

BIOMEDICAL ENGINEERING AND VENTRICULAR ASSIST DEVICE (VAD) PROGRAM SUPPORT: THE OTTAWA HEART INSTITUTE EXPERIENCE

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INTRODUCTION

Cardiovascular disease is one of the major leading causes of death in Canada. Alongside this is the increasing prevalence of congestive heart failure (CHF). While heart transplantation is the preferred therapy for end-stage CHF, the availability of donor hearts is severely limited¹. This has seen the growing acceptance of mechanical circulatory support devices as a proven and effective treatment. The University of Ottawa Heart Institute (UOHI) has taken a prominent role in the utilization of ventricular assist devices (VAD) as an effective treatment for CHF. The main purpose of VAD support is to unload the failing heart and assist in maintaining sufficient cardiac output and vital organ perfusion². In 1986, the Mechanical Support Program was established to bridge the group of end-stage heart disease patients that are awaiting transplant¹. This program, initially utilizing total artificial hearts, has recently relied upon VADs as a method of mechanical support. The program is a multidisciplinary collaboration including cardiac surgery, cardiology, anesthesiology, perfusion, nursing, and biomedical engineering (BME). Each of these disciplines offers a unique skill set to maximize the success of patient outcomes. BME plays a unique technical support role in the mechanical support program.

VENTRICULAR ASSIST DEVICE (VAD) PROGRAMS

It is widely accepted that in order to maximize clinical success, a multidisciplinary team is required to support a VAD program^{2,3,4}. The team is a collaboration between cardiac surgery, cardiology,

anesthesiology, perfusion, and specialized nursing. In addition, a strong biomedical engineering program is essential for calibration and monitoring of the complex technology⁵. The UOHI has a well established Biomedical Engineering program responsible for the overall lifecycle management of medical devices utilized. The variety of services includes maintenance services, service management, risk management, physical assets inventory and control, device failure reporting, regulation monitoring, consultation, and project management. Due to the complex technical nature of the VAD program, BME provides a specialized technical support network for physicians, advanced practice nurses (APN), perfusion, and clinical patients. As a member of the UOHI Transplant Committee, BME offers technical viewpoints on a weekly basis regarding technology issues and device status pertaining to VAD patients.

BIOMEDICAL ENGINEERING CONTRIBUTIONS

As a technology support resource, BME participates in the broad areas of Technology Preparation, Technical Support, On-Call Support, Patient Home Inspection, Inventory Control, Patient and Family Education, and Technology Assessment and Monitoring.

Technology Preparation: BME ensures technology readiness by performing technology procurement and acquisition. In particular, ensuring appropriate and available backup systems and devices are available for all patients utilizing VAD technology support. In particular, medical battery assessment,

monitoring, and preparation are vital for successful clinical outcomes particularly during critical times^{6,7,8}.

Technical Support: BME are staffed with technology professionals, specially trained for the support of various VAD technologies. The UOHI has prescribed several different technologies for VAD support, each of which is supported by BME. In-house BME staff has been OEM trained on the Thoratec PVAD Dual Drive Console, Thoratec PVAD TLC-II Portable Console, and Thoratec HeartMate II LVAS Console. In addition, support for the less invasive Abiomed Impella MPC is to be scheduled. This specialized technical training allows BME to provide a comprehensive emergency and scheduled preventive maintenance program for VAD support. As part of this program as well, BME monitors “hours-of-use” of systems in accordance with manufacturers scheduled maintenance requirements. In the event that external support is required, BME facilitates outside service and support of medical devices and acts as a technical liaison with these resources. Although there exists a primary contact for BME support, it is recognized that due to absences, training, and conflicting priorities, it is essential to provide technical backup. As a result, cross training is performed to additional BME staff in the general aspects of VAD support. These include VAD battery assessment and conditioning, asset inventory and control, procurement and acquisition, basic technical troubleshooting, and processes for obtaining outside manufacturer support.

On-Call Support: Understanding the sudden and sometimes unpredictable nature of VAD implant requirements, BME provides 24x7 after hours on-call support for the program. This available technical support allows for a safe and effective safety net for technology issues that may arise

Patient Home Inspection: In preparation of VAD patients to make the transition from in-patient to

outpatient support, it is essential to ensure that proper home inspections are performed by qualified technical personnel. Home inspections are essential as directed by manufacturers prior to patients being discharged from healthcare facilities. Inspections include identification of key areas within the patient home for providing AC power to the Power Base Unit (PBU) which acts as both a power source and battery charging station for the HeartMate II System Controller. In addition proper electrical grounding, infrastructure safety issues, and patient safety aspects are also inspected in detail. A total of 9 home inspections have been performed by BME over the last 10 months across Ontario and Western Quebec.

Inventory Control: Of key importance to any hospital BME program is accurate and ongoing monitoring of assets through a comprehensive medical technology inventory control program. All assets associated with the VAD program are uniquely identified including drivers, controllers, medical device batteries, and ancillary equipment. Technology is tracked to the individual patient as both an inpatient and outpatient. As part of the BME quality assurance program for medical battery management, BME works closely with the multidisciplinary team to coordinate technology replacement during regularly scheduled and urgent clinic visits.

Patient and Family Education: During the patient’s stay at the hospital and prior to discharge, BME familiarizes themselves with each patient and explains their role as part of the patient care team. This technical role provides reassurance to the patient and the patient’s family of the broad support net providing direct care. BME participates in broad training of the patient on the technology and its basic management. This technical viewpoint adds a comfort level to the patient and their family.

Technology Assessment and Monitoring: The rapid development of medical technology requires constant monitoring. Changing technologies require unique maintenance and assessment protocols. In particular, differing battery technologies and requirements require tailored maintenance schedules and procedures to maximize battery life and patient safety. Most recently, UOHI utilized a new Lithium Ion (Li-ion) battery technology as a replacement for sealed lead acid (SLA) batteries. BME recognized that this progression required a change to assessment and conditioning protocols. In addition, device alert and recall monitoring is of vital importance requiring a comprehensive system of inventory control.

DISCUSSION

BME provides a technical perspective on the management of medical devices and patients associated with the Ottawa Heart Institute VAD program. BME contributes to the inter-disciplinary clinical team required for the complex care required by our VAD patients. Specialized training and participation of BME staff ensures the highest level of patient care experienced by our patients. In just under 12 months, BME has been directly involved in 14 VAD patients, 9 patient home inspections, and has offered technical expertise on new technologies becoming available. BME monitors and supports 120 medical device batteries, 8 chargers, 5 portable drivers, 2 in-hospital drivers, and 14 controllers. The unique expertise and perspective that BME offers the program contributes to one of the longest and successful VAD programs in Canada.

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