Mechanical Circulatory Support as an Alternative Solution in Circumstances Leading to a Shortage of Organ Donors

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Short title: MCS as alternative solution

Keywords: left ventricular assist device; mechanical circulatory support; heart failure.

Data availability statement. The authors confirm that the data supporting the findings of this study are available within the article.

Source of Funding Statement. None.

Conflict of interest. Piet Jansen is Chief Medical Officer at CARMAT SA. There are no conflicts of interests from other authors.

Patient consent statement. Signed informed consent was obtained from patients.

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Clinical trial registration. CARMAT total artificial heart international pivotal clinical study NCT02962973.

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Abstract

Background. Mechanical circulatory support (MCS) has been applied as an effective therapy for patients with end stage heart failure (HF). The existing donor organ shortage issue in Kazakhstan, and hence long waiting times, have resulted in left ventricular assist device (LVAD) implantation being the predominant surgical treatment method for this condition. The purpose of this study is to analyze clinical outcomes of MCS program data in our Center.

Methods. This study involves a retrospective analysis of 324 patients with different types of implantable MCS including LVAD (n=319), fully implantable LVAD (FIVAD, n=2), and total artificial heart (TAH, n=3). FIVAD and TAH cases were analyzed separately from other VAD types due to their small numbers.

Results. Initially, LVADs were implanted as bridge-to-transplant (BTT) in 214 (67.1%) of patients and as a destination therapy (DT) in 105 (32.9%) cases, but only 30 (9.4%) patients proceeded to transplant. The overall survival rate of all LVAD patients at years 1, 2, 3, and 4 was 84.3%, 69.7%, 62.8%, and 52.5%, respectively. The distance from the clinic (Nur-Sultan) to patients' cities of residence (average 1015 ± 668 kilometers) was not associated with patient survival.

Conclusions. Developing MCS programs is crucial in providing care for patients with HF. Using LVAD as DT produced satisfactory outcomes with favorable survival rates, which are comparable to the outcomes reported in other studies. Further trials are needed to investigate the results of TAH and FIVAD implantation in order to establish them as an acceptable alternative treatment to heart transplantation.

Introduction

Heart failure (HF) is one of the major challenges for healthcare systems around the globe, as it is associated with high prevalence and mortality.[1] Although heart transplantation is considered as the gold standard for the treatment of this condition, it is practically limited due to several obstacles, one of which is the shortage of organ donations. Mechanical circulatory support (MCS) has been established as an effective treatment for HF, either as a temporary supportive treatment (bridge to transplant or BTT) or as a permanent therapy (destination therapy or DT).[2]

There is now a range of alternative MCS devices available to clinicians thanks to the latest developments in technology, research and medicine. One of the earliest and most frequently used MSC device types – Left Ventricular Assist Device (LVAD) – is known to improve quality of life and life expectancy in most patients with chronic heart failure.[3] Both the quality and numbers of implants are increasing globally every year.[2,4] Registry data have shown a 1-year survival rate of 85% among patients who have undergone LVAD device implantation as BTT and a 2-year survival rate of 76% among patients with LVAD as DT.[5]

MCS Program in Kazakhstan

In our country, according to epidemiological data, HF is diagnosed in 4% of the population as a complication of most cardiovascular diseases, especially arterial hypertension and ischemic heart disease.[6] In Kazakhstan, the MCS Program was launched in 2011 at the National Research Cardiac Surgery Centre (NRCSC or Centre). No treatment options for advanced HF (such as heart transplantation or MCS) were available in the country before 2011. Our Centre is still the sole coordinator of the country's MCS program, which is fully supported and financed by the Government of the Republic of Kazakhstan.[7-9] The first LVAD implantation in the Republic of Kazakhstan was performed in November 2011 at the NRCSC.

It is important to note that the heart transplant program within the country remains at the developmental stage, hence the indication for most LVAD patients is as a DT, sometimes even if they were initially planned as BTT.

Carmat Total Artificial Heart

The Carmat total artificial heart (TAH) is a bioprosthetic implantable electro-hydraulically actuated pulsatile biventricular pump that was developed by a group of French surgeons and engineers.[10] Our clinic is one of the enrolling centres in the CARMAT TAH international pivotal clinical study (NCT02962973). The first implantation of the device outside of France was performed in our Centre on October 19, 2017.

Fully implantable ventricular assist device

In December of 2018 the first-in-human implantation of the fully implantable ventricular assist device (FIVAD) was performed at the NRCSC.[11] A coplanar energy transfer (CET) system Leviticus-Cardio was integrated with the Jarvik 2000 LVAD. This device is implanted with a retroauricular pedestal that connects to an external power source, which can be used as a back-up in case of failure of the CET system.[11]

Patient management and monitoring following MCS implantation

Due to long distances between the Centre and regional clinics (in some cases exceeding 2000 km), local patient follow-up by trained medical personnel is of particular importance following patient discharge after LVAD implantation. Post-operative patient management in NRCSC is largely consistent with the manufacturer's recommendations[12, 13] and has been extensively described in previous publications.[9] After stabilization, the patients are transferred from the Intensive Care Unit (ICU) to a regular surgical ward, and then to the Rehabilitation Unit, from which the patients are discharged.

Every patient receives an ID card with a serial number and the contact details of the VAD coordinators located in the city of Nur-Sultan. During the first 4 years of the MCS program development, a specialized unit was in place at NRCSC, for late rehabilitation and patient monitoring at 1, 3, 6 months following VAD implantation. As regional rehabilitation units developed and the capacity of the local VAD coordinators increased, the need for the specialized unit within the Centre was obviated.

Currently, patients at home communicate with their VAD coordinator and nurses on a weekly basis by sending photographs of the driveline exit site, and international normal ratio (INR) results via electronic devices. Patients from different regions of the country also travel to the NRCSC as part of long-term outpatient follow-up and, in cases of serious complications that are not manageable within their region of residence.

Regarding TAH and FIVAD cases, all patients stayed in the capital and were monitored as part of clinical trials by specialists at the Centre, and researchers from Carmat and Leviticus, until they received heart transplants. Initially it was planned to discharge the patients to their hometowns and train local coordinators on their management, however donor hearts became available sooner than anticipated.

The purpose of this study is to analyze and report clinical outcomes of MCS implantation in patients with chronic HF, using data collected at the NRCSC.

Materials and methods

This study is a retrospective analysis of 324 patients receiving a single MCS device at NRCSC: 321 LVADs, either as DT or BTT, who were discharged from inpatient care with follow-up care provided by a local VAD coordinator - HeartMate II, and HeartMate 3 (Abbot Inc, USA), HeartWare HVAD

(HeartWare International, Framingham MA, USA), Jarvik 2000 (Jarvik Heart, Inc., New York, NY) + Leviticus Cardio (fully implantable ventricular assist device, Leviticus-Cardio Ltd., Petach Tikva, Israel), and CARMAT total artificial heart (CARMAT SA, Vélizy, France) (Figure 1). Patients were profiled according to the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS).[14]

Since the number of CARMAT TAH (n=3) and FIVAD (n=2) implants is very small, compared to the total number of LVAD implantations, in this study we investigate TAH and FIVAD patient outcomes as case reports, in order to avoid incomparable results, separate from HeartMate II, HeartMate 3, HeartWare HVAD LVAD patients (n=319).

For LVAD patient outcomes, descriptive statistics were determined for the continuous data, including the number of patients, and are reported as mean values with standard deviations (SD). Survival analysis is presented as a Kaplan-Meier survival curve. All statistical analyses were conducted using IBM SPSS Statistics version 22.

Results

From the launch of the MCS program in November 2011 until December 2019, 336 patients received devices of 6 types (Figure 1). In this study we analyze data of 324 patients who received a single MCS device: LVADs (n=319) including FIVAD (n=2), or Carmat TAH (n=3).

LVAD Outcomes

Patient characteristics are presented in Table 1. The mean age was 50 years (SD 13), ranging from 9 to 73 years. Dilated and ischemic cardiomyopathies were the predominant underlaying etiologies of heart failure. The majority of patients had INTERMACS profile 3 (n=124, 38.9%) or profile 4 (n=140, 43.9%)[15]. For more than half of the patients' (n=181, 56.7%), the place of residence was more than 1000 km away from the NRCSC (Table 1, Figure 2). The mean duration of patient stay in the ICU after device implant was 5.9 days (SD 6.7), while the total of postoperative length of hospital stay averaged 26 days (SD 13.5) (Table 1). The mean duration on VAD support was 815 days (SD 614). The longest duration is more than 2830 days (still ongoing).

According to the Kaplan-Meier survival analysis results, the survival rate at years 1, 2, 3, and 4 was 84.3%, 69.7%, 62.8%, and 52.5%, respectively (Figure 3). The highest survival rates are observed in patients with HeartMate 3 assist devices (Figure 4).

LVAD was implanted as BTT in 214 (67.1%) and as DT in 105 (32.9%) cases, but only 30 (9.4%) patients were transplanted (Table 1). So, the adjusted DT group (those who were discharged from the hospital with follow-up care provided by a local VAD coordinator, and those who are still awaiting the

heart transplantation) consists of 274 (85.9%) patients. Survival rates of patients residing closer (<1000 km) to Nur-Sultan did not differ significantly from that of patients living farther (≥1000 km) from the capital (Figure 5).

The most common adverse event arising within 30 days after surgery was right ventricular (RV) heart failure (n=88, 27.6%) (Table 2). Common adverse events after 30 days following implantation included driveline infections (n=119, 37.3%) and stroke (n=56, 17.6%), resulting from accidental trauma to the exit site and absence of precise control of patient's blood pressure and INR, respectively.

Carmat TAH Outcomes

In total, our Centre has performed 3 CARMAT implants since 2017. X-ray image of the chest after Carmat TAH implantation is presented in Figure 6 (Figure 6, A). With Patient #1, a bleeding complication occurred on the day of implantation, shortly after transfer to the intensive care unit (ICU), and 2 weeks later; both were resolved successfully. These events extended the patient's length of stay in the ICU to 16 days and hospital stay to 68 days. Patients #2 and #3 had shorter periods of ICU (3 days and 7 days, respectively) and a hospital stay of 48 days in both cases, and were free from complications (Table 3). All patients were then discharged and returned to their normal daily activities (Table 3).

After implantation of CARMAT TAH, the internal pressure sensors of the device were used to estimate Transpulmonary Resistance (eTPR) in all 3 patients, who had pulmonary hypertension before implant. For the first Carmat patient, we initiated a trial the 96th postoperative day to evaluate whether his pulmonary vascular resistance (PVR) had decreased to a level that would permit a successful heart transplantation. This had been prompted by changes in the estimated decrease in eTPR monitored by the CARMAT TAH pressure sensors. Initially, the eTPR decreased to 0.27 WU between the first and third month post-implant. Thereafter, initiation of Sildenafil on the 96th postoperative day (up to 450mg/day) induced an additional decrement of approximately 0.4 WU over a period of 3 months suggesting transplant eligibility and thus the patient was duly listed. A similar phenomenon was observed for the other 2 Carmat patients (Figure 7). Following the observed eTPR decrease, the patients were duly listed with subsequent heart transplants on days 243, 155 and 109 post TAH implantation. During the explanation process no adhesions were found between the pericardium and device itself, which shortened the initially anticipated length of transplantation. The first patient suffered a stroke with subsequent left-sided decompressive craniectomy on the 111 day after heart transplantation. This patient had a disappointing outcome, for which there was no measurable relationship between the CARMAT TAH implantation itself and this late adverse event. The patients #2 and #3 were discharged home within 3-4 weeks following heart transplantation and had an uneventful progress to transplant.

FIVAD Outcomes

In December 2018 the first-in-human implantation of the fully implantable ventricular assist device (FIVAD) was performed at the NRCSC in two patients (51 and 24 years old). **Figure 6, B** shows chest X-ray image after FIVAD implantation. Surgical implants were performed according to protocol with successful initiation of the wireless LVAD function. In the postoperative period Patient #1 had a stroke; pump thrombosis was confirmed with the subsequent switching off the pump by the team on the 35th postoperative day. Subsequently the patient was in a stable condition, on inotropes with satisfactory end-organ function, and was listed for heart transplantation in high urgency status. Due to long waiting times in Kazakhstan the patient's clinical status declined, and he died on the 75th postoperative day, as a result of the multiorgan failure.

Patient #2 had an uneventful postoperative period and was discharged from the hospital after 1 month. He returned to his normal life without restrictions. This patient had the opportunity to swim in a pool, without any adverse events. He was successfully transplanted on the 63rd post-implantation day.

Discussion

Most of the patients in this study were in INTERMACS profiles 3-4, compared to the majority of patients in the IMACS (International Society for Heart and Lung Transplantation Registry for Mechanical Circulatory Support) database who were in profiles 2-3.[15] The mean age of our patients was 50 ± 13 years, while the majority of patients in the IMACS database are in the 50 to 60-year-old age group,[16] and there have been studies using data of similarly aged patients.[17, 18]

As stated previously, while MCS device implantation is performed both as BTT and DT, in reality only a small proportion of patients in this study received heart transplants: 30 out of 319 patients (9.4%).

Survival rates following LVAD implantation in the adjusted DT group appear to resemble reported results from other studies.[18-20] When comparing device types, the HeartMate 3 patients were found to have better survival outcomes than HeartMate II and HeartWare patients, and several factors could have contributed to this finding. Firstly, our MCS program started in 2011 with the implantation of the HeartMate II and HeartWare LVADs in the most severe patients with INTERMACS profiles 1-2. Secondly, by the time of the introduction of HeartMate 3 in 2014, patient selection and pre-operative preparation had been improved, and some professional capacity had been developed due to an increase in the experience and skills development of team members, which could have possibly affected these outcomes. Thirdly, HeartMate 3 is the new generation VAD with an artificial pulse, technical properties of which were improved taking into consideration the results of the research of previous device types.[21] The survival rates of

patients with MCS devices have also proven to be comparable with that of heart transplantation.[22-24] This serves as grounds to believe that, in cases of limited donors organ availability, healthcare systems may rely on implantable MCS as an alternative method of increasing patients' life expectancy and improving their quality of life.

An important finding in this study was the absence of a significant impact of distance from the Centre (the city of Nur-Sultan) to the patients' cities of residence, on their survival rate, which implies that remoteness of the coordinating VAD centre does not pose inherent risks to patient survival or complication rates. It can be assumed that this factor is contributed to by continuous on-site and off-site training and support of the regional VAD coordinators, by specialists of NRCSC.

Regarding adverse events, almost a third of the study population developed RV heart failure within 30 days of LVAD implantation, however it is important to note that 44.2% of the patients had RV dysfunction prior to the surgery. This high incidence had prompted us to initiate a TAH program.

The most common adverse event after 30 days of implant was driveline infection. Surveying the patients with such complications we found out that the main cause was accidental trauma to the exit site. This adverse event is hardly avoidable with the driveline being always exposed as an open wound, which is why the only solution for the problem could be implementation of wireless charging of the devices.

With CARMAT TAH our experience confirmed the excellent hemocompatibility profile that this pump provides, with none of the associated complications reported with other current devices. The device also gives the opportunity to evaluate changes in pulmonary vascular resistance while on support, which is an important function when using this device as a BTT: it helps to determine when patients may become eligible for heart transplantation.

FIVAD with a CET system Leviticus-Cardio is a promising technology for patients resulting in the obviation of driveline-related problems and a high quality of life is expected.

Conclusion

This paper analyzed the results of a single centre's data on the application of implantable MCS devices as a treatment for end stage heart failure. Based on the findings of the study, several recommendations can be generated to improve care of patients with chronic HF. First, the key to successful implementation of the VAD program lies not only in the work of a single team and a single centre but also in the development of a national VAD support system. Strong governmental support is also crucial in implementing and developing an MCS program. Second, the introduction of a TAH program may increase the survival of patients with biventricular failure. Third, a fully implantable ventricular assist device is a promising system for better quality of life

for patients and can resolve the driveline related complications. Further investigations of this system are needed in a larger group of patients in order to estimate long-term results. Finally, in circumstances when obstacles exist for developing a heart transplantation program, MCS can serve as an alternative for improving patients' health outcomes and quality of life.

Author contributions. All authors participated in data interpretation, drafting, critical revision, approval of the article.

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Legends

Figure 1. Spectrum of assist devices implanted at the NRCSC from November 2011 to December 2019.

Abbreviations. LVAD - left ventricular assist device; BiVAD - biventricular assist device; TAH - total artificial heart; HM II – HeartMate II; HW – HeartWare; HM 3 – HeartMate 3.

Figure 2. Map of the Republic of Kazakhstan with the number of LVAD patients in each region of residence (excluding 2 patients from Kyrgyzstan and Georgia) and the driving distances from the NRCSC.

Figure 3. Kaplan-Meier survival curve for patients following LVAD implantation.

Figure 4. Kaplan-Meier survival curve for patients following implantation of different types of LVAD.

Figure 5. Kaplan-Meier survival curve for adjusted DT group of patients following LVAD implantation depending on the distances between their cities of residence and the centre (city of Nur-Sultan) (1 - ≤999 km, 2 - ≥1000 km).

Figure 6. Chest X-rays of patients after implantation of CARMAT total artificial heart (A) and fully implantable assist device (B).

Figure 7. Monitoring of the CARMAT Transpulmonary Resistance (TPR) in CARMAT TAH patients.