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Supporting pediatric patients with short-term continuous-flow devices

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BACKGROUND: Short-term continuous-flow ventricular assist devices (STCF-VADs) are increasingly being used in the pediatric population. However, little is known about the outcomes in patients supported with these devices.

METHODS: All pediatric patients supported with a STCF-VAD, including the Thoratec PediMag or CentriMag, or the Maquet RotaFlow, between January 2005 and May 2014, were included in this retrospective single-center study.

RESULTS: Twenty-seven patients (15 girls [56%]) underwent 33 STCF-VAD runs in 28 separate hospital admissions. The STCF-VAD was implanted 1 time in 23 patients (85%), 2 times in 2 patients (7%), and 3 times in 2 patients (7%). Implantation occurred most commonly in the context of congenital heart disease in 14 runs (42.2%), cardiomyopathy in 11 (33%), and after transplant in 6 (18%). The median age at implantation was 1.7 (interquartile range [IQR] 0.1, 4.1) years, and median weight was 8.9 kg (IQR 3.7, 18 kg). Patients were supported for a median duration of 12 days (IQR 6, 23 days) per run; the longest duration was 75 days. Before implantation, 15 runs (45%) were supported by extracorporeal membrane oxygenation (ECMO). After implantation, an oxygenator was required in 20 runs (61%) and continuous renal replacement therapy in 21 (64%). Overall, 7 runs (21%) resulted in weaning for recovery, 14 (42%) converted to a long-term VAD, 4 (12%) resulted in direct transplantation, 3 (9%) were converted to ECMO, and 5 (15%) runs resulted in death on the device or within 1 month after decannulation. The most common complication was bleeding requiring reoperation in 24% of runs. In addition, 18% of runs were associated with neurologic events and 15% with a culture-positive infection. Hospital discharge occurred in 19 of 28 STCF-VAD admissions (67%). In follow-up, with a median duration of 9.2 months (IQR 2.3, 38.3 months), 17 patients (63%) survived.

CONCLUSIONS: STCF-VADs can successfully bridge most pediatric patients to recovery, long-term device, or transplant, with an acceptable complication profile. Although these devices are designed for short-term support, longer support is possible and may serve as an alternative approach to patients not suitable for the current long-term devices.

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There is growing interest in the use of short-term continuous-flow ventricular assist devices (STCF-VAD) in the pediatric population. These pumps, combined with various cannulation strategies, can be used in a left VAD

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configuration, with left atrial or left ventricular cannulation acting as the inflow and aortic cannulation as the outflow. Alternatively, right heart VAD (RVAD) support can be achieved with right atrial and pulmonary artery cannulation. Although this represents the classic configuration for these devices, alternative cannulation strategies may be required when implanting patients with congenital heart disease.

Currently, there are a limited number of short-term devices that have been used in the pediatric population, with the CentriMag or PediMag (Thoratec Corporation) and the RotaFlow (Maquet) representing 3 possible options. The RotaFlow uses magnetic suspension around a single monopivot bearing, and the CentriMag is magnetically levitated, with no bearing or seals.[1] Although the 2 pumps are similar, the lack of bearings in the CentriMag has the added potential of less thrombus formation.[2] Although STCF-VAD configurations may improve outcomes compared with extracorporeal membrane oxygenation (ECMO) in certain populations of children, this is largely unproven. The published pediatric experience is limited to single case reports or small case series.[3–5]

In pediatric patients, ECMO has traditionally been used for short-term mechanical support and durable VADs for longer-term support. The use of STCF-VADs may allow for evaluation of recovery, assessment of neurologic status, and better assessment of treatment options without the time constraints of ECMO. In addition, advantages of STCF-VADs compared with other forms of short-term support, such as ECMO, include the option of different cannulation strategies and the ability to connect the pumps to more secure cannulas such as those manufactured for the EXCOR (Berlin Heart).[6] This adaption allows for safe mobilization and rehabilitation in this patient population, which is difficult with ECMO.

Despite these potential advantages, little information is available in the pediatric population with respect to complications and outcomes after STCF-VAD use. Therefore we sought to describe our single-center pediatric experience with the CentriMag and PediMag and the RotaFlow as STCF-VADs.

Methods

The local Research Ethics Board approved the study protocol, and the requirement for individual patient consent was waived.

Patient population

This was a retrospective study of all pediatric patients (aged 0–17 years) supported with the CentriMag/PediMag or RotaFlow who were cannulated in a VAD configuration (right ventricle-pulmonary artery, left atrium/left ventricle–aorta) from January 1, 2005, to May 30, 2014, at the Stollery Children's Hospital, Edmonton, Alberta, Canada. Patients were cannulated using bypass cannulas or Berlin Heart EXCOR cannulas, depending on the clinical situation and expected duration of therapy. Each trial of short-term device therapy was considered a separate event and was included as a separate VAD run. Patient demographic and clinical characteristics were collected.

Outcome

The primary outcome of this study was decannulation from the STCF-VAD due to transplantation, recovery, conversion to a longer-term VAD, and death or death within 1 month of weaning off the device. Complete follow-up data were available for all patients. Five types of VAD-related complications were explored in this cohort and included bleeding, neurologic events, infection, ischemic organ damage, and mechanical device failure. We defined significant bleeding as the requirement for reexploration for bleeding or hematoma. Neurologic events included intracranial bleeding or ischemic stroke diagnosed by computed tomography CT) scan. Infections were defined as the presence of an organism from the blood, urine, cannula site, or sputum with associated clinical symptoms. In the absence of a defined organism, antibiotic use alone was not considered as evidence of infection.

We also sought to describe ischemic events in other organs, such as the gastrointestinal tract or spleen, diagnosed by imaging or pathologic specimen.

Finally, mechanical device failure was defined as malfunction of one or more components rendering the system incapable of functioning and requiring a device exchange. This did not include exchanges for pump thrombosis or clots in the circuit.

Statistical analysis

Descriptive statistical methods were used. Continuous variables are described as median with interquartile range (IQR) due to non-normality of the data, and absolute numbers are presented with proportions for categoric variables. The duration of support was calculated as the number of days between implant and removal of the device, regardless of the reason for decannulation.

Patient management

Device selection in our institution depends on the clinical situation and potential for recovery. For patients who acutely deteriorate, ECMO is first-line therapy, with conversion to a short- or long-term VAD within 5 to 10 days of ECMO initiation. Conversion to a short-term VAD usually occurs in the context of the potential for recovery, if further time is required for transplant assessment (e.g., neurologic assessment) or if renal replacement therapy or an oxygenator were needed in the system. If it was deemed a patient would move on to a long-term device or be bridged to transplant with a short-term device, a comprehensive transplant assessment did occur, including evaluation of neurologic function by clinical examination and imaging when deemed necessary. Patients were kept awake and as mobile as possible based on stability of the cannulas.

Anti-coagulation with unfractionated heparin (UFH) was started within 12 to 24 hours of device implantation, depending on the degree of post-operative bleeding based on chest tube output. An acceptable chest tube output as a trigger for starting UFH was considered < 2 ml/kg/h. UFH was titrated to a target anti-Xa level of 0.35 to 0.6 U/ml, with a goal activated clotting time range that correlated with the anti-Xa target. Anti-coagulation goals and agents were adjusted individually depending on the circuit condition as well as on the patient's bleeding and thrombotic profile.