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A Novel Rotary Pulsatile Flow Pump for Cardiopulmonary Bypass

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Abstract

It has been suggested that pulsatile blood flow is superior to continuous flow in cardiopulmonary bypass (CPB). However, adoption of pulsatile flow (PF) technology has been limited due to practicality and complexity of creating a consistent physiologic pulse. A pediatric pulsatile rotary ventricular pump (PRVP) was designed to address this problem. We evaluated the PRVP in an animal model, and determined its ability to generate PF during CPB.

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The PRVP (modified peristaltic pump, with tapering of the outlet of the pump chamber) was tested in 4 piglets (10-12kg). Cannulation was performed with right atrial and aortic cannulae, and pressure sensors were inserted into the femoral arteries. Pressure curves were obtained at different levels of flow and compared with both the animal's baseline physiologic function and a continuous flow (CF) roller pump.

Pressure and flow waveforms demonstrated significant pulsatility in the PRVP setup compared to CF at all tested conditions. Measurement of hemodynamic energy data, including the percent pulsatile energy and the surplus hydraulic energy, also revealed a significant increase in pulsatility with the PRVP ($p < 0.001$).

PRVP creates physiologically significant PF, similar to the pulsatility of a native heart, and has the potential to be easily implemented in pediatric CPB.

Keywords

Pediatric; Cardiopulmonary bypass; CABG new technology

Cardiopulmonary bypass (CPB) revolutionized cardiovascular surgery over 50 years ago when a heart-lung machine was used successfully in the clinical setting by John Gibbon in 1953 during the repair of atrial septum defects.[1] CPB is now frequently used for multiple surgical procedures. The utilization of CPB has evolved over the years, but several questions remain about the optimal characteristics of a CPB system. One controversy relates to the use of pulsatile flow (PF) vs. continuous flow (CF). This issue has been studied in many experimental and clinical models. Despite these studies, there is no consensus regarding optimal flow mechanics in CPB.

It has been suggested that PF is superior to CF. Alkan et al, demonstrated that pediatric heart surgery patients who had PF as a component of their CPB required less inotropic support and had shorter ICU and hospital length of stay compared with those in the non-pulsatile flow group.[2] In a prospective, randomized trial of adult cardiac surgery patients, the pulsatile group had lower rates of balloon pump use, myocardial infarction, and death.[3] PF is associated with improved microcirculation, less inflammatory response, decrease in inotropic support, shorter hospital stay, and superior organ perfusion including renal preservation. PF has also been shown to increase end-organ and cerebral perfusion.[4-10] Several mechanisms have been proposed including reduction of pro-inflammatory cytokine release with PF, likely due to decreased endothelial injury.[11,12] Non-pulsatile flow causes greater increase in systemic vascular resistance due to vasoconstriction.[13] Despite these and other studies demonstrating the clear advantages to PF, this technology is used in only 7% of USA centers.[14] Possible reasons for this have been identified and refuted elsewhere.[15,16] The use of PF has been additionally slowed by lack of a practical, easily adopted means of generating a high quality physiologic pulse.[17] Generation of pulsatile flow depends on an energy gradient; precise quantification in terms of hemodynamic energy levels is therefore a necessity, not an option. A novel pulsatile device has been previously described, referred to as the pediatric pulsatile rotary ventricular pump (PRVP). The PRVP is capable of creating normal physiologic pulse in a hydraulic benchtop model of a pediatric

sized patient.[18] The purpose of this study was to test the PRVP system in an infant/pediatric CPB model in piglets. It was hypothesized that this pump would create adequate pulsatile flow with minimal priming volume.

Materials and Methods

Pump Design

The PRVP is a scaled embodiment of previously described M-pump technology (MC3 Inc, Ann Arbor MI) designed for CF CPB support. It consists of a collapsible conduit called the pump chamber, wrapped under tension around freely rotating rollers mounted on a simple, three roller pumphead. The design benefits include startling principle operation, pressure limited output, suction limited input, afterload insensitivity, an inability to pump air or drain a venous reservoir, and avoidance of retrograde flow. These features have been described in detail.[19-21] In addition to reduced scale, the PRVP also includes modifications to the pump chamber designed to create the desired pulsatile flow, with a priming volume of 8cc.. The M-Pump was originally marketed and used successfully for adult CPB procedures where its intuitive operation and improved safety above that offered by centrifugal pumps won ready acceptance by perfusionists.

As shown in Figure 1a, the M-pump consists of a collapsible conduit with unique cross-sectional design called the pump chamber, wrapped under tension around three freely rotating rollers mounted on a rotor. In its “free” condition, the pump's cross-sectional shape is collapsed and occluded (Figure 1a). The pump chamber will prime only when fluid is supplied at a pressure above the atmospheric pressure and will assume the cross sectional shape shown in Figure 1b. Once the inlet region of the pump chamber is primed and the rotor rotates, fluid is driven by peristaltic motion toward the outlet region of the pump chamber.

The PRVP incorporates innovations resulting in improved pulsatile flow generation without the use of active electronic controls, while maintaining a constant RPM. Fluid remains isolated between the rollers as it advances toward the outlet. The outlet region is characterized by a tapering cross-section which results in pressurization of the advancing fluid. As the lead roller disengages the tubing, an initial pressurized discharge into the extracorporeal circuit (ECC) results, followed by a period of steady reduced flow as the roller passes over the smaller cross section portion of the outlet region. The resulting flow and pressure are pulsatile and periodic with each roller pass.

Surgical Technique

This study was approved by the University of Michigan University Committee on Use and Care of Animals (UCUCA). All piglets received humane care in compliance with the Guide for the Care and Use of Laboratory Animals. Four infant female piglets (10-12kg) were anesthetized, ventilated, and instrumented. General anesthesia was administered and maintained with Isoflurane (0.8-3.0%) utilizing a Narcomed 6000 ventilator (Draeger Medical Inc, Telford PA) while the animal was surgically instrumented. A cutdown was performed to the right femoral vein and artery for intravenous access and measurement of

mean arterial pressure (MAP). Arterial blood gases were obtained every 30 minutes after intubation to verify appropriate metabolic status. The left femoral artery was dissected and a 5Fr pressure probe (Millar Instruments, Houston TX) was inserted into the descending aorta within approximately 1-2cm of the arch to measure MAP. A median sternotomy was made to access the thoracic cavity. A 10mm vascular flow probe (Transonic Systems, Ithaca NY) was inserted around the aorta between the two cephalic branches to monitor aortic blood flow. A norepinephrine infusion (0.5-2.0 $\mu\text{g}/\text{min}$) was used as needed to maintain MAP $>40\text{mmHg}$ during sternotomy and manipulation of the heart and great vessels, after surgical instrumentation the infusion was discontinued. Following heparinization (450 U/kg), the aorta was cannulated with a 12Fr aortic cannula (Medtronic DLP Model 77012, Minneapolis MN) inserted approximately 1-1.5cm into the aorta and secured by dual pursestring suture. The right atrium was cannulated with a 24Fr right angle metal tip drainage cannula (Medtronic DLP model 69324, Minneapolis MN). The cannulae were connected to the CPB circuit (described below). The average time on bypass was two hours. Activated coagulation times (ACT's) were $>600\text{s}$ throughout the experiment.

CPB Circuit

The CPB circuit used was a basic clinical pediatric CPB circuit, except that no vents or cardioplegia were used. The PRVP pulsatile pump was tested and compared in parallel with a Stöckert 6" non-pulsatile roller pump that was used to collect CF data. The CPB circuit consisted of 1/4" ID $\times$ 1/16" wall tubing for venous drainage and 1/4" ID $\times$ 3/32" wall tubing for arterial reinfusion. Venous drainage was via gravity to a Terumo Baby RX open venous reservoir and Terumo CAPIOX® RX-05 (Terumo Medical Corp, Ann Arbor MI). Blood exiting the reservoir was diverted in parallel to either the CF roller pump (1/4" I.D. tubing) or the PRVP via a "Y" connection (Figure 2). The pump not in use was isolated by clamps from the circuit to minimize flow artifact. Arterial blood exiting the gas exchange device was infused into the ascending aorta in 3 of 4 animals. In one animal the blood was pumped through a pediatric arterial filter (Terumo Capiox AF02, Terumo Corp, Ann Arbor MI) prior to reinfusion into the ascending aorta. An extracorporeal flow probe (Transonic Systems, Ithaca, NY) was attached just proximal to the reinfusion cannula to measure systemic blood flow. Priming volume of the system was 500cc.

Data Acquisition and Calculation

Pressure and flow rate data were sampled and recorded using customized LabVIEW software (National Instruments, Austin TX) and a compact DAQ (NI cDAQ-9172) including general purpose bridge amplifier (NI9237) and analogue input (NI9219) modules. All pressure sensors received pre and post two point calibrations using standing water columns of known height. At each measurement point, pressure and flow waveforms were sampled at a rate of 100 Hz for 30 seconds using our LabVIEW based data acquisition system. For each measurement the full 30-second data sample was used to calculate MAP, energy equivalent pressure (EEP), surplus hydraulic energy (SHE), and percentage pulsatile energy (PPE) using the equations shown in Table 1. In addition, the maximum rate of change of pressure (dP/dt_{max}), maximum rate of change of flow rate (dQ/dt_{max}) and pulse pressure (systolic–diastolic) were derived and recorded within each sample. To evaluate the

effects of PF vs. CF on aortic hemodynamics, a group average and standard deviation for EEP, SHE, and PPE were generated at each standard flow rate across all animals.

Baseline data for each study was gathered from the piglet native circulation following instrumentation but prior to cannulation for CPB. This established a basis of comparison between native hemodynamics and those of CF and PF perfusion that would be used during CPB. Bypass was initiated using the roller pump in CF mode. The blood flow rate was gradually increased until full bypass flows were attained. The animal was stabilized on bypass for approximately 15-30 minutes. Arterial blood gases were drawn to confirm adequacy of perfusion. Baseline data at full CF was recorded. The pump flow rate was then increased in 250mL increments to achieve flows of 0.5 L/min, 0.750 L/min, and 1.0 L/min. Pressure and flow rate waveforms were recorded at each flow increment. A second set of data was obtained by increasing the flow rate in similar 250mL increments until full bypass flows were again established. At that point the arterial pump was weaned off and the PRVP engaged so that the same data sequence could be collected in PF mode. The data cycles were repeated 2-3 times in PF mode and a second time in CF mode.

Statistical analysis was performed in Microsoft Office Excel 2007 (Redmond WA) using a one-way ANOVA approach, where values of $p < 0.05$ were considered statistically significant. The independent variables were pump type (roller, PRVP, no pump). The dependent variables were PPE, EEP, SHE, perfusion flow rate, aortic pulse, femoral pulse, aortic pressure, femoral pressure, peak cannula flow rate, and max change in cannula flow rate. All results are expressed as mean values along with standard error.

Results

All piglets were supported successfully on CPB following instrumentation. There were no immediate complications from surgical manipulation. No clot formation was observed at the end of the study in any circuit loop or component in all the experiments. The maximum CPB flow obtained was 122 ± 12 mL/min/kg. Representative flow and pressure waveforms for the CF (roller pump) and PF (PRVP) are shown in Figures 3 and 4. The PRVP waveforms reveal significantly more pulsatility when compared with those of the roller pump. The PRVP is characterized by a more rapid rise of pressure during the systolic period followed by a gradual fall in pressure during the diastolic phase. This characteristic is preserved over the range of flows tested and remains intact in the femoral artery (Figure 5).

Hemodynamic energy data comparison between PRVP and roller pump is summarized in Table 2 and was derived using the aortic cannula flow and the aortic pressure waveforms. The percentage increase in hemodynamic energy content during pulsatile flow over an equivalent steady flow at the measured MAP is presented as the Percent Pulsatile Energy or PPE. At each flow rate the PRVP's PPE was significantly higher ($p < 0.001$) than the roller pump and under all conditions remained above 10%, reaching as high as 21%. The increase in energy content per unit volume of pulsatile flow compared to equivalent steady flow at the measured MAP is given as SHE. SHE showed a similar trend as the PPE, ranging from 2.4 to 7.0 times greater for the PRVP than the roller pump. The absolute value of the hemodynamic energy was calculated as the energy equivalent pressure or EEP. EEP is

highly dependent upon the magnitude of the MAP at the time of measurement, rendering direct comparisons between flows difficult in light of varying MAPs throughout our animal study. We were unable to distinguish a difference in EEP between pumps. Analysis of PRVP waveforms at each flow rate is summarized in Table 3. The maximum rate of change of pressure (dp/dt_{max}), pulse pressure (systolic–diastolic), peak cannula flow rate (dQ/dt_{max}) and beat rate (BPM) were statistically similar between baseline animal and PRVP at 1.0 L/min flow. Values of dp/dt_{max} and pulse pressure were reduced with decreasing perfusion flow rates, most notably in the femoral artery where the dp/dt_{max} at 0.5 L/min fell to 32% of the value recorded at 1.0 L/min, and the pulse pressure was 50% of that at full perfusion flow rate. This is in contrast to the hydraulic energy values of the pulse flow which trended higher at lower perfusion rates (Table 2). Pulse rates for the PRVP were in the range of 50–120 pulses per minute over the range of flows tested. Extracorporeal circuit pressures measured just proximal to the aortic cannula increased with increasing flow rates and remained below 350 mmHg peak pressure in all cases (Figure 6).

Discussion

Pulsatile perfusion has been thought of as the best physiologic mode for CPB to address the morbidities associated with pediatric bypass, yet this remains controversial. This controversy is rooted in part in a historical lack of consistent reporting of quantifiable measures of pulsatile flow. Classic measures of pulsatility have included pulse pressure (systolic pressure–diastolic pressure) and maximum rate of change of pressure (dp/dt_{max}). Significant efforts have been made more recently to standardize a set of metrics for quantifying pulsatile flow. Undar et al, have advocated characterizing pulsatility in terms of EEP, SHE, and PPE.[22,23] EEP refers to the ratio of the area under the hemodynamic power curve and the area under the pump flow curve. In nonpulsatile flow, the EEP will be equivalent to the mean arterial pressure. SHE is the difference between the EEP and the MAP multiplied by a constant, and refers to the surplus energy created by a pulsation. This method seems to be the most accurate and clinically relevant, since the generation of a pulse alone does not necessarily result in transmission of surplus energy relative to nonpulsatile pumps.[24] It is hypothesized that it is this excess energy that is the mechanism for improved tissue perfusion with pulsatile flow.[25] PPE is related to the ratio of the EEP and the MAP.

The results of this study confirm that PRVP design is capable of safely and simply producing a physiologically significant pulse in an in-vivo piglet model. The pulse generated by the PRVP system is similar to the animal's native heart, and more closely resembles its normal physiology than the roller pump. In addition, this model has previously been studied by other groups due to the piglets having similar hemodynamics, cardiovascular physiology and vascular resistance characteristics to those of human.[26,27]

Modern centrifugal pumps have been shown capable of generating pulsatile flow [28] but have been largely excluded from pediatric bypass for other reasons. The non-occlusive nature of centrifugal pumps poses risk of gravity induced retrograde flow with possible risk of air entrainment at the aortic cannulation site.[29] Additionally, the high speed impeller rotation necessary to produce pressure-driven flows poses a risk of cavitation and blood

damage under conditions of low blood flow rate and high operating pressures that can be characteristic during pediatric CPB.[30-33] Furthermore, centrifugal pumps are afterload sensitive, making precise control of blood flow rate challenging in the pediatric population. [34] Conventional roller pumps can produce pulsatile flow but are rarely able to generate a physiologic waveform.[35] Significant variation in hemodynamic energy created by various pulsatile roller pumps has been demonstrated.[21,27,28] The PRVP avoids these drawbacks and provides consistent pulsatile energy that can be used in CPB.

Undar et al, developed in the late 90's a physiological pulsatile pump (PPP) using a hydraulic driven pump with dual pumping chamber mechanism, one located immediately after the venous reservoir and the second immediately after the oxygenator. [8,36] The PPP was tested successfully in piglets, but the authors concluded that all components of the circuit (oxygenator, arterial filter and aortic cannulae) need to be carefully chosen. In addition, this system required the use of unidirectional valves and large priming volumes. Wang et al, published an in-vitro model of a non-occlusive pediatric pulsatile roller pump for acute (CPB) and chronic support (extracorporeal life support and bi-ventricular assist systems), in which roller pump could demonstrating effective pulsatile flow in the three simulated circulatory support circuits, especially at higher flow rates. However, this system has limitation including the pump chamber inability to be completely flat, which increase the risk of generating negative pressure (upstream of pump tubing blockage) or air embolism when the chamber is empty at high flow rates.[37]

There are several limitations to this system: 1) the pump rate and rpm, determine the pulse frequency and it cannot be adjusted manually; 2) this study only evaluated the mechanics of producing pulsatile flow and did not evaluate the clinical impact of the pulsatility, in regards to hemolysis, end-organ perfusion, or myocardial preservation; 3) small sample size. Future studies with the piglet model must address these concerns.

Conclusion

The novel PRVP is capable of providing full flow support of a piglet during CPB. The PRVP creates greater pulsatility than a continuous flow roller pump over the range of flow rates used during pediatric CPB. The mechanically induced pulsatility is similar to that observed with the native heart. The PRVP offers a safe, simple, drop-in replacement for conventional roller pumps for pediatric open heart surgery that may provide significant physiologic pulsatile flow resulting in improved end organ perfusion and potentially better outcomes.

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Figure 1. PRVP pump technology. (a) shows pump in its free condition, and the cross-sectional shape collapsed and occluded. (b) Illustrates pump chamber filled.

Figure 2.
Diagram of the CPB circuit for PRVP and Stöcker Roller Pump.

Pump Flow Waveforms at 0.70 mL/min (PRVP and Roller) compared to Baseline Piglet Pulse

Figure 3.

Representative flow waveforms in the normal piglet prior to CPB (dotted black line) with an average cardiac output of ~ 0.950 mL/min, the PRVP (solid black line), and the roller pump (solid gray line) at 0.70 mL/min.

Figure 4. Aortic Pressure of PRVP- (black line) vs. Roller Pump (gray line) at Different Pump Blood Flows

Figure 5. Femoral Pressure of PRVP- (black line) vs. Roller Pump (gray line) at Different Pump Blood Flows

Figure 6. Pre-cannula Average Pressure with Peak Values (values normalized to 50mmHg MAP)

Table 1
Pulsatility calculations -Pantalos et al.[26]

EEP

$$EEP (mmHg) = \frac{\int Q \cdot P dt}{\int Q dt}$$

SHE

$$SHE \left(\frac{ergs}{cm^3} \right) = 1332 \times \left[\frac{\int Q \cdot P dt}{\int Q dt} - MAP \right]$$

PPE

$$\left[\left(\frac{EEP}{MAP} \right) - 1 \right] \times 100$$

MAP=mean arterial pressure (mmHg), P= arterial pressure (mmHg), Q = pump flow (L/min), t=time

Table 2
Hydraulic Energy Value Comparison PRVP vs. Roller Pump At Different Pump Flows

VARIABLE	0.5 (L/min)		0.75 (L/min)		1.0 (L/min)	
	PRVP	Roller	PRVP	Roller	PRVP	Roller
PPE (%)	21.3	2.6	14.7	2.1	10.5	4.1
<i>p Value</i>	<0.001		<0.001		<0.001	
EEP (mmHg)	43.3	44.5	56.6	59.9	70.7	73.3
<i>p Value</i>	0.8		0.7		0.3	
SHE(ergs/cm³)	10,466	1,479	9,487	1,600	8,701	3,515
<i>p Value</i>	<0.001		0.001		<0.001	

Table 3

Complete PRVP Waveforms Analysis At Each Flow Rate

VARIABLE	Units	Flow rate (L/min)			
		0.50	0.75	1.0	Baseline
Perfusion Flow rate	mL/min/Kg	47.7 ±0.4	69.8 ±5	100.8 ±14	109.4 ±12
Aortic Pulse Pressure	mmHg	27.8 ±12	30.2 ±12	33.3 ±10	39.5 ±17
Femoral Pulse Pressure	mmHg	16.8 ±4	24.8 ±9	33.9 ±8	45.8 ±15
Aortic Pressure Max rate of change dP/dt _{Max}	mmHg/sec	265 ±101	317 ±62	382 ±81	338 ±108
Femoral Pressure Max rate of change dP/dt _{Max}	mmHg/sec	176 ±30	322 ±90	543 ±30	503 ±189
Peak Cannula Flow rate	L/min	1.87±0.1	2.30 ±0.2	2.62 ±0.2	2.76 ±0.4
Cannula Flow rate Max rate of change dQ/dt _{Max}	L/min/sec	21.7 ±2	30.5 ±1	37.9 ±2	NA