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EDITOR'S NOTE

Dr Manoj Durairaj

Heart Transplant Surgeon, MS, MCh. (AIIMS, New Delhi), FACC.

Director, Marian Cardiac Centre and Research Foundation.

Program Director, Department of Heart and Lung Transplantation, Sahyadri Hospitals, Pune.

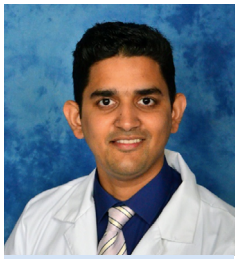
Dear Colleagues,

Greetings from the Editor's desk. The May 2022 issue of the Revival features a succinct review on an interesting topic "Emerging role of ventricular assist devices in adult congenital heart diseases". Dr Maruti Haranal is a congenital heart surgeon practising at U N Mehta Institute of Cardiology, Ahmedabad. He has special interest in paediatric VAD and Ex Vivo perfusion of DCD hearts in paediatrics. Children who have undergone a palliative or corrective repair of congenital heart diseases have a risk of developing ventricular dysfunction during adult life which leads to heart failure. The risk of mortality in this subset is 20 times more than a structurally normal heart. Dr Haranal has addressed the role of VAD in this unique subset of patients and walked us through on the applications of VAD in ACHD with univentricular and biventricular failure. I thank Dr Ganapathy Subramaniam for accepting to be the Guest Editor of this issue and for providing his insight on this unique problem and sharing his personal experience.

On behalf of the Editorial team, I invite our readers to send us more such out of the box articles. We are here to back up your efforts and give you the platform. Wishing you all a Happy Reading!

- Dr Manoj Durairaj
Editor "The Revival"

SUB EDITOR



Dr Talha Meeran

MBBS, MD, FACC, Consultant Cardiologist, Dept of Advanced Cardiac Sciences and Cardiac Transplant, Sir HN Reliance Foundation Hospital, Mumbai.

Dear Colleagues,

The May edition of the REVIVAL features Dr Maruti Haranal taking on a challenging topic of role of VADs in adult congenital heart disease. VADs in this patient sub-group is still in its infancy around the world and needs more robust animal and human data before making it into the real world practice. However, it is truly encouraging to learn about the exciting developments particularly with the viscous Impella pumps and the percutaneous double lumen cannula for cavo-pulmonary support in failing Fontan circulations. Dr Ganapathy's role as an invited expert and the guest editor for this edition helps us gain a much needed local Indian perspective. With the huge gap in the demand and supply of cadaveric organs in our country, I am sure the VADs are here to stay for the long run.

Sincerely,
Dr Talha Meeran
Sub Editor "The Revival"

PRESIDENTIAL MESSAGE

Prof. (Dr) V. Nandakumar

Director & Chief, Division of Cardio Vascular/Thoracic Surgery & Cardiac Transplantation, Metromed International Cardiac Centre, Calicut, Kerala.

Dear Colleagues,

The May issue of 'The Revival' covers an interesting topic namely Emerging role of Ventricular Assist Devices in adult congenital heart diseases.This is a less explored area and has an important role to play in the management of heart failure in these patients.
Dr. Maruti Haranal vividly explains the need for these devices in such patients as a bridge to recovery, transplantation or as destination therapy and how the potential mechanisms of heart failure in these patients differ from structurally normal hearts.

Invited expert commentary from Dr. Ganapathy Subramanium adds to the value of this article.

Best wishes Best wishes,

- Prof. (Dr) V. Nandakumar
President

Please call or write to us:
Call: 9822322072, 9167048815,
manojdurairaj@hotmail.com,
talha.meeran@gmail.com

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Special thanks to Guest Author Dr Maruti Haranal and Guest Editor Dr K Ganapathy Subramaniam for authoring this month's article.

Designed by Maithili Kulkarni

EMERGING ROLE OF VENTRICULAR ASSIST DEVICES IN ADULT CONGENITAL HEART DISEASES: A BRIEF REVIEW

GUEST AUTHOR

Dr Maruti Haranal

Department of Pediatric Cardiac Surgery, U N Mehta Institute of Cardiology and Research, Ahmedabad, India

Dr. Maruti Haranal currently practices at U N Mehta Hospital of Cardiology and Research (Ahmedabad), in the Department of Paediatric cardiac surgery. He has completed his M Ch. in Cardiac surgery from Sri Jayadeva Institute of Cardiovascular Sciences and Research, Bengaluru. He is trained in congenital cardiac surgery from The hospital for sick children, Toronto (Canada) and National heart institute (IJN, Kuala Lumpur, Malaysia). His main area of training was in pediatric VADs and Heart transplant during his tenure in Sick kids hospital. He was involved in several research projects during his fellowship program, including ex-vivo perfusion of DCD hearts in pediatrics. He holds numerous publications in the field of interest in both national and international Journals.

He has won several awards and honors including young investigator award from Malaysian Cardiothoracic surgeon association. He is a reviewer in many indexed journals both in India and Europe and currently is one of the section editors of congenital heart diseases in Indian journal of thoracic and cardiovascular surgery.

GUEST EDITOR

Dr K Ganapathy Subramaniam

Sr Consultant Cardiac Surgeon. Pediatric and Congenital Heart disease Heart and Lung Transplant unit MGM Healthcare. Aminjikarai, Chennai.

Senior Consultant Pediatric Cardiac Surgeon at Sri Padmavathi Children's Heart Centre at Tirupati, Visiting Consultant at Institute of Child Health, Egmore and MGM Hospital , Aminjakarai.

Completed Medical Education at AIIMS, New Delhi , and Trained in Pediatric Cardiac Surgery and Transplantation at AIIMS, Dr K.M. Cherian and Dr K.R.Balakrishnan.

Publications, presentations and invited lectures at National and International journals and forum.

Helped in setting up and developing Pediatric Cardiac and transplant programmes at centres across the country. Areas of interest include Mechanical circulatory support and transplantation, Neonatal Cardiac Surgery and Improving accesibility, safety and affordability of Cardiac Surgery in general and Pediatric Cardiac Surgery in particular.

Acknowledgment: Dr. Shivang Saxena, Department of Pediatric Cardiac Surgery, U N Mehta Institute of Cardiology and Research, Ahmedabad, India

Introduction

Various advances in surgical and medical care of children born with heart defects has led to the emergence of subgroup of young adults known as adults with congenital heart disease (ACHD). Heart failure (HF) is the leading cause of mortality and morbidity in this subset. Management of HF is challenging in these patients due to structural variations and their physiological outcomes. A large population based study showed that chronic HF as the leading cause of mortality in ACHD population (Fig 1) [1]. Etiology of HF is divergent in this group and pose a significant challenge to various medical treatment modalities compared to those with structurally normal heart. Heart transplantation is of limited utility in this subset either because of donor shortage or associated co-morbidities making these patients ineligible for transplantation. Ventricular Assist Devices (VADs) have evolved as an alternative strategy to support the failing myocardium in ACHD patients. Hence, it is imperative to gain adequate knowledge on the use of VADs in ACHD population in order to reduce the mortality and morbidity.

Heart failure in ACHD

The patients who underwent repair (palliative or corrective) of congenital heart diseases (CHDs) in the childhood are at an increased risk of developing HF during adult life. HF can occur both in repaired biventricular and univentricular physiology. A review by Stout et al. clearly depicts, late ventricular dysfunction as the cause of HF in patients with repaired CHD [2]. Also, there is over a 20-fold increase in the risk of death in HF patients with CHD compared to those with a structurally normal heart. The potential mechanisms of HF among ACHD patients include myocardial injury during prior procedures, ongoing ventricular overload (volume or pressure) due to residual lesions, altered coronary perfusion,

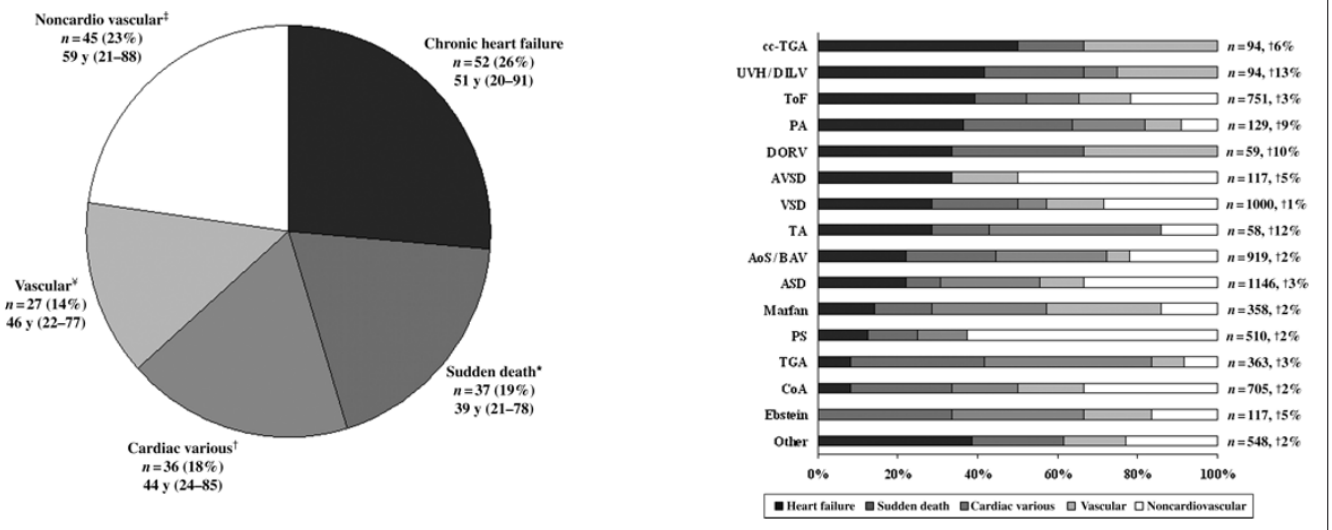

Figure 1. Mortality in adult congenital heart diseases: CONCOR Registry

cc-TGA, congenitally corrected transposition of the great arteries; PA, pulmonary atresia associated with ventricular septal defect; UVH/DILV, univentricular heart/double inlet left ventricle; AVSD, atrioventricular septal defect; ToF, tetralogy of Fallot; ASD, atrial septal defect; DORV, double outlet right ventricle; AoS/BAV, aortic stenosis/bicuspid aortic valve; PS, pulmonary stenosis; TA, tricuspid atresia; TGA, transposition of the great arteries; CoA, aortic coarctation; VSD, ventricular septal defect; Ebstein, Ebstein's anomaly; Marfan, Marfan syndrome.

pre-existing ventricular non-compaction, altered anatomy, and neurohormonal activation. The patients who have a morphological right ventricle (RV) as a systemic ventricle, i.e., the patients who underwent an atrial switch procedure for d-transposition of the great arteries (TGA), or the patients who underwent a physiologic repair for congenitally corrected TGA (ccTGA), are at a particularly high risk of late ventricular dysfunction. Furthermore, the patients who developed myocardial fibrosis, as in the repaired tetralogy of Fallot patients or the RV in the systemic circulation are strongly associated with the development of late ventricular dysfunction.

The Fontan circulation, which has no subpulmonary ventricle to drive the systemic venous circulation, inevitably is susceptible to subtle anatomic or physiologic changes over the years, resulting in a failing Fontan circulation. The mechanisms of Fontan failure is complex and multi-factorial [3, 4, 5]. In the setting of classic Fontan configuration, a massively dilated right atrium with resultant energy-inefficient circulation and refractory atrial arrhythmias are the main causes of failure. Some of those patients may be a candidate for a conversion procedure to the extracardiac Fontan configuration. The contemporary form of Fontan operation, total cavopulmonary connection (TCPC) with either an extracardiac graft or a lateral tunnel, has been popularized since 90's and the majority of the patients who are currently reaching adulthood have a TCPC configuration.

The mechanisms of the failing TCPC-type Fontan circulation include progressive increased in pulmonary vascular resistance and Fontan pressure, systolic or diastolic dysfunction of the systemic ventricle, and mechanical obstruction of the Fontan pathway either from anatomic distortion or failed reconstruction, or thrombosis and subclinical pulmonary emboli. In addition, some patients experience clinical deterioration by having protein losing enterocolitis or plastic bronchitis, even the Fontan pressure remains unchanged.

Ventricular Assist Devices (VADs)

Ventricular Assist Devices (VAD) have evolved as an alternative treatment modality in supporting failing myocardium, however they are used less frequently in ACHD patients compared to those with structurally normal heart because of their unique anatomical and physiological variations. They can be used for short term or medium and long term support. Inherent advantages include: small priming volume, less anticoagulation and blood products with subsequent reduction in the infection rate and sensitization, patient can be extubated, and early mobilization. VADs have undergone technological innovations to provide improved efficacy and better quality of life.

Table 1 summarises various types of VADs.

Short term	Mid and Long term
Centrifugal ventricular assist devices (VADs) – • ROTAFLOW • PediMag • CentriMag (St. Jude, Minneapolis, MN) Impella Tandem Heart	Pulsatile flow devices • Excor • PVAD/IVAD Continuous flow devices • DuraHeart • HeartWare HVAD • HeartMate II • Jarvik 2000 • SynCardia TAH

Table 1. Classification of VADs

VADs can also be categorized into first, second and third generation depending on the pump type, drive mechanism, flow and device characteristics. They can be used as a bridge to decision, bridge to recovery (BRT), bridge to bridge, and bridge to transplant (BTT) or as a destination therapy (DT).

TAH (SynCardia Systems, Inc.; Tucson, Ariz) consists of right and left sided pumps and can be used as a bridge to transplant or as destination therapy. TAH pumps can be configured in a variety of ways to addresse various physiologic (single ventricle/two ventricle) and anatomical variations peculiar to CHD. TAH provides optimal hemodynamic support in patients having CHD with residual lesion compared to VAD or BiVAD alone; however, implantation of TAH is much more challenging than VAD implantation. One of the major advances in the implantation of TAH is the development of patient specific virtual implantation based on cross-sectional imaging studies.

An important change in VAD technology is the introduction of continuous flow devices (CF-VAD). Over the past few decades there has been a major shift in the use of Pulsatile flow VAD (PF-VAD) to CF-VAD. Studies have shown that superior survival rate for CF-in comparison to PF-LVADs.

Percutaneous VADs (pVADs) are another significant technological innovation in VADs, which are increasingly used as short term support in patients with critical cardiogenic shock and post-cardiotomy failure. Tandem Heart (TandemLife, Pittsburgh, PA) is a pVAD that uses cannulas placed into the right atrium or trans-septally facilitating the direct unloading of either the right or left heart.

Interagency registry for mechanically assisted circulatory support (INTERMACS) scale is a helpful tool to stratify HF patients with ACHD requiring MCS. They are classified based on severity of symptoms and trajectory of decline over time, which helps in prognosticating those with advanced HF receiving MCS.

Implanting VAD is challenging in ACHD patients because of ventricular morphology, residual lesions, systemic venous abnormalities, limited vascular access, previous multiple surgeries (sternotomies/thoracotomies), pulmonary hypertension, aorto-pulmonary collaterals, coagulopathy, and end organ dysfunction.

VADs in biventricular physiology

The use of VADs in ACHD patients is encouraging. A systematic review of durable MCS in teenager and ACHD by Steiner et al. [6] showed the frequent utilization of MCS in patients with ACHD. Short-term survival rates in published series are approximately 70% and durable MCS use as a bridge to transplant was 77%. In an INTERMACS analysis by Vanderpluym et al, 21% of cases were successfully bridged to transplant and 51% were alive with the devices. The analysis also showed the promising role of LVAD for the treatment of HF in ACHD with similar survival rates to those with Non-ACHD [7] (Fig. 2).

Shah et al. emphasized the use of VADs either BTT or DT in patients with ACHD [8].

The SynCardia TAH has now been implanted in over 50 patients younger than 21 years and in more than 20 patients with ACHD. From1986 to 2012, there have been 24 implants in this patient group, which is approximately 2% of all implants. The median age of patients was 28 years (13–56 years), median support time was 24 days (1–359 days) and overall survival was 62%.

TAH appears to be a good option for end-stage congenital heart patients who require multiple procedures so that a ventricular assist device can be implanted. The use of EXCOR (Berlin Heart GmbH) is limited in ACHD patients and the literature on use of Jarvik-2000 (Jarvik Heart, Inc., NY, USA) is lacking.

Fishberger et al. showed the usefulness of percutaneous RV support (Impella) (Abiomed Inc, Danvers, MA) in providing hemodynamic stability during mapping and ablation of intra-atrial re-entrant tachycardia in patients post Mustard operation for TGA. The cumulative worldwide experience in the use of total artificial heart in patients with congenital heart disease is not vast though [9].

Systemic RV failure is a devastating complication in patients in whom morphological RV acts as systemic ventricle to support the circulation as in post Senning or in patients with ccTGA. VAD implantation in these patients is much more challenging owing to the unique anatomy and physiology. However, studies have shown that implantation of VAD in failing systemic RV has the potential to improve physiology and can be used as a bridge to heart transplantation [10, 11].

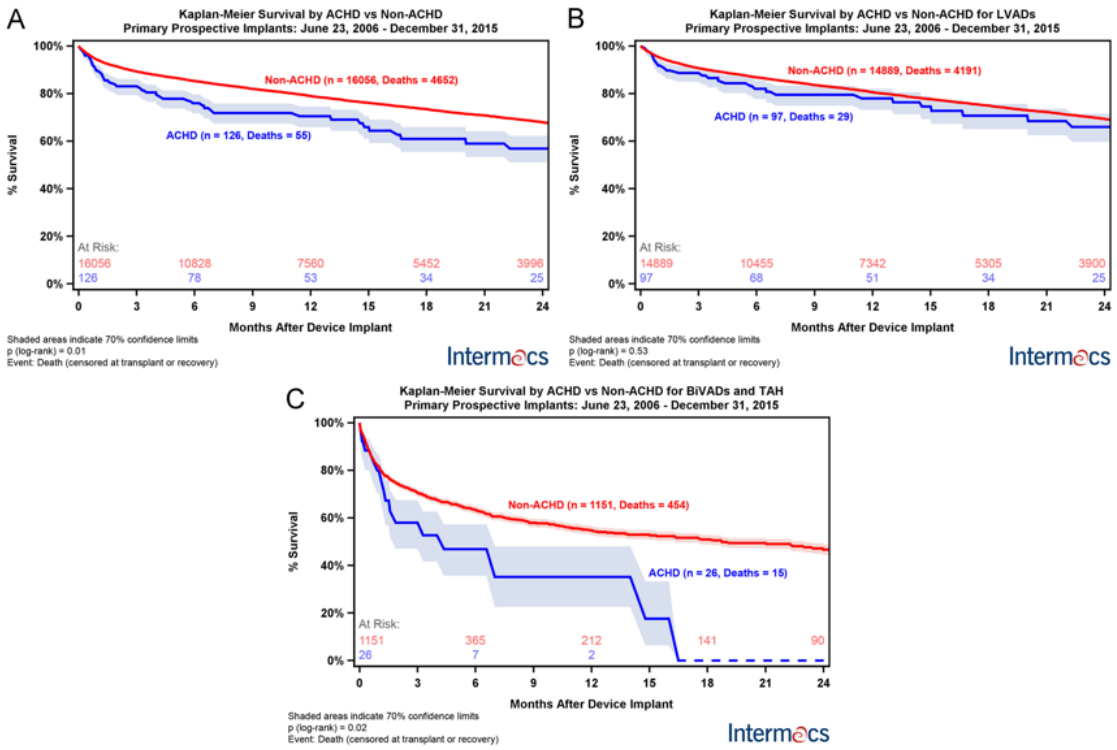

Figure 2. Outcomes following implantation of MCS in ACHD: An analysis of the INTERMACS

A. Kaplan Meier Survival by ACHD versus Non-ACHD
B. Kaplan Meier Survival by ACHD versus Non-ACHD for LVAD
C. Kaplan Meier Survival by ACHD versus Non-ACHD for BiVAD and TAH
MCS- Mechanical Circulatory Support; ACHD – Adult Congenital Heart Disease
INTERMACS - Interagency registry for mechanically assisted circulatory support; LVAD- Left Ventricular Assist Devices; BiVAD – Biventricular Assist Device; TAH – Total Artificial Heart

VADs in single ventricle physiology

There is growing evidence that VAD support can be successful in selected patients with the failing Fontan circulation. However, it remains unclear when VAD implantation should be considered and what percentage of patients will benefit from a systemic VAD alone. Patients with isolated, or predominant ventricular systolic dysfunction, are likely to benefit from VAD alone. However, such cases among the patients with failing Fontan are rare. A VAD will surely not help the clinical situation if the end-diastolic pressure of the systemic ventricle is not high (at least above 12 mm Hg). However, patients with Fontan repair accounted for 14% of cases in a study by Steiner et al. [6] which showed an increasing use of durable VADs in patients with ACHD with short term survival rate of 70%..

Fontan failure patients with marked end-organ dysfunction, protein losing enteropathy, and/or plastic bronchitis who are otherwise not good transplant candidates may benefit from TAH. The feasibility of using a TAH in the failing Fontan has been demonstrated in a recent case report by Rossano et al. [12].

Isolated ventricular systolic dysfunction is relatively uncommon in Failing Fontan and failure may be independent of ventricular function. Often failure is driven by elevated pulmonary vascular resistance/pressure. Hence, VAD may or may not help in these patients and cavopulmonary support may be necessary. Isolated ventricular systolic dysfunction is relatively uncommon in Failing Fontan and failure may be independent of ventricular function. Often failure is driven by elevated pulmonary vascular resistance/pressure. Hence, VAD may or may not help in these patients and cavopulmonary support may be necessary. Prêtre et al. reported the first clinical experience with isolated cavopulmonary support in a case of failing Fontan as a bridge to transplant [13].

There are substantial research efforts on development of MCS for the failing Fontan circulation. Our group previously showed that a percutaneously implanted microaxial pump (Impella) for cavopulmonary assist in the failing classic Fontan physiology lowers the Fontan pressure, attenuate systemic venous congestion, and augment systemic oxygen delivery [14].

Wang et al used percutaneous Wang-Zwische double-lumen

cannula (DLC) for cavopulmonary support for 2 hours in a failing Fontan sheep model [15]. Derk et al. in a pig model showed the feasibility of an axial pump (Jarvik 2000) to restore baseline hemodynamics and cardiac output in Fontan circulation [16]. Rodefeld et al used a 3-dimensional computational model and showed that a single viscous Impeller pump augments the cavopulmonary blood flow and can be used as a bridge to recovery or transplant in patients with established univentricular Fontan circulations [17]. Toronto group is currently investigating a novel multi-lumen cannula to support the failing Fontan circulation by a computational fluid dynamic simulation model [18].

CONCLUSION:

The advent of VADs has made it feasible to support ACHD hearts despite the inherent surgical challenges present in this population. Complex ACHD is not a contraindication to the use of VADs and should be considered as a treatment option early in the care of these patients. INTERMACS scores have trended toward lower acuity, suggesting implantation earlier in the course of advanced HF, as has been recommended for patients with acquired disease. LVADs have shown promising role in treating HF in ACHD patients. Role of VAD as DT is increasing. Use of VADs for supporting failing systemic RV is encouraging.The subgroup of ACHD with failing Fontan is an area of ongoing clinical research. Even though the failing Fontan subgroup represents a significant proportion of the ACHD population, the best available modality to support these hearts is yet to be determined. With further research as well as technological advancements, it may be possible to improve the prognosis in this subset.

Dr. Ganapathy Subramanium: Personal comments and experience:

TAH is good for selected patients. It is a pulsatile pump which requires two good atrial cuffs of the recipient to suture the inflow part of the cannula. The biggest advantage of TAH is that one need not bother about the RV , which is one of the Achilles heel of LVAD implantation . RV failure and support happens in close to 30% following LVAD implantation in adult non congenital population . The support and management of failing RV determines the success of the LVAD.

The second theoretical advantage is that it is a pulsatile pump and theoretically is supposed to maintain endothelium and microcirculation better than a continuous flow pump.

The biggest disadvantage is the cost ,[personal communication .(close to 1.8 crore INR, which includes the proctor expenses], the survival at one year even in the published literature is close to 60%. There is lack of experience in its use in ACHD population.

TAH may be promising , but it is yet to live up to its promise.

Zhu et al. showed that in a acute single ventricle model, created by connecting the atria to pulmonary artery after closing the tricuspid valve, a IMPELLA introduced from the pulmonary artery to atrium maintained hemodynamics temporarily.

The usual Impellas are designed to suck from the distal lumen and pump in the proximal lumen , when it is positioned inside the LV cavity. Impella RP which is designed for RV support – the only pump exclusively designed for RV support can be used, which sucks from the proximal lumen and pumps distally .

All the pumps which are designed for Cavo pulmonary support are either in animal experimental stage or have been studied used computational fluid dynamics model and have not yet come into clinical arena, to the best of my knowledge. Even the viscous Impella pump by Rodefeld group , which is based on a rotating outer motor to evenly distribute the SVC and IVC blood into both the pulmonary arteries needs surgical implantation and has not yet reached clinical stage.

The greatest trouble with supporting ACHD patients mechanically is that- the continuous flow pumps when used as LVAD in the presence of intracardiac shunt can cause significant systemic desaturation. Even a small PFO in the presence of continuous flow VAD can lead to significant systemic desaturation.

The pulmonary flow has to be interrupted and maintained either by either a 1) systemic to pulmonary artery shunt or a 2) Superior Cavo pulmonary shunt – in which case we have to higher flows and that the saturation in this mixed circulation would be between 80-90% depending on the size of shunt and the state of pulmonary vascular resistance.

The other option is to completely separate the systemic and pulmonary circulation by performing a Fontan and then use a LVAD to support the circulation, which would suck oxygenated blood across the pulmonary circulation and

would maintain the circulation as a normal Fontan circulation does. This is possible when there is severe ventricular dysfunction and would not work if there is elevated pulmonary vascular resistance.

To surmount these problems the solution we have used when confronted with grown up child or adult with complex ACHD who is in INTERMACS category 1 or 2 with ventricular dysfunction with or without previous palliation is to use a ECMO. The use of oxygenator – eliminates the complexity of septating the circulation . We have used them as a bridge to transplantation with a maximum support duration of close to 50 days . Our experience in this subgroup of 13 patients who have been bridged to transplantation with mechanical circulatory support is one year survival of 72%.

The percutaneous VAD in cardiogenic shock is rapidly evolving and some of the developments in this arena can be translated for Paediatric or ACHD patients . For example Aortix **(Procyrion, TX, USA)** – a axial flow pump implanted in the descending aorta to accelerate the blood flow to the renal arteries and reverse the cardiorenal syndrome can be used in Fontan circulation to accelerate the blood in the pulmonary circulation .

MCS of ACHD is still in 'infant' stage and has not yet reached the 'adult' stage. Custom designed cannulas and indigenous development of mechanical circulatory pumps would hopefully allow us to help the underserved population of Adult Congenital Heart disease patients.

The subject of myocardial recovery post VAD implantation is gradually gaining attention. According to Pedimacs data upto 27% of mechanical support for congenital heart disease could be explanted successfully . Appropriate medical management can increase this number and may increase VAD implanted in ACHD as a bridge to recovery . The subject of myocardial recovery post mechanical support needs much more attention than what is has received in the past .

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PRESIDENT

DR V NANDAKUMAR
Mob: 9843015888
Email: drvnandakumar@gmail.com

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DR RONY MATHEW
Mob: 9846097812
Email: drronymathew@yahoo.com

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Mob: 9980072785
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SECRETARY

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DR RAJAGOPAL S
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Email: srajagovindam@gmail.com

TREASURER

DR PRAVEEN G PAI
Mob: 9847334434
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DR GEEVAR ZACHARIAH
(2013-2014 and 2014-2015)
Mob: 9846066816
Email: geevarzachariah@gmail.com

DR SHIV K NAIR (2015-2016)
Email: shivnairmd@ gmail.com

DR K VENUGOPAL (2016-2017)
Email: venugopalknair@gmail.com

DR JOSE CHACKO PERIAPURAM
(2017-2018)
Mob: 9847043224
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Mob: 9846076006
Email: drppmohanan@yahoo.com

MEMBERS

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Mob: 9447344882
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DR COL JAMES THOMAS
Mob: 9892797060
Email: thomasdrjames@yahoo.in

DR JACOB ABRAHAM
Mob: 9847128123
Email: jacabraham1@gmail.com

DR JAYAGOPAL P B
Mob: 9847023777
Email: jaigopallakshmi@gmail.com

DR KARTHIK VASUDEVAN
Mob: 9845281450
Email: karvasudevan@gmail.com

DR C S HIREMATH
Mob: 9481119646
Email: hiremath.cs@sss.hms.org.in

DR MANOJ DURAIRAJ
Mob: 9822322072
Email: manojdurairaj@hotmail.com

DR RAJESH RAMANKUTTY
Mob: 9846005737
Email: drrajesh_mr@yahoo.com

DR V K CHOPRA
Mob: 9560898900
Email: chopravk@gmail.com

DR TALHA MEERAN
Mob: 9167048815
Email: talha.meeran@gmail.com