

## Our experience with implantation of VentrAssist left ventricular assist device

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### ABSTRACT

Perioperative anaesthetic management of the VentrAssist™ left ventricular assist device (LVAD) is a challenge for anaesthesiologists because patients presenting for this operation have long-standing cardiac failure and often have associated hepatic and renal impairment, which may significantly alter the pharmacokinetics of administered drugs and render the patients coagulopathic. The VentrAssist is implanted by midline sternotomy. A brief period of cardiopulmonary bypass (CPB) for apical cannulation of left ventricle is needed. The centrifugal pump, which produces non-pulsatile, continuous flow, is positioned in the left sub-diaphragmatic pocket. This LVAD is preload dependent and afterload sensitive. Transoesophageal echocardiography is an essential tool to rule out contraindications and to ensure proper inflow cannula position, and following the implantation of LVAD, to ensure right ventricular (RV) function. The anaesthesiologist should be prepared to manage cardiac decompensation and acute desaturation before initiation of CPB, as well as RV failure and severe coagulopathic bleeding after CPB. Three patients had undergone implantation of VentrAssist in our hospital. This pump provides flow of 5 l/min depending on preload, afterload and pump speed. All the patients were discharged after an average of 30 days. There was no perioperative mortality.

**Key words:** Cardiac failure, left ventricular assist device, VentrAssist™

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### INTRODUCTION

The prevalence of chronic heart failure (CHF) and the shortage of donor hearts have led to the development of left ventricular assist devices (LVADs) for both bridge to transplant (BTT) and destination therapy (DT).<sup>[1,2]</sup> Because cardiopulmonary bypass (CPB) is required for implantation of these devices, anaesthetising these critically compromised patients requires extensive monitoring, skillful anaesthetic management and expert postoperative care.<sup>[3]</sup>

### CASE REPORT

In the present article about our experience with implantation of VentrAssist™ LVAD, three adult patients with end-stage CHF who met pre-specified

eligibility criteria [Table 1] were able to participate LVAD implantation programme initiated in 2008. After obtaining approval from institutional review board and written informed consent from the patients, VentrAssist LVAD implantation procedure was performed in these patients. In the first patient, VentrAssist LVAD implantation was performed as DT since he was elderly and non-transplantable. In the second and third patients, VentrAssist LVAD implantation was performed as BTT.

Diagnosis of the patients was as follows:

- Patient 1: Status post coronary artery bypass grafting, ejection fraction 15%, congestive cardiac failure and New York Heart Association (NYHA) class IV, renal and hepatic dysfunction
- Patient 2: Idiopathic cardiomyopathy, ejection fraction 20% and NYHA class IV

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Table 1: Inclusion and exclusion criteria<sup>[4]</sup>

Criterion	Destination therapy (n=1)	Complex bridge to transplant (n=2)
Inclusion	New York heart association class IV heart failure  One or more of the following Two courses of inotropic therapy within the previous 6 months and/or inotropes with intra-aortic balloon support  Inotropic therapy and has failed at least two weaning attempts  Three hospital admissions for heart failure within the previous 12 months, despite optimal medical therapy VO <sub>2</sub> max ≤14 ml/kg/min (patient able to complete test) Left ventricular ejection fraction ≤25% assessed scan Heart failure refractory to optimal medical therapy	Transplant eligible, according to the Alfred Hospital transplant eligibility criteria  One or more of the following Unlikely to receive an approved device for bridge to transplant due to age (>55 years) in accordance with current guidelines for LVAD placement Smaller body habitus (body surface area <1.7 m <sup>2</sup> ) who may require a prolonged bridge (>3 months) Requires a bridge to transplant device when no suitable registered device is available
Exclusion	Acute cardiogenic shock as defined by cardiac index <1.8 l/min <sup>2</sup> and/or systolic blood pressure <80 mmHg Hypertrophic obstructive cardiomyopathy Prosthetic valve or moderate/severe aortic regurgitation Patient has undergone transplant, cardiomyoplasty or left ventricular reduction surgery  Refractory recurrent arrhythmias Right-sided heart failure refractory to therapy Pulmonary hypertension with right heart failure refractory to therapy Serum creatinine >0.22 mmol/l Liver enzymes >10×ULN Revascularisation within 3 months Patient <18 years of age Body mass index >35 kg/m <sup>2</sup> Recent stroke, bleeding, diathesis	Serum creatinine >0.22 mmol/l at the time of enrollment or surgery Gamma-glutamyl transferase >10×ULN Body mass index >35 kg/m <sup>2</sup> Stroke within 90 days of enrolment or a history of symptomatic cerebrovascular disease or intracardiac clot determined by transoesophageal echocardiography Aortic aneurysm Participation in another clinical trial Body surface area <1.4 m <sup>2</sup>

LVAD – Left ventricular assist device; ULN – Upper limit for normal; VO<sub>2</sub> max – Maximal rate of oxygen consumption

Patient 3: Ischaemic cardiomyopathy, status post percutaneous coronary angioplasty (PTCA) and stenting to left anterior descending artery, ejection fraction 15% and NYHA class IV

On the day prior to the surgery, under aseptic precaution, a large bore peripheral cannula (14 G), radial artery cannula (20 G), triple lumen central venous cannula (7 F, 15 cm) and intra-aortic balloon pump (IABP) were inserted under local anaesthesia for patients 1 and 2. Third patient was on IABP and milrinone 0.5 µg/kg/min since 5 days preoperatively. Prophylactic antibiotics consisting of cefepime 2 g intravenous (IV) BD, moxifloxacin 400 mg IV BD and fluconazole 200 mg IV BD were administered before the surgery. Anaesthesia was induced with fentanyl 4-5 µg/kg IV and midazolam 0.1 mg/kg IV, and the tracheal intubation was achieved with pancuronium 0.1 mg/kg IV. Volume-controlled ventilation was started with a 10 ml/kg tidal volume. Anaesthesia was maintained with inhalational mixture of O<sub>2</sub> + air (50:50), isoflurane (1%) and fentanyl 5 µg/kg IV intermittently. In addition to routine monitoring, continuous cardiac output was being measured by thermodilution

technique via the Swan Ganz continuous cardiac output catheter and Vigilance monitor (both by Edwards Lifesciences Corp., Irvine, CA, USA). Measurement of activated clotting time (ACT), thromboelastography (TEG) and transoesophageal echocardiography (TOE) were performed when required. Temperature of the patient was maintained using warming blanket and fluid warmer. Methyl prednisolone 30 mg/kg IV was given to reduce systemic inflammatory response. To minimise blood loss in perioperative period, ε-aminocaproic acid total of 15 g in divided doses was given IV before, during and after CPB.

#### Operative procedure

The heart and ascending aorta were approached through a mid-line sternotomy. A small pocket in the left sub-diaphragm region was created to house the device. Heparin 400 units/kg was administered to achieve an ACT >400 s. The ascending aorta and right atrium were cannulated for CPB. The IABP was stopped and CPB was initiated. With the heart beating, the apex of the left ventricle was cored using a core device, and the inflow cannula was inserted and secured. The end of the outflow cannula was anastomosed to ascending aorta.

During CPB period, the mean arterial pressure (above 60-70 mmHg), sinus rhythm, heart rate (around 80/min), core temperature (34°C to 37°C) and steep Trendelenberg position were maintained. The de-airing of the pump and chambers of the heart was performed. Finally, the patients were gradually weaned from CPB. When the CPB flow was 1 l/min, the pump was started at a minimum speed of 1800 rpm. The pump speed was increased by 1000 rpm increments throughout the entire operating range until aortic valve opening could be verified with TOE and observed on the arterial pressure wave form. If the pump speed was too fast, the arterial pressure wave form decreased and the aortic notch was absent (indicating a closed aortic valve). The presence of a pulsatile wave form with a aortic notch indicated some aortic outflow and was verified with TOE.

After verification of satisfactory positioning and function of the device with TOE, the effect of heparin was reversed with protamine, 1:1 ratio. Blood products were transfused as mentioned in Table 2. After stabilising the haemodynamics, de-cannulation of aorta and right atrium was performed. Chest was closed after achieving complete haemostasis. All the patients were sedated with propofol infusion (5-50 µg/kg/min) and transferred to the intensive care unit. Haemodynamic stability was maintained with inotropic drugs and pulmonary vasodilators as mentioned in Table 2.

### Postoperative course

Anticoagulation therapy with heparin was initiated and the dose was titrated to achieve activated partial thromboplastin time 45-55 s. Prophylactic antibiotic therapy was continued for 5 days postoperatively. Aspirin 150 mg/day was commenced on second

postoperative day (POD) and warfarin on fifth POD. The dose of warfarin was titrated to maintain an international normalised ratio (INR) of 2 to 2.5. Inotropic supports were gradually reduced and patients were completely weaned from inotropes by 48-72 h postoperatively. Weaning from mechanical ventilation was done according to institutional protocol; patients 1 and 3 were extubated on third POD, but patient 2 was extubated on first POD. Small doses of morphine (2-5 mg increments) were administered as needed for analgesia before and after extubation.

Perioperative data are shown in Table 2 and the VentrAssist pump parameters are shown in Table 3. Haemodynamic, renal and hepatic functions were improved in all patients when compared to preoperative values as shown in Table 4.

All the patients underwent a structured physical rehabilitation programme. All of them were in NYHA class-I cardiac status at the time of discharge. All patients were discharged after 30 (mean) days of the LVAD implantation. At the time of writing, all the patients were at home in NYHA class I, able to perform activities of daily living and freely mobile in the community.

## DISCUSSION

In this article, we describe implantation of the VentrAssist LVAD [Figure 1] which was successfully performed in patients with terminal heart failure. The VentrAssist is a third-generation centrifugal LVAD.<sup>[5-7]</sup> Anaesthetic management of these critically ill patients in heart failure, associated with renal and hepatic impairment, and presenting for repeat cardiac surgery is a challenge.<sup>[8]</sup>

Table 2: Demographic characteristics and perioperative data

	Patient 1	Patient 2	Patient 3
Age (years)	53	29	45
Weight (kg)	79	60	65
BSA (m <sup>2</sup> )	1.69	1.62	1.53
Gender	M	M	M
Duration of heart failure (years)	5	2	0.5
Left ventricular ejection fraction	15%	20%	15-20%
Duration of CPB (minutes)	150	120	122
Duration of procedure (hours)	8	5.5	6
Intraoperative PRBC (units)	5	3	3
Intraoperative FFP (units)	3	5	2
Intraoperative platelets (units)	6	Nil	5
Intraoperative cryoprecipitate (units)	3	Nil	5
Estimated blood loss (ml)	1500	1200	1400
Vasoactive drugs at ICU admission	Adrenaline 0.05 µg/kg/min Milrinone 0.1 µg/kg/min, vasopressin (20/40 4 cc/h)	GTN 0.05 µg/kg/min Milrinone 0.1 µg/kg/min	Milrinone (0.5 µg/kg/min) Adrenaline 0.1 µg/kg/min

GTN – Glyceryl trinitrate; CPB – Cardiopulmonary bypass

Table 3: Pump parameters

	Patient 1			Patient 2			Patient 3		
	Baseline	48 h	72 h	Baseline	48 h	72 h	Baseline	48 h	72 h
Pump speed (rpm)	1800	1950	1950	1800	2000	2200	1800	1900	1950
Estimated flow (Lpm)	5.7	5.4	5.8	4.3	5.2	5.8	3.7	4.2	5.2
Pulsatility index (PI)	36	44	52	64	70	78	60	66	50
Over pumping index (OI)	39	51	50	54	56	58	57	59	50
Pump power (W)	3.6	4.3	4.1	4.2	4.0	3.9	4.1	4.1	3.9
Haematocrit range (%)	30	32	28	32	26	30	28	29	25

Rpm – Revolution per minute; Lpm – Liters per minute; W – Watts

Table 4: Baseline and 48 and 72 h post-implant haemodynamic data

	Patient 1			Patient 2			Patient 3		
	Baseline value	At 48 h	At 72 h	Baseline value	At 48 h	At 72 h	Baseline value	At 48 h	At 72 h
Cardiac output (l/min)	3.4	4	6	4	4.7	3.8	6.5	5.3	6.5
Cardiac index (l/min/m <sup>2</sup> )	1.8	3.7	4	2	2.8	5.8	4.3	3.5	4.5
Heart rate (bpm)	58	94	96	70	90	94	98	96	111
Systemic blood pressure (mmHg)									
Systolic BP	100	110	112	120	130	136	120	113	110
Diastolic BP	80	90	92	70	80	86	66	86	82
Mean BP	84	90	96	60	70	76	76	80	86
SVR (dynes)	1693	977	979	1198	1298	1080	1473	1392	961
PVR (dynes)	334	286	280	302	280	286	184	212	185
Pulmonary artery pressure (mmHg)									
Systolic	55	40	36	50	42	40	70	60	40
Diastolic	30	26	22	35	28	26	35	30	25
Mean	25	20	20	30	22	20	48	40	28
PCWP (mmHg)	21	14	13	19	15	14	35	20	15
CVP	15	13	12	15	12	13	18	14	14
BUN (mg/dl)	33	22	20	35	22	21	28	20	21
Creatinine (mg/dl)	1.9	1.5	1.1	2	1.5	1.5	1.8	1.5	1.6
Total bilirubin (mg/dl)	2.1	1.5	0.8	1.5	1.2	0.9	1.2	1	1
SGOT (U/l)	78	66	30	70	60	62	72	70	65
SGPT (U/l)	82	28	26	92	70	65	80	80	72
LDH (U/l)	1646	1802	1102	1200	1102	1098	1300	1198	1102

SVR – Systemic vascular resistance; PVR – Pulmonary vascular resistance

These patients were receiving amiodarone, angiotensin converting enzyme (ACE) inhibitors,  $\beta$ -blockers and diuretics. The data suggest that the combined use of amiodarone and ACE inhibitors might result in severe haemodynamic compromise during cardiac surgery.<sup>[4]</sup> A patient suffering from cardiac failure with hepatic and renal impairment may have significant altered pharmacokinetics for administered drugs.<sup>[9]</sup> The anaesthesiologist should be prepared to manage cardiac decompensation and acute desaturation before institution of CPB and severe coagulopathy bleeding after CPB.<sup>[10]</sup> These patients have a high incidence of perioperative infection, so appropriate antibiotic prophylaxis is imperative.

To achieve these goals, we optimised these patients by inserting IABP under local anaesthesia;<sup>[11]</sup> triple

lumen CVP cannula, radial artery cannula and wide bore peripheral cannula were also inserted under local anaesthesia, the day before surgery. The mean arterial pressure of more than 70 mmHg,<sup>[12]</sup> CVP of 8-10 mmHg and urine output of 1 ml/kg/h were maintained during perioperative period. In addition to these, metabolic acidosis was appropriately corrected. Perioperative bleeding is a major concern in these patients. This bleeding was multifactorial in origin (e.g., hepatic impairment, extensive surgery, redo surgery, effects of CPB, etc.), hence  $\epsilon$ -aminocaproic acid was used.<sup>[13]</sup> We treated perioperative bleeding by administering blood products depending on the results of TEG.

Since the heart is beating during CPB, a good coronary perfusion pressure should be maintained and preparation should be made for managing right-sided

heart failure, which occurs in 30% of patients.<sup>[14]</sup> To avoid hypothermia, all administered intravenous fluids should be warmed using warming devices such as hotline and also warming blankets are used.

TOE examination is critically important during and after implantation of VentrAssist LVAD. In pre-bypass period, TOE was used to optimise left ventricular filling to maintain cardiovascular stability. Then, a thorough cardiac evaluation should be performed to ascertain whether a patent foramen ovale is present, using an agitated saline injection. If a patent foramen ovale is found, this needs to be repaired [Figure 2]. On CPB, TOE was used to ensure that inflow cannula of LVAD was appropriately directed away from left ventricular septum (to avoid inlet occlusion) and towards the mitral valve, so that the left ventricle can drain completely<sup>[15]</sup> [Figure 3]. TOE was also used for complete de-airing of all the chambers of the heart. The major concern on weaning from CPB is the right ventricular failure; TOE becomes a key monitor of right ventricular function. To treat right heart impairment preemptively, milrinone and adrenaline were started on CPB.<sup>[16]</sup> The VentrAssist is “preload dependent and afterload sensitive.” So, good right ventricular function and as low as possible pulmonary artery pressure are required for preload.<sup>[7]</sup>

The pulse pressure is influenced by LV contractility, intravascular volume, preload and afterload pressure, and by pump speed. Owing to the reduced pulse pressure during continuous flow LVAD support, it is often difficult to palpate a pulse and measure blood pressure accurately by the auscultatory or automated methods. In the early postoperative period, an arterial catheter is necessary to monitor blood pressure properly. After the arterial catheter was removed, the blood pressure was assessed using Doppler and transthoracic echocardiography (TTE). A flat arterial blood pressure waveform with a low pulse pressure indicates the LV function is extremely poor or that the set pump speed is close to exceeding the available preload (LV volume). When pulsatility is absent, ventricular suction and collapse are more likely to occur. It is desirable to have some arterial pulsatility and aortic valve opening support.<sup>[17]</sup>

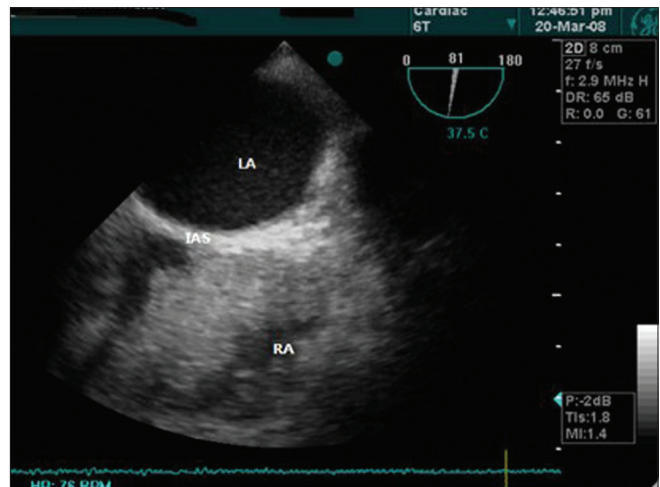
A prospective, multicentre, international clinical trial has confirmed the favourable efficacy and safety profile of the VentrAssist patient.<sup>[8]</sup>

## CONCLUSION

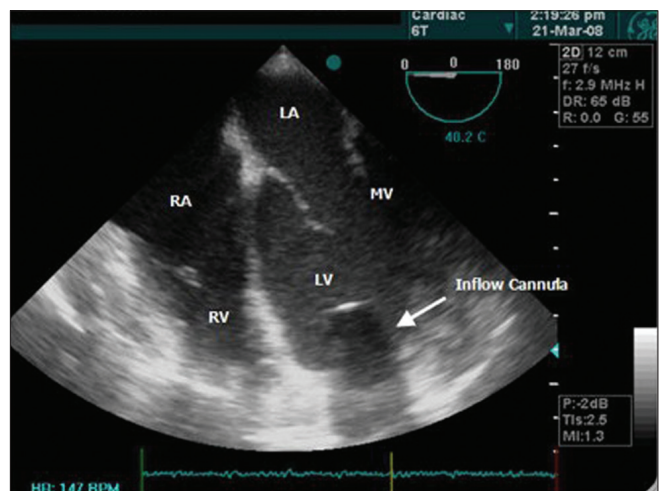
Anaesthetic management of patients undergoing VentrAssist LVAD implantation is unique. Our initial anaesthetic experience is promising.



**Figure 1:** The VentrAssist™ blood pump encased in a welded titanium shell and features a silicone percutaneous lead



**Figure 2:** The bubble test in the mid-oesophageal bicaval view of transoesophageal echocardiography



**Figure 3:** The position of the inlet cannulae from the left ventricle in the mid-oesophageal bicaval four-chamber view

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## Announcement

### FAMILY BENEVOLENT FUND OF ISA

Family Benevolent Fund (FBF) is one of the welfare programs of Indian Society of Anaesthesiologists (ISA). It is registered under the Societies Registration Act. Please visit the website [www.isafbf.com](http://www.isafbf.com). Membership is limited only to ISA members and President and Secretary are in the executive body of FBF. ISA member can be a member of FBF by paying the Membership fee depending on the age of members.

Up to 35 years	-	3,000/-
Up to 40 years	-	4,500/-
Up to 45 years	-	6,000/-
Up to 50 years	-	8,000/-
Up to 55 years	-	10,000/-
Up to 60 years	-	15,000/-

Age proof is required, the membership fee increased from April 2010. Immediate settlement of Fraternity amount to the nominee, in case of death of a member. So far 14 members were supported with an amount of Rs.18 Lakhs.

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