILURE

Heart failure(HF) is one of the major health issue associated with significant morbidity and mortality globally. Also, HF patients are receiving survival benefits due to newer medicines, implantable devices and HF surgeries. Hence, more patients require heart trans-plantation (HTx) or ventricular assist devices (VADs) to gain good quality of life. VAD is a durable mechanical circulatory support than can replace the function of the left ventricle, right ventricle or both. HTx remains the gold standard for these patients in both adult and Pediatric patients. However, the lack of donor heart availability and few general contra-indications make this option unsuitable to a few patients. Use of VADs has grown steadily over the last few years. With improved durability and lesser comp-lications, VADs are gaining an advantage as a bridge to transplant(BT) or destination therapy (DT). Figure 1 shows number of VADs implants every year in USA(Patients enrolled in clinical trials are not included, and data from a number of centers not yet included with change in Registry).

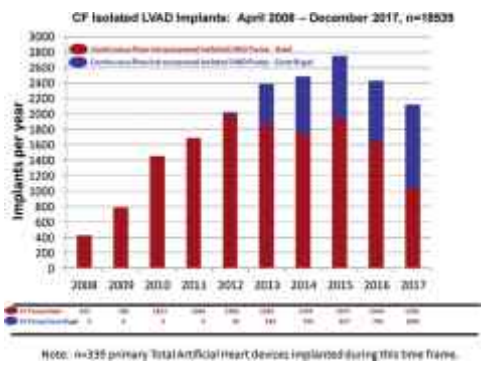

Figure-1

Though HTx and VADs, both are proven treatment of refractory heart failure though clinicians must know contraindications of them. End-stage lung, liver, or renal disease, metastatic disease, medical non-adherence or active drug addiction, active infectious disease belong to both modalities. While, the inability to tolerate systemic anti-coagulation (recent CVA, GI bleed, etc.) and moderate to severe RV dysfunction disfavour VADs. Advanced age is a relative contraindication of HTx.

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The current continuous-flow LVADs are similar in function with 5 main components: an inflow cannula, a pump, an outflow cannula, a percutaneous driveline, and an electrical controller. The inflow cannula is inserted into the apex or diaphragmatic surface of the LV, and the outflow cannula is anastomosed to the aorta, usually the ascending portion (Figure 2 and 3). Blood exits passively through the LV into the propulsion chamber of the VAD and is then actively propelled into the arterial circulation.

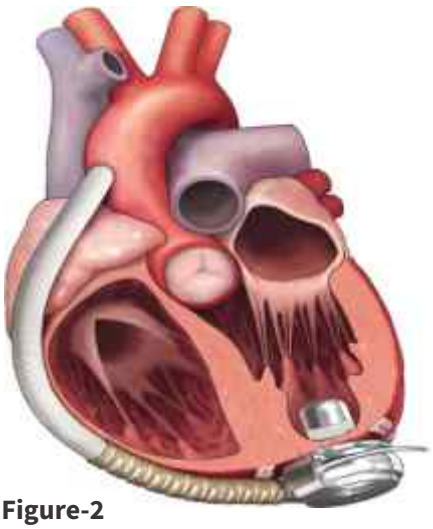


Figure-2

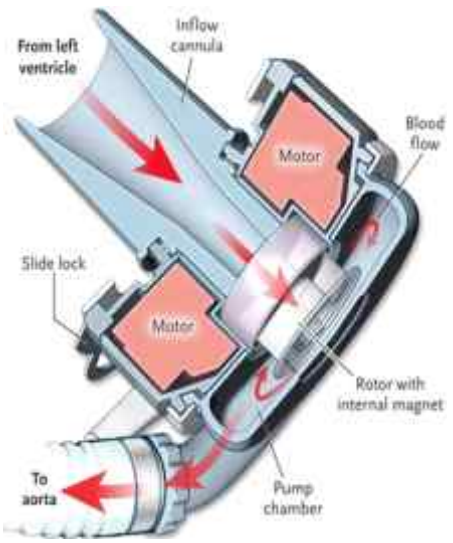
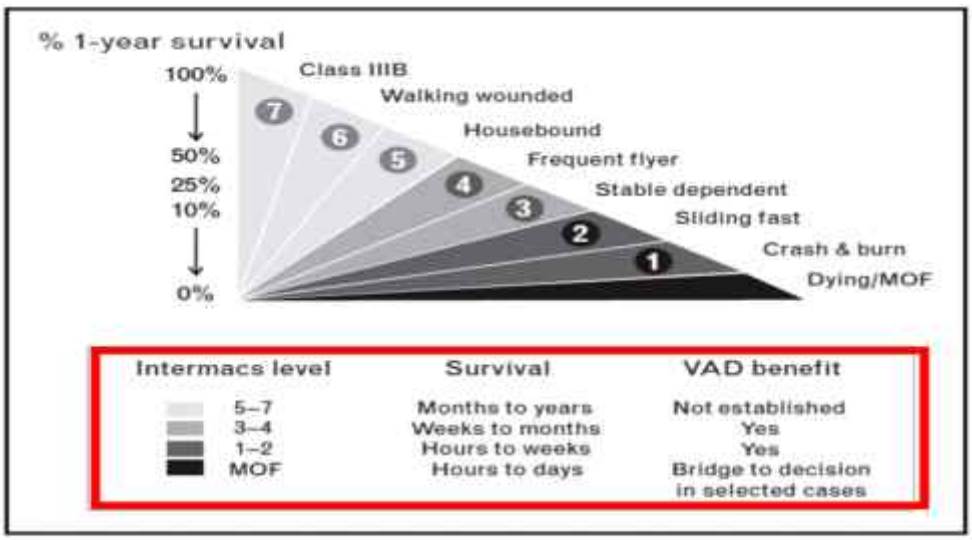


Figure-3

INTERMACS REGISTRY

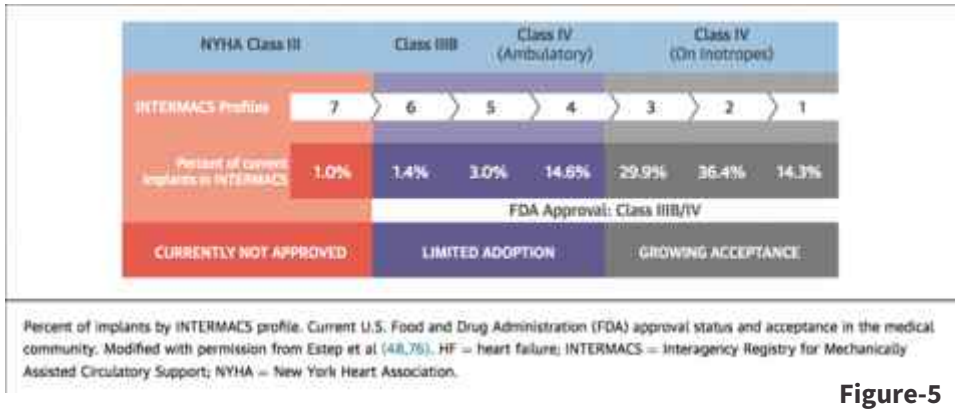
The current classification of patients with New York Heart Association Class IV symptoms does not offer adequate description to allow optimal selection of patients for the existing options of medical and pacing therapies, cardiac transplantation and mechanical circulatory support. Hence, seven clinical profiles and an arrhythmia modifier were developed and implemented into the first year of data collection for the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS). Figure 4 & 5 ensure further understanding these profiles and their impact on outcome should help to better select patients and therapies in the advanced stages of disease.

It is clear that candidate selection has the greatest impact on success with MCS. Current American College of Cardiology / American Heart Association guidelines define the indications for LVAD as advanced systolic HF with LV ejection fraction <25% and NYHA class III–IV functional status despite guideline-directed medical and device therapy (Figure 5).



The figure illustrates seven INTERMACS levels of clinical severity of end-stage heart failure with the corresponding survival. The time frame for consideration of mechanical circulatory support and evidence from clinical trials of 1-year survival benefit with LVAD implantation is shown in the table.

Figure-4



Percent of implants by INTERMACS profile. Current U.S. Food and Drug Administration (FDA) approval status and acceptance in the medical community. Modified with permission from Estep et al (48,76). HF = heart failure; INTERMACS = Interagency Registry for Mechanically Assisted Circulatory Support; NYHA = New York Heart Association.

Figure-5

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GI bleed is one of the most common complications of VADs due to anti-coagulation and absence of pulsatile flow. The opposite anticoagulation problem, device thrombosis, is less common but potentially a more morbid complication of LVAD therapy. Despite all the precautions and evaluation of RV status before the implant, RV failure post-LVAD implantation is common (5%–13%). Infection is a significant problem in LVAD patients with the driveline the most common source. Ventricular arrhythmias can occur when the device significantly unloads the LV and significantly reduces it in size, which predisposes the apical cannula to touching the endocardium, triggering ventricular arrhythmia. The greatest cause of death in the first 6 months following LVAD implant is multisystem organ failure, RV failure, and stroke (ischemic or haemorrhagic). The need for RV assist device at the original operation is the biggest contributor to early mortality with a hazard ratio of 3.76. Other risk factors include dialysis, chronic pulmonary disease, peripheral vascular disease, and renal dysfunction, as well as the overall nutritional state. Over time post-LVAD, stroke dominates as the major cause of death. Figure-6 shows Survival in years following left ventricular assist device (LVAD) implant by indication for the LVAD.

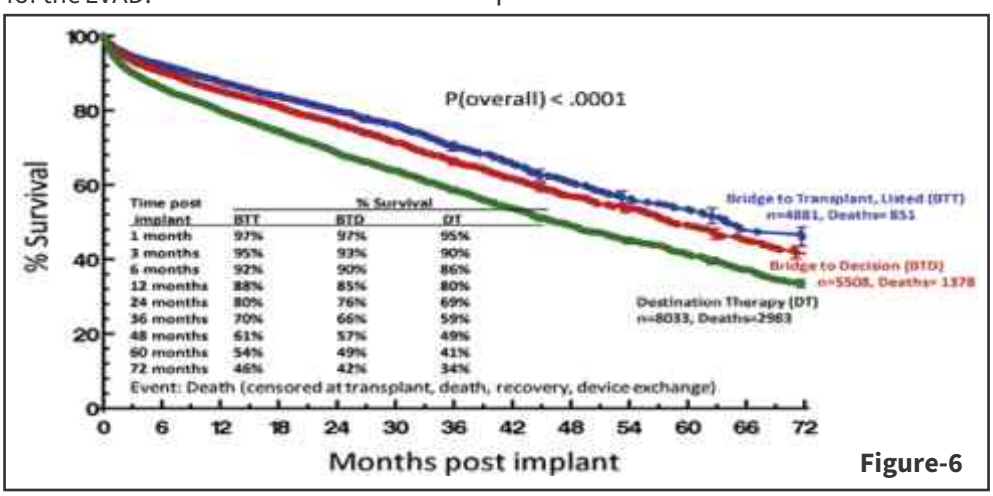

Figure-6

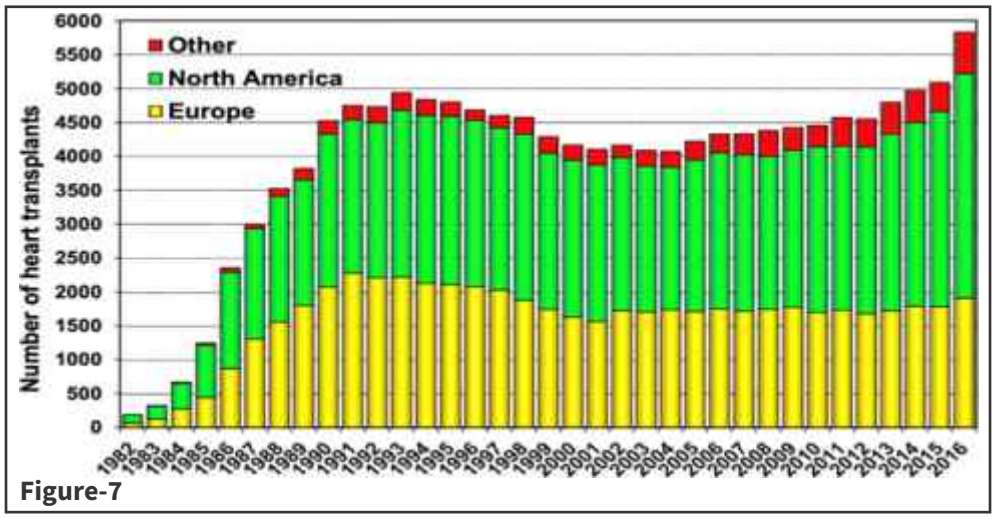

Figure-7

After a continual decline between 1993 and 2004, heart transplant volumes have steadily increased more recently and reached an all-time high in 2015 of 5074 heart transplants (both adult and pediatric heart transplants) (Figure-7)

The most common underlying recipient diagnosis now is nonischaemic dilated cardiomyopathy in 49.8%, followed by ischemic cardiomyopathy in 33.8%, with congenital heart disease (3.1%), hypertrophic cardiomyopathy (3.1%), restrictive cardiomyopathy (3.4%), valvular cardiomyopathy (2.8%), retransplantation (2.9%), and other (1.2%) causes making up smaller proportions.

Survival remains excellent following heart transplantation and higher than any form of treatment for advanced HF. The current 1-year survival is 86%, and median survival for all heart transplants performed between 1982 and June 2015 is now 12.2 years in adults (16.1 years in children) particularly the short-term survival (figure 8) and after adjustment for baseline donor and recipient risk factors post-transplant survival has increased continuously over recent years. The 5-year survival is estimated to be 69% and 85% conditional on surviving the first year.

The leading causes of death change over time after heart transplantation with graft failure and multiorgan failure being the most common causes of death in the first 30 days after transplantation being responsible for 40.5% and 17.6% of deaths at 30 days post-transplant, respectively, and non-cytomegalovirus infection being the commonest cause of death by the end of the first year (responsible for 31.6% of deaths at 1 year). For the first 3 years, graft and multiorgan failure and infection continue to predominate whereas after 3 to 5 years, cardiac allograft vasculopathy, malignancy, and renal failure increase and become progressively more important causes of death with

Adult Heart Transplants
Cause of Death (Deaths: January 1994 – June 2017)

Cause of Death	0-30 Days (N=7,048)	31 Days - 1 Year (N=6,076)	>1-3 Years (N=4,298)	>3-5 Years (N=3,693)	>5-10 Years (N=9,428)	>10-15 Years (N=6,759)	>15 Years (N=5,176)
Cardiac Allograft Vasculopathy	90 (1.3%)	212 (3.5%)	494 (11.5%)	483 (13.1%)	1,201 (12.7%)	834 (12.3%)	560 (10.8%)
Acute Rejection	294 (4.2%)	516 (8.5%)	413 (9.6%)	172 (4.7%)	177 (1.9%)	62 (0.9%)	28 (0.5%)
Lymphoma	2 (0.0%)	64 (1.1%)	104 (2.4%)	115 (3.1%)	312 (3.3%)	183 (2.7%)	109 (2.1%)
Malignancy, Other	4 (0.1%)	151 (2.5%)	529 (12.3%)	720 (19.5%)	2,036 (21.6%)	1,438 (21.3%)	985 (19.0%)
CMV	3 (0.0%)	58 (1.0%)	21 (0.5%)	6 (0.2%)	8 (0.1%)	4 (0.1%)	2 (0.0%)
Infection, Non-CMV	981 (13.9%)	1,928 (31.7%)	574 (13.4%)	389 (10.5%)	1,006 (10.7%)	736 (10.9%)	638 (12.3%)
Graft Failure	2,858 (40.6%)	1,074 (17.7%)	1,137 (26.5%)	888 (24.0%)	1,835 (19.5%)	1,176 (17.4%)	862 (16.7%)
Technical	500 (7.1%)	93 (1.5%)	31 (0.7%)	28 (0.8%)	94 (1.0%)	81 (1.2%)	68 (1.3%)
Other	312 (4.4%)	401 (6.6%)	338 (7.9%)	281 (7.6%)	719 (7.6%)	449 (6.6%)	381 (7.4%)
Multiple Organ Failure	1,243 (17.6%)	964 (15.9%)	261 (6.1%)	209 (5.7%)	650 (6.9%)	571 (8.4%)	486 (9.4%)
Renal Failure	30 (0.4%)	53 (0.9%)	57 (1.3%)	114 (3.1%)	516 (5.5%)	538 (8.0%)	509 (9.8%)
Pulmonary	189 (2.7%)	230 (3.8%)	175 (4.1%)	164 (4.4%)	429 (4.6%)	318 (4.7%)	252 (4.9%)
Cerebrovascular	542 (7.7%)	332 (5.5%)	164 (3.8%)	124 (3.4%)	445 (4.7%)	369 (5.5%)	296 (5.7%)
Total Deaths (N)	8,121	6,979	5,276	4,647	12,489	9,763	7,735

Percentages represent % of deaths in the respective time period. Total number of deaths includes deaths with unknown causes.

Figure 8

increasing time after transplantation (Figure 8). Incidence of acute rejection has decreased over time with better immunosuppression and immune surveillance and accounts for no more than 9.55 of deaths in years 1 to 3 but likely contributes to other morbidities and graft failure. The below data from ISHLT(2018) shows adverse events and complications following heart transplant over time post-transplant.

Although complications with LVAD therapy are not uncommon, most of them are manageable and current outcomes clearly support the use of LVAD in advanced HF. On the other hand, HTx remains a benchmark option for many patients but suitable donor availability remains a constant problem. There are important distinctions to be made between candidates for each treatment. For instance, pulmonary hypertension is a significant contraindication for transplantation but not for LVAD therapy. In contrast, patients with severe right ventricular failure are less optimal candidates for LVAD, but may experience good outcomes with transplantation. With regards to renal dysfunction, current data show that LVAD implantation can lead to an improvement. On the other hand, LVAD is not a treatment for all and there are multiple subgroups of patients who have contraindications for LVAD implantation, including those prone to infection, elderly patients and patients with untreated aortic regurgitation. Furthermore, LVAD implantation may be associated with increased tendency to ventricular tachyarrhythmia. Whether a distinction between BTT and DT patients is clinically meaningful, remains a questionable issue. There is a possibility that patients awaiting transplantation on LVAD support may develop contra-indications to transplant, or never receive a suitable organ given the paucity of donors. Another very important point is cost as VAD treatment is almost four times costlier than HTx in Indian scenario.

Further research into the above areas promises to further improve the outcomes for these patients.

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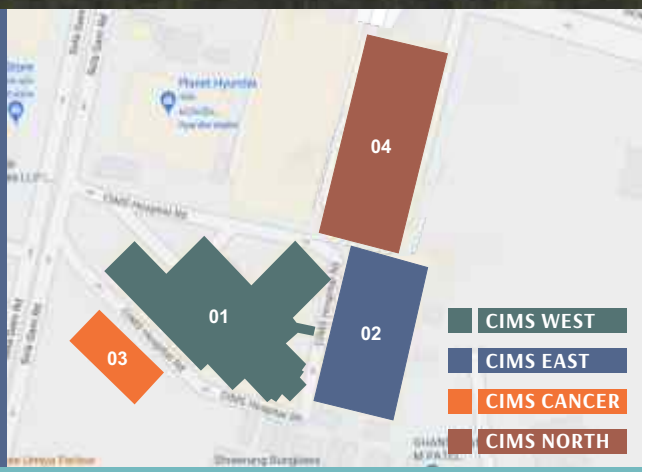

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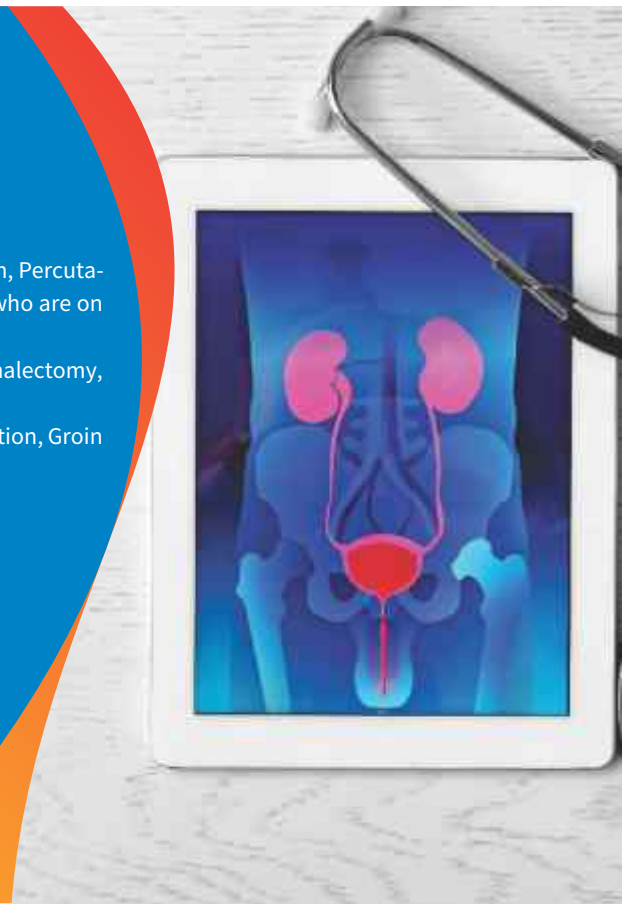

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