First experience of magnetically levitated extracorporeal left ventricular assist device for cardiogenic shock in China

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Abstract

We report the first case of an investigational maglev extracorporeal ventricular assist device (extra-VAD) use in China for a patient with cardiogenic shock post-coronary artery bypass surgery. There were no extra-VAD devices available for clinical use in China. The patient was successfully supported for 9 days and recovered to hospital discharge. Throughout the support, the patient’s haemodynamic and haematologic parameters demonstrated good patient recovery and no device-related complications were observed. Our results encourage extra-VAD use in short-term to mid-term bridging the cardiogenic shock patients in China and potentially other developing countries for both clinical and health economic benefits.

Keywords  Maglev; Extracorporeal ventricular assist device; Cardiogenic shock

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Introduction

In China, temporary mechanical circulatory support (MCS) options for acute cardiogenic shock (CS) are limited. Veno-arterial extracorporeal membrane oxygenation (VA-ECMO) support has gained popularity (~5000 runs per year) in recent years. However, the high complication rates and costs of ECMO underscore the need for safer, more effective, and targeted MCS therapy for CS. Extracorporeal ventricular assist devices (extra-VADs) with third-generation blood pump technology, characterized by magnetically levitated (maglev) contactless rotor, has demonstrated favourable survival rates (up to 70%) and complication profile in CS in other countries. Here we report the first case of maglev extra-VAD ( investigational device) use in China for a patient with CS post-coronary artery bypass (CABG) surgery. The patient was successfully supported with the maglev extra-VAD for 9 days and recovered to hospital discharge (Figure 1).

Case report

A 62-year-old male patient with a history of coronary artery disease status post two percutaneous coronary intervention procedures 14 years and 4 months prior presented with non-ST elevation myocardial infarction and was found to have severe coronary artery stenosis again. Echo evaluation showed extensive left ventricular (LV) infarction, apical aneurysm, LV dilation (LV end-diastolic diameter 5.3 cm), and systolic dysfunction (LV ejection fraction 30%, the arterial blood pressure 80/40 mmHg, lactic acid 4.37 mmol/L, and BNP 65.3 pg/mL). The patient underwent CABG, ventricular aneurysmectomy, and mitral valvuloplasty but could not be weaned from cardiopulmonary bypass (CPB). Considering the severe LV dysfunction, there was concern that VA-ECMO could potentially impede LV recovery and overload the pulmonary circulation. Thus, a domestically developed investigational maglev Extra-VAD, MoyoAssist® (magAssist Inc., Suzhou, China), was implanted as humanitarian use with the informed consent of the patient’s family.
The perfusion cannula of the CPB was retained on the ascending aorta and connected to the investigational VAD. The venous cannula of the CPB was removed after a 24 French inflow cannula of the investigational VAD was connected to the roof of the left atrium medial to the right pulmonary veins. To avoid LV thrombus and aortic valve complication, the pump flow was set to around 3 L/min to maintain aortic valve opening under echocardiographic guidance. The patient was stabilized with the mean aortic pressure kept around 80 mmHg and transferred to the ICU.

Table 1 shows the lab test results during the whole period of Extra-VAD implantation. High-sensitivity troponin I (TNI) reached 437 293 ng/L at post-op CS, which was the highest in our record, and decreased quickly to 154 972.1 ng/L the day after, demonstrated a rapid improvement of cardiac function. Continuous renal replacement therapy was used due to oliguria on POD 2. Lactate dehydrogenase (LDH) reached the peak of 1082 U/L on POD 2, decreased to 321 U/L on POD 9. Lactic acid was 4.37 mmol/L on POD 1 and decreased to 1.53 mmol/L on POD 3. Heparin was used for anticoagulation.

Table 1 Lab test results during extra-VAD implantation

|                | POD 1     | POD 2     | POD 3     | POD 4     | POD 5     | POD 6     | POD 7     | POD 8     | POD 9     |
|----------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| Blood compatibility and anticoagulation management |           |           |           |           |           |           |           |           |           |
| RBC            | —         | 3.38      | 2.89      | 2.61      | 2.67      | 2.63      | 2.54      | 2.41      | 2.23      |
| WBC            | —         | 8.34      | 8.12      | 6.44      | 6.8       | 7.25      | 7.49      | 4.97      | 3.48      |
| PLT            | —         | 120       | 99        | 76        | 92        | 119       | 111       | 99        | 83        |
| ACT s          | 183.5     | 188.1     | 190.5     | 174       | 180       | 185.75    | 195.42    | 198.5     | 192       |
| D-Dimer mg/L   | —         | —         | —         | 0.28      | 0.32      | 0.42      | 1.05      | 1.89      | 2.2       |
| Biochemical test |          |           |           |           |           |           |           |           |           |
| TnI ng/L       | 13 970    | 437 293   | 154 972   | 70 731    | 49 721    | 55 622    | 39 715    | 34 568    | 20 617    |
| LDH U/L        | 260       | 1082      | 877       | 752       | 588       | 473       | 393       | 342       | 321       |
| Lac mmol/L     | 4.37      | 1.45      | 1.53      | 1.53      | 1.08      | 1.12      | 0.98      | 1.36      | 1.375     |
| CK U/L         | 228       | 5,028     | 4,076     | 3,048     | 1,669     | 990       | 570       | 360       | 222       |
| CRP mg/L       | —         | 52.7      | —         | 280       | 193       | 232       | 241       | 197       | 174       |
| bilirubin μmol/L | 14.1     | 32.6      | 22.8      | 17.5      | 28.8      | 45.2      | 56.1      | 63.6      | 14.1      |
| BUN mmol/L     | —         | 9.65      | 16.02     | 12.01     | 8.97      | 8.73      | 9.06      | 8.53      | 7.87      |
| Blood transfusion |         |           |           |           |           |           |           |           |           |
| Plasma mL      | 1,050     | 150       | 400       | 800       | 300       | —         | —         | 400       | 200       |
| RBC U          | 12.5      | 1.5       | 1.5       | 4         | —         | —         | —         | —         | 1.5       |
| PLT U          | —         | —         | 1         | 1         | 1         | —         | —         | —         | —         |

ACT, active clotting time; BUN, blood urea nitrogen; CK, creatine kinase; CRP, C-reactive protein; LAC, lactic acid; LDH, lactate dehydrogenase; PLT, platelet; RBC, red blood cell; TNI, high-sensitivity troponin I; WBC, white blood cell.
with a target ACT between 180 and 200 s. On POD 9, the patient was weaned off the extra-VAD and later discharged from the hospital. After removal of the Extra-VAD, LV ejection fraction was 39% and LV end-diastolic diameter was 4.4 cm, demonstrating signs of recovery.

**Discussion**

We report the first-in-man use of MoyoAssist®, the first extra-VAD developed in China with a fully maglev rotor and a blood flow path optimized by computational fluid dynamic analysis. The system can generate up to 8 L/min of flow and has good portability (system weight <10 kg). MoyoAssist® is an investigational device undergoing registered multi-center clinical trial. Another maglev extracorporeal VAD, CentriMag (Abbott Laboratories, Illinois, USA), is not yet approved in China.

This case was particularly difficult because the patient underwent a complex cardiac surgery before device implantation. His cardiac function was extremely poor as suggested by the TNI and the systolic blood pressure, which made the patient unsuitable for VA-ECMO treatment because of high incidence of LV distension and pulmonary oedema.

Central cannulation is not common for temporary MCS in China so surgical issues are particularly important to address. In our case, the conversion from CPB to the VAD circuit was straightforward and quick, taking only 5 min. Due to the poor LV function, it was initially challenging to balance adequate device flow and aortic valve opening to minimize the risk of LV thrombus. Throughout the duration of support, pulse pressure was carefully monitored and no LV thrombus was observed while renal and hepatic functions were stable. It was easy to maintain normal left atrial pressure and no pulmonary congestion (white lung) was observed.

Furthermore, the anticoagulation management was easier compared with our experience with VA-ECMO. Other than a minor amount of bleeding at the cannulation sites, there was no bleeding or thrombotic complication. No haemolysis was observed. Blood transfusion was listed in Table 1. The amount of blood transfusion was mainly attributed to the OP was the patient’s second open chest procedure, resulting in a higher amount of blood loss; it is much lower compared to our ECMO experience.

In addition to clinical benefits, there are also important health economic benefits for using extra-VADs in developing countries. For CS, extra-VADs may lead to faster LV recovery and fewer complications, translating to reduced costs. Durable implantable VAD therapy is available for end-stage heart failure patients but its high cost and care requirement preclude its use for the majority of patients in developing countries. Our case demonstrates that the extra-VAD may offer a more cost-effective solution for short-term to mid-term bridging support and reduce the economic burden on patients.

In conclusion, our results are encouraging for wider adoption of the extra-VAD in China. We envision that it will play an important role as bridging support, particularly in cases when the ultimate endpoint (recovery or heart transplantation) is not clear such as acute CS or fulminant myocarditis. More data are needed to verify the clinical and economic benefits we demonstrated in this case.

**Conflict of interest**

None declared.

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