Modified TandemHeart Ventricular Assist Device for Infant and Pediatric Circulatory Support

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Purpose. The development of pediatric ventricular assist device (VAD) circuits with lower flow ranges for infants and small children is ongoing. We present our results with modifying a readily available adult VAD to support the pediatric population.

Description. The TandemHeart VAD (CardiacAssist, Pittsburgh, PA) circuit was modified to include a variable restrictive recirculation shunt to permit lower flow ranges in small pediatric patients.

Evaluation. Initial benchtop flow rates and pressures were studied. Hemolysis trials were performed using whole bovine blood to compare plasma-free hemoglobin levels between modified and unmodified VAD circuits. The modified VAD was surgically implanted in 7 piglets (6 to 14 kg) and which supported them for 4 hours. Levels of hemolysis did not increase and full hemodynamic support was achieved. The modified TandemHeart VAD with a recirculation shunt was subsequently implanted in 2 pediatric patients who were bridged to transplant successfully.

Conclusions. Because of its simplicity, availability, low prime volume, greater patient flow range, and lower cost, the modified TandemHeart VAD with a recirculation shunt should be considered as an alternative to extracorporeal membrane oxygenation and other pulsatile VADs in children.

Managing heart failure in the pediatric population is complex. Wait-list times for pediatric heart transplantation can range from weeks to months and supporting children with heart failure during this time can be challenging. Ventricular assist devices (VADs) have become standard therapy for refractory heart failure in the adult population [1]. However, for pediatric patients extracorporeal membrane oxygenation (ECMO) is usually the first choice for cardiac support [2]. The development of pediatric VAD circuits to deliver lower flows and pressures has been tentative due to complications from thrombosis, bleeding, and the complex anatomy of congenital heart disease [3, 4]. Pediatric VADs currently require special equipment with expensive and intricate supplies to keep in stock. Training and staffing issues also come into play with pediatric VADs. Consequently, many centers still rely on ECMO for circulatory support. However, a study by Jeewa and colleagues [5] demonstrated that pediatric heart transplant patients had a reduction in wait-list mortality from 38% with ECMO to 13% with a VAD.

Technology

The TandemHeart (CardiacAssist, Pittsburgh, PA) VAD is a centrifugal pump that is currently approved by the United States Food and Drug Administration for clinical use in adults. For this study we modified the TandemHeart circuit design with the goal of providing a lower range of flows to accommodate the infant and pediatric population. The modification consists of a recirculation shunt which can be variably opened and closed to allow appropriate lower flow to an infant or small child (Fig 1). The flow rate of a centrifugal pump is determined by the inflow to outflow pressure gradient generated by the pump and outflow resistance. Resistance to outflow of the centrifugal pump is determined by the pump circuit (tubing, connectors, cannulae) and the patient’s systemic vascular resistance (SVR). The concept of our modified TandemHeart VAD uses both the operational theory of centrifugal pumps and the principles of blood flow resistance [6, 7].

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The modified TandemHeart VAD circuit includes a variable restrictive recirculation shunt that can compensate for greater flow ranges and resistances of the VAD circuit and the patient’s changing SVR. Using a gate clamp, the recirculation shunt flow can be adjusted by increasing or decreasing the radius of the recirculation shunt appropriately to the patient’s flow requirements. The modified TandemHeart shunt allows continuous flow without static blood flow points. The flow to the patient can be varied without raising or lowering revolutions per minute (RPM) of the VAD using the gate clamp.

**Technique**

Using a benchtop saline primed test loop, flow rates and pressures were initially studied to test the concept of the recirculation shunt. Using whole bovine blood we performed hemolysis studies to analyze plasma-free hemoglobin comparing modified and unmodified VAD circuits. We then implanted the modified VAD in 7 piglets.

**Table 1. Benchtop Flow Rates**

<table>
<thead>
<tr>
<th>Gate Clamp on Arterial Line</th>
<th>RPM</th>
<th>Flow (mL/min) 3/16” Tubing</th>
<th>Flow (mL/min) 1/4” Tubing</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Open</td>
<td>3,500</td>
<td>2,200</td>
<td>1,340</td>
<td>2,600</td>
</tr>
<tr>
<td>Partial occlusion</td>
<td>4,000</td>
<td>2,900</td>
<td>640</td>
<td>3,400</td>
</tr>
<tr>
<td></td>
<td>4,500</td>
<td>3,300</td>
<td>710</td>
<td>3,900</td>
</tr>
<tr>
<td></td>
<td>5,000</td>
<td>3,700</td>
<td>790</td>
<td>4,300</td>
</tr>
</tbody>
</table>

Flow rates and pressures were studied with a test loop on the benchtop to identify the ideal size and length of the recirculation shunt for different flow goals. Systemic flows can be easily and precisely adjusted between 500-1,300 mL/minute by adjusting the pump RPM with a fixed shunt.

RPM = revolutions per minute.
Finally, the modified VAD was implanted in 2 pediatric patients as a bridge to transplantation.

The TandemHeart VAD was initially benchtop tested using a standard saline wet-circuit bucket test loop (Fig 2). The TandemHeart standard 3/8" tubing was downsized to 1/4" tubing with 3/8" to 1/4" connectors (Terumo Cardiovascular, Ann Arbor, MI). A 15-cm standard polyvinyl chloride tubing shunt (Terumo Cardiovascular, Ann Arbor, MI) was placed between the arterial and venous limbs of the circuit to allow shunt recirculation. The TandemHeart VAD was primed and air was removed according to TandemHeart protocols. An adjustable screw occlusion gate clamp (CardiacAssist, Inc) was placed on the arterial outflow limb distal to the shunt to control or release outflow resistance. Pump speed varied between 3,500 and 5,000 revolutions per minute by the TandemHeart driver. Preoperative and postoperative shunt flows and pressures were recorded using standard pressure transducers (Smith’s Medical, St. Paul MN) and Transonic flow probes (Transonic System Inc, Ithaca, NY). The study was conducted with both a 3/16" and a 1/4" shunt.

Initially the saline primed test loop ran with no outflow occlusion. With a 3/16" shunt and the TandemHeart running at 3,500 RPM, 2,200 mL/minute flowed through the shunt and 1,340 mL/minute of flow went through the arterial limb into the bucket reservoir. In the open 1/4" shunt with the TandemHeart running at 3,500 RPM, 2,600 mL/minute flowed through the shunt and 1,220 mL/minute of flow went through the arterial limb into the bucket reservoir. To simulate the vascular resistance of the patient and arterial cannula, a gate screw occlusion device was placed on the arterial limb to increase outflow resistance and divert more flow through the shunt. Once the occlusion was set, we varied the pump speed between 3,500 and 5,000 RPM and recorded shunt flow and systemic flow (Table 1).

Based on the preliminary benchtop data, we proceeded to hemolysis testing to determine levels of plasma-free hemoglobin (PfHb) using standard hemolysis testing protocols with a Beckman DU-64 UV/visible spectrophotometer (Beckman Coulter, Brea, CA). We compared modified (test) and unmodified (control) TandemHeart VAD circuits [8]. Heparinized, filtered slaughterhouse whole bovine blood (Densco Marketing, Woodstock, IL) at 37°C was used for the 4-hour study with PfHb samples being analyzed every hour. Flows were kept at 4,000 RPMs in the test circuits. Results are shown in Figure 3. The modified VAD with a recirculation shunt did not increase levels of hemolysis.

Following Institutional Animal Care and Use Committee approval (#13-020), the modified VAD was surgically implanted in 7 piglets (6 to 14 kg, mean = 8.7 ± 3.2 kg). All animals received humane care in compliance with the “Guide for the Care and Use of Laboratory Animals” (National Institutes of Health publication 85-23, revised 1985). A median sternotomy was performed. Cannulation of the left atrium was with a right-angled 18 Fr venous cannula (Edwards Lifesciences, Irvine, CA) and cannulation of the ascending aorta with a right-angled 14 Fr arterial cannula (Edwards Lifesciences, Irvine, CA) (Fig 4). The modified VAD was connected to the surgical circuit and the left atrium was drained through a 10 Fr atrial cannula (Edwards Lifesciences, Irvine, CA). The TandemHeart VAD was primed and air was removed according to TandemHeart protocols. An adjustable screw occlusion gate clamp (CardiacAssist, Inc) was placed on the arterial outflow limb distal to the shunt to control or release outflow resistance. Pump speed varied between 3,500 and 5,000 revolutions per minute by the TandemHeart driver. Preoperative and postoperative shunt flows and pressures were recorded using standard pressure transducers (Smith’s Medical, St. Paul MN) and Transonic flow probes (Transonic System Inc, Ithaca, NY). The study was conducted with both a 3/16" and a 1/4" shunt.

Table 2. Details of Surgically Implanted Ventricular Assist Devices (VAD) in Piglets

<table>
<thead>
<tr>
<th>Weight (kg)</th>
<th>Time on Modified VAD (hours)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>4</td>
<td>No complications</td>
</tr>
<tr>
<td>12</td>
<td>4</td>
<td>No complications</td>
</tr>
<tr>
<td>14</td>
<td>4</td>
<td>No complications</td>
</tr>
<tr>
<td>6</td>
<td>0.8</td>
<td>Air became entrained in VAD during cannula adjustment, study terminated</td>
</tr>
<tr>
<td>6</td>
<td>2.4</td>
<td>Study terminated because of blood loss</td>
</tr>
<tr>
<td>6</td>
<td>3</td>
<td>Study terminated due to time constraints</td>
</tr>
<tr>
<td>6</td>
<td>4</td>
<td>No complications</td>
</tr>
</tbody>
</table>
The aorta was cannulated with a straight 10 Fr arterial cannula (Medtronic DLP, Minneapolis, MN). Cannulae were connected to the modified TandemHeart VAD. The animals were supported on the device for 4 hours while they remained under anesthesia (Table 2). During this time, hemodynamic data (blood pressure, heart rate, arterial and venous blood gas analysis, activated clotting time) and PfHb were performed at 1-hour intervals. Results of PfHb are shown in Figure 4. At the end of the study period the animals were sacrificed and the device was explanted and inspected for signs of thrombus. There was no evidence of thrombus in any of the devices.

Clinical Experience

After this bench and animal experience we used the modified TandemHeart VAD with a recirculation shunt in 2 patients. We previously reported this technique in a 9-year-old patient without using the recirculation shunt and gate clamp [9]. The first patient in whom we used the recirculation shunt was a 10-month-old infant diagnosed with restrictive cardiomyopathy. The child weighed 10 kg with a body surface area of 0.44\(\text{m}^2\). The second patient was a 5-year-old child diagnosed with myocarditis who weighed 18.7 kg with a body surface area of 0.74\(\text{m}^2\). Both were cannulated centrally through median sternotomy.

The TandemHeart is preassembled with 1600\(\text{cm}^3\) of 3/8\(\text{in}\) tubing on the inlet and outlet sides of the VAD. We cut this 3/8\(\text{in}\) tubing down to 3\(\text{in}\) stubs on each side. Then we attached a 1/4\(\text{in}\) × 1/4\(\text{in}\) × 3/8\(\text{in}\) “Y” connector to the inlet and outlet stubs. A 4\(\text{in}\) section of 1/4\(\text{in}\) tubing was used as the shunt bridge. The venous cannula was directly attached to the inlet (venous) 1/4\(\text{in}\) arm of the Y connector. Four inches of 1/4\(\text{in}\) tubing were attached to the outlet (arterial) arm of the Y connector. The circuit was completed by attaching this tubing to a 3/16\(\text{in}\) × 1/4\(\text{in}\) connector that is inserted into the 6-mm Dacron graft (Gelweave, Vascutek Ltd., Renfrewshire, Scotland) sutured to the aorta. The total prime of the circuit is 30 ml.

The dome of the left atrium is dissected between the aorta and superior caval vein and a purse string suture is placed. An appropriately sized right angle venous cannula is selected. Prior to cannulation, a short piece of Gore-Tex graft (W.L. Gore & Associates, Flagstaff, AZ) is placed over the cannula. The left atrium is then cannulated and air removed from the cannula, which is then attached to the venous limb of the circuit. The Gore-Tex graft is guided down to the left atrium and secured with pledgeted 5-0 Prolene (Ethicon, Blue Ash, OH) suture at 4 quadrants. Finally the graft is secured to the cannula tubing with several heavy silk ties. This outer graft aids hemostasis at the cannulation site, secures the cannula in place, and ensures it will not twist. A 6-mm Dacron graft is sutured to the ascending aorta and connected to the arterial limb of the circuit with a 1/4\(\text{in}\) connector secured with heavy suture and tie bands (Fig 5). Anticoagulation protocol was based on our ECMO protocol with goal activated clotting times of 175 to 200.

Two patients were supported on the modified VAD for 5 days (10-month-old) and 13 days (5-year-old). Patient lactate measurements are shown in Figure 6. Lactate
levels improved and then remained stable. Both patients were successfully transplanted without complication.

Comment

Pediatric heart centers treat a wide range of patients requiring ventricular assist and heart transplantation, from the neonate to the adult with congenital heart disease. One concern in the pediatric heart failure population is the economics of VAD implantation. Maintaining an armada of expensive VADs and training staff to competently manage multiple VAD devices is cost prohibitive for most pediatric heart centers. We developed a modified circuit design to allow a lower range of flows to accommodate small patients’ sizes using a standard TandemHeart ventricular assist device. The TandemHeart VAD is an adult VAD with fixed mechanical controls and requires a minimal pump RPM of 3,500 or 1 liter of flow. By incorporating a recirculation shunt between the arterial outflow and venous inflow we can maintain a minimal 3,500 RPM while providing a wide range of flows to the patient, depending on the patient’s SVR and the circuit resistance. Using data from ultrasonic flow probes, we can adjust the desired arterial flow to the patient by adjusting shunt resistance using an adjustable screw occlusion gate clamp on the bridge shunt. Our benchtop and hemolysis lab studies demonstrated the feasibility of using a modified VAD technique. Use of the shunt did not increase hemolysis. Animal studies confirmed that this technique could support the circulation. It was subsequently applied to an infant and a small child as a bridge to cardiac transplantation without complication. Thus, we made a simple adaptation to a single VAD to accommodate nearly an entire patient range. Because of its simplicity, availability, low prime volume, highly variable patient flow range, and clinical cost effectiveness, the modified TandemHeart VAD using a recirculation shunt with a gate screw occlusion device should be considered as an alternative to ECMO and other pulsatile VADs in children.

Disclosures and Freedom of Investigation

The authors had freedom of investigation in all aspects of this study and have no financial or regulatory information to disclose.

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References


Disclaimer

The Society of Thoracic Surgeons, the Southern Thoracic Surgical Association, and The Annals of Thoracic Surgery neither endorse nor discourage use of the new technology described in this article.

INVITED COMMENTARY

Several factors have combined in recent years to increase the use of ventricular assist devices (VADs) in children. The development of pediatric-specific devices and the progressive miniaturization of adult devices (making them amenable to implantation in smaller and smaller children) have both had a significant impact on our ability to support children with heart failure. However, significant challenges remain in providing appropriate mechanical