

What's New in MCS

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Reviews:

★★ [Acute tamponade of the left paracorporeal pump house due to membrane defect in a patient with a Berlin Heart EXCOR® biventricular assist device](#)

Völs S, Holmberg M, Redfors B, Dellgren G. Eur J Cardiothorac Surg. 2014; 46:743-4

In this interesting report, Volz et al report a case of acute tamponade of the left paracorporeal pump house in a patient supported by a Berlin Heart EXCOR biventricular assist device (BiVAD) caused by mechanical defect in the membrane of the arterial chamber. The patient suffered a decompensated heart failure complicating aortic surgery. Extracorporeal membrane oxygenation (ECMO) was conducted. He was scheduled for heart transplantation, and a BiVAD (Berlin Heart EXCOR) was implanted as bridge-to-transplantation. Two months after discharge, he experienced dyspnoea and received error signals from his BiVAD. Relatives released him from his BiVAD companion driver, connected him to the hand pump and transported him to our institution.

On arrival, he was in cardiogenic shock and was stabilized by ECMO. Inspection of the arterial chamber revealed a wear hole and delamination of the diaphragm, which had led to a tamponade by air insufflation into the three-layer membrane. New BiVAD paracorporeal pumps were connected, and the patient was subsequently successfully transplanted. The case depicts the difficulty of diagnosis in this specific patient setting. Despite transparent design of the BiVAD chambers, the development of a chamber tamponade remained undetected until explantation of the system.

★★ [Ambulatory Extra-Aortic Counterpulsation in Patients With Moderate to Severe Chronic Heart Failure](#)

Abraham WT, Aggarwal S, Prabhu SD, Cecere R, Pamboukian SV, Bank AJ, Sun B, Pae WE Jr, Hayward CS, McCarthy PM, Peters WS, Verta P, Slaughter MS. JACC Heart Fail. 2014; 2:526-33

There is an unmet need for additional therapies for American College of Cardiology/American Heart Association Stage C and NYHA functional class III and ambulatory functional class IV heart failure patients. The C-Pulse System (Sunshine Heart, Inc., Eden Prairie, Minnesota), includes a novel implantable, nonobligatory, non-blood contacting counterpulsation heart assist pump developed for minimally invasive implantation without the need for cardiopulmonary bypass. System was designed to provide an effective low-risk and low-cost mechanical heart assist device for use in patients with

chronic American College of Cardiology/ American Heart Association Stage C and NYHA functional class III and ambulatory functional class IV heart failure. The device is designed to be turned off safely or weaned if there is sustained cardiac recovery and similarly, in failure modes, is considered to have a low risk of death or disability, other than the recurrence of heart failure symptoms. No anticoagulants are required, reducing the risk of bleeding complications, and the extravascular nature of the implant mitigates the risk of intravascular thrombus formation, thromboembolism, and bloodborne infection. The attraction of the device concluded with the design of this study. Patients 18 to 75 years of age were eligible for this study if they had American College of Cardiology/American Heart Association Stage C heart failure with a left ventricular ejection fraction <35% and remained in NYHA functional class III or ambulatory functional class IV despite optimal medical therapy. Patients were required to have been receiving optimal drug treatment (e.g., angiotensin-converting enzyme inhibitors, beta-blockers) for at least 3 months and to have had a biventricular pacemaker for at least 3 months, if indicated. Patients were also required to have an implantable cardioverter defibrillator, if indicated. Other major inclusion criteria included a 6-min walk distance (6MWD) between 100 to 350 m and exercise peak oxygen consumption (pVO₂) between 10 and 18 ml/kg/min for men and 9 and 16 ml/kg/min for women. The C-Pulse System consists of a surgically implanted extra-aortic balloon cuff and epicardial electrocardiography sense lead; an exchangeable, wire-wound percutaneous interface lead (PIL); and an external battery-powered pneumatic driver. Under general anesthesia, the cuff was wrapped around the ascending aorta and the bipolar epicardial lead was placed on the left ventricle. The surgery did not require use of cardiopulmonary bypass or systemic anticoagulation. A driver was attached to the patient connector and a programmer was used to adjust cuff inflation volume and timing of inflation and deflation in relation to the cardiac cycle to optimize the counterpulsation effect. The non-blood contacting feature of the C-Pulse System allows the device to be intermittently turned off as tolerated. Follow-up visits included a repeat of baseline tests: physical examination, medication summary, and assessment of NYHA functional class, QoL as measured by the Minnesota Living with Heart Failure questionnaire and the Kansas City Cardiomyopathy Questionnaire, 6MWD, and pVO₂ (repeated at 6 months only). There were no operative deaths. One-year survival was 85%. The composite device-related adverse event rate through 6 months, as classified by the Clinical Events Committee, was 50%. This result was influenced by the exit site infection rate of 40%. Significant improvements were noted in NYHA functional class at both 6 and 12 months. The Minnesota Living with Heart Failure QoL score significantly improved at 6 and 12 months. The Kansas City Cardiomyopathy Questionnaire score also significantly improved at 6 and 12 months. The 6MWD showed a trend toward improvement at 6 months and significantly improved at 12 months. There was no improvement in pVO₂ at 6 months. The results of this feasibility study suggest that the C-Pulse System may be safe and effective in patients with moderate to severe heart failure. C-Pulse patients did not experience rehospitalizations for stroke, thrombosis, sepsis, and bleeding as is often observed with LVADs. C-Pulse System allows the device to be intermittently turned off as tolerated.

Albeit this study advocating the device, composite device-related adverse event rate is 50% and this must be a major concern. Removal of the device as needed should have been more thoroughly defined. The long term effects on aortic wall also must be demonstrated.

★★★ [Current aspects of extracorporeal membrane oxygenation in a tertiary referral centre: determinants of survival at follow-up](#)

Flécher E, Anselmi A, Corbineau H, Langanay T, Verhoye JP, Félix C, Laurent G, Le Tulzo Y, Malledant Y, Leguerrier A. Eur J Cardiothorac Surg. 2014; 46:665-71

Flécher et al describe the development of the overall ECMO programme in their institution aiming to address the major characteristics of a large and current population of patients receiving ECMO therapy and to assess the impact of changing trends, indications, organizational issues on the early clinical results as well as providing the average 6-month clinical follow-up among different patient subgroups and at identifying the factors associated with worse survival. They reviewed the prospectively collected data of 325 patients receiving ECMO therapy at a tertiary referral centre during the 2005–2013 period.

Patients who survive the 30th post-implantation day display a globally steady survival over the later follow-up, irrespective of the indication to ECMO and to the modality of support (VA vs VV). They observed worse results among patients receiving ECMO for post-cardiotomy myocardial failure. Patients receiving ECMO support for EGF (early graft failure) display the best survival rates both at the 30th post-implantation day and at follow-up.

In conclusion they present a direct outcome comparison among different patient subgroups issued from a multidisciplinary collaboration in a large-volume tertiary centre.

★★ [Drive-line infections and sepsis in patients receiving the HVAD system as a left ventricular assist device](#)

John R, Aaronson KD, Pae WE, Acker MA, Hathaway DR, Najarian KB, Slaughter MS. J Heart Lung Transplant. 2014; 33:1066-73

The HVAD for use as a bridge to transplantation (BTT) in patients with severe heart failure bears excellent survival rates while adverse event profile was favorable, and quality of life was significantly improved. Drive-line infections and sepsis occurred in 12.1% of patients (0.29 event per patient year [EPPY]) and 11.4% of patients (0.24 EPPY), respectively. Although this is numerically lower than previously reported infections with the HeartMate II device in pivotal trials, improved understanding of HVAD infections may reduce the incidence and improve both the quality of life and cost-effectiveness of LVAD support. John et al report an analysis of the incidence of drive-line infections and sepsis occurring in 32 patients from the ADVANCE BTT and Continued Access Protocol (CAP) trial. Patients were followed for 4180 days after implant or until cardiac transplantation, device explant for recovery, or death. Patients with drive-line infections or sepsis had larger body mass index (BMI) compared to those without infection. Infection prophylaxis varied among centers. Most sites used rifampin, vancomycin, bactroban and/or nystatin as post-surgical prophylaxis, and dressing-site protocols were instructed to begin 24 to 48 hours post-implant. Drive-line exit-site infections occurred in 16.9% (56 of 332) of patients and most events occurred 430 days post-implant. Local trauma to the drive-line site was reported in 11% of drive-line infections. Sepsis occurred in 17.2% of patients. Median time to any drive-line or sepsis event was 171 days. Drive-line infections were primarily due to *Staphylococcus aureus*, there were also a significant number of streptococcus and enterococcus organisms identified. Eleven cases of sepsis were either concurrent or were preceded (within 10 days) by a urinary tract infection (UTI) with positive urine cultures. The most common antibiotics employed in infection management included vancomycin and piperacillin. The incidence of drive-line infection and sepsis was low in patients receiving the HVAD pump. Of the patients with sepsis, 17.5% died due to sepsis-related causes (accounting for 3% of the overall patient population), whereas drive-line infections had no adverse effect on survival, and most patients required only antibiotic treatment to manage the event. The infection rates remain similar

to the relatively low rates observed in the pivotal ADVANCE BTT trial. The rates of both drive-line infections and sepsis events were fairly consistent in the 0- to 30-day vs 430-day period (0.34 vs 0.24 for early vs late drive-line infections, and 0.38 vs 0.21 for early vs late sepsis events). The mortality rate of all sepsis events was 14%. Stroke events associated with sepsis usually result in worse outcomes. The stroke-related sepsis mortality rate was 70%. Drive-line exit-site infections had no adverse impact on overall survival. They found *S. aureus* to be the most common organism in drive-line infections, with 15.6% being methicillin-resistant.

In conclusion, in this analysis they have demonstrated that, although rates of drive-line exit site and sepsis infections are low in patients receiving an HVAD as a bridge to transplantation, infection remains a significant adverse event in this population. The low rates they observed may reflect the thin, flexible drive line, pericardial pump implant without a pump pocket, and improved techniques in the clinical care of the drive-line.

When considering the comparison of two devices in terms of infection rate, the standardization of the wound care is obligatory. Therefore, the rates must be evaluated within the same institution on to a device to device basis and an overall reflection must be extracted.

★ [Factors determining post-operative readmissions after left ventricular assist device implantation](#)

Tsiouris A, Paone G, Nemeh HW, Brewer RJ, Morgan JA. J Heart Lung Transplant. 2014; 33:1041-7

Tsiouris et al focused on post-operative readmission characteristics for continuous-flow LVAD patients in this paper. The results reflected 138 LVAD patients was 26.1%, with a median LOS (length of stay) for readmission of 11.7 days. Most patients were readmitted within the first 10 days of discharge. The most common etiology for 30-day re admission was recurrent heart failure, followed by GIB (gastrointestinal bleeding) and then musculoskeletal/incisional chest pain. Predictors of 30-day readmission were the occurrence of post-operative GIB and shorter LOS.

★★ [Long-Term Right Ventricular Support with a Centrifugal Ventricular Assist Device Placed in the Right Atrium](#)

Marasco SF, Stornebrink RK, Murphy DA, Bergin PJ, Lo C, McGiffin DC. J Card Surg. 2014; 29: 839-42

The series of Marasco et al describes the technique and results of right ventricular assist device (RVAD) support with the off-label use of the centrifugal HeartWare HVAD (HeartWare Inc., Framingham, MA, USA) for long-term support. They based their technique on the hypothesis that right atrial cannulation rather than right ventricular cannulation is likely to give better flow and less suck down events overall. Results revealed that device complications in this position were negligible, giving reliable right-sided support and allowing patients to live independently in the community while awaiting transplantation.

★ [Mechanical cardiac support in children with congenital heart disease with intention to bridge to heart transplantation](#)

De Rita F, Hasan A, Haynes S, Crossland D, Kirk R, Ferguson L, Peng E, Griselli M. Eur J Cardiothorac Surg. 2014; 46:656-62

In this paper, De Rita et al investigated the impact of MCS as bridge to OHTx in patients with CHD less than 16 years of age. From 1998 to 2013, 106 patients investigated received 113 episodes of MCS with paracorporeal devices as bridge to OHTx. They suggested that children with CHD supported with mechanical assist devices for acute or end-stage heart failure can be satisfactorily bridged to heart transplantation despite the significant cumulative morbidity. Nearly two-third of them survive to discharge after transplantation. Most importantly, single-ventricle when compared with the biventricular circulation does not increase the risk for death before transplantation and hospital discharge.

★ [Modified Tandem Heart Ventricular Assist Device for Infant and Pediatric Circulatory Support](#)

T Kulat B, Russell HM, Sarwark AE, R Zingle N, Moss ST, Mongé MC, Backer CL. Ann Thorac Surg. 2014; 98:1437-41

Kulat et al modified Tandem heart accompanying recirculation shunt with a gate screw occlusion device as an alternative to ECMO and other pulsatile VADs in children. Its simplicity, availability, low prime volume, highly variable patient flow range, and clinical cost effectiveness rendered this modification highly attractive with good clinical results.

★ [The "Sport Model": Extracorporeal Membrane Oxygenation Using the Subclavian Artery](#)

Biscotti M, Bacchetta M. Ann Thorac Surg. 2014; 98:1487-9

The benefits of the tunneled cannulation using an end-to-side graft on the subclavian artery providing the benefits of central cannulation while mitigating the potential complications of percutaneous peripheral cannulation was presented by Biscotti performing The "Sport Model" for ECMO configuration. The right internal jugular vein is cannulated percutaneously with a 23F Arterial Biomedicus cannula (Medtronic). They anticipate to be ambulatory while on ECMO while providing safe and durable means of venoarterial extracorporeal membrane oxygenation support.

★★ [Two Decades' Experience with Interfacility Transport on Extracorporeal Membrane Oxygenation](#)

Bryner B, Cooley E, Copenhaver W, Brierley K, Teman N, Landis D, Rycus P, Hemmila M, Napolitano LM, Haft J, Park PK, Bartlett RH. Ann Thorac Surg. 2014; 98:1363-70

In this retrospective review of a 20-year, Bryner et al presents single-institution experience with inter-hospital ECMO transport as well as a systematic review of reports of transfers of patients on ECMO. Results of both were compared with historical data from the international registry of the Extracorporeal Life Support Organization (ELSO). Their results showed that the requirement to perform inter-facility transport on ECMO does not confer a survival disadvantage. They also concluded when patients are appropriately selected, transport on ECMO can safely extend lifesaving therapy to patients whose other options are exhausted.

Additional Articles:

European Journal of Cardiothoracic Surgery

- D'Udekem Y. The hurdles of providing mechanical circulatory support to children with congenital heart disease. *Eur J Cardiothorac Surg.* 2014 ; 46:663-4
- Vanhuyse F, Bertram M, Folliguet T, Villemot JP. A detached pedestal during cardiac assist with Jarvik 2000. *Eur J Cardiothorac Surg.* 2014;46:751

Journal of Heart and Lung Transplantation

- Cogswell R, Smith E, Hamel A, Bauman L, Herr A, Duval S, John R, Roman D, Adatya S, Colvin-Adams M, Garry D, Martin C, Missov E, Pritzker M, Roberts J, Eckman P. Substance abuse at the time of left ventricular assist device implantation is associated with increased mortality. *J Heart Lung Transplant.* 2014;33:1048-55

American Journal of Cardiology

- Hasin T, Kushwaha SS, Lesnick TG, Kremers W, Boilson BA, Schirger JA, Clavell AL, Rodeheffer RJ, Frantz RP, Edwards BS, Pereira NL, Stulak JM, Joyce L, Daly R, Park SJ, Jaffe AS. Early trends in N-terminal pro-brain natriuretic peptide values after left ventricular assist device implantation for chronic heart failure. *Am J Cardiol.* 2014; 114:1257-63

Journal of the American College of Cardiology

- Milano CA. Chronic counterpulsation devices for heart failure. *JACC Heart Fail.* 2014;2:534-5

Annals of Thoracic Surgery

- Shekar K, Fraser JF Can Timely ECMO Initiation Mitigate Pre-ECMO Risk Factors for Acute Kidney Injury? *Ann Thorac Surg.* 2014;98:1523