Pulsatile control of rotary blood pumps: Does the modulation waveform matter?

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Objective: Mechanical support of a failing heart is typically performed with rotary blood pumps running at constant speed, which results in a limited control on cardiac workload and nonpulsatile hemodynamics. A potential solution to overcome these limitations is to modulate the pump speed to create pulses. This study aims at developing a pulsatile control algorithm for rotary pumps, while investigating its effect on left ventricle unloading and the hemodynamics.

Methods: The CentriMag (Levitronix GmbH, Zürich, Switzerland) rotary blood pump was implanted in 5 sheep and cannulated from the ventricular apex to the descending aorta. A modified controller was connected to the pump yielding direct speed control via analog voltage. Pump speed modulation patterns, including sine, saw tooth, triangle, and square waveforms with 2 different phase shifts, were synchronized with heartbeat. Various hemodynamic parameters, such as left ventricular pressure and volume, coronary flow, and arterial pressure, were analyzed to examine the influence of pump support.

Results: The pump speed modulation significantly affected left ventricular pressure and volume and arterial pressure, whereas coronary flow was not influenced by pump support mode. Stroke work in the pulsatile modes varied from 69% to 91% of baseline value and from 74% to 96% of constant speed value. Consequently, cardiac workload can be adjusted to provide relaxation, which may lead to myocardial recovery.

Conclusions: A synchronized pulsing rotary blood pump offers a simple and powerful control modality for heart unloading. This technique provides pulsatile hemodynamics, which is more physiologic than continuous blood flow and may be useful for perfusion of the other organs. (J Thorac Cardiovasc Surg 2012;144:970-7)

For the past decade, ventricular assist devices (VADs) based on rotary blood pumps (RBPs) have been increasingly used for short- and long-term mechanical support of patients with severe heart failure. The nonphysiologic flow characteristics of these devices provide a continuous blood flow (altered slightly by heart contractility) in contrast with the first generation of VADs based on pulsatile pumps[1] because of the typical use of constant speed in clinically available RBPs. Studies on the effect of continuous flow for long-term support show that nonpulsatile flow increases the incidence of gastrointestinal bleeding[2,3]; in addition, it increases the risk of adverse events, such as peripheral vasculature stiffening and hemorrhagic strokes.[4-6]

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A promising application of VADs, in addition to their use in bridge-to-transplantation and destination therapy, is the bridge-to-myocardial recovery.[7,8] Although the mechanism of functional recovery of a failing heart is not completely understood, cardiac unloading by assist devices has been suggested as a mechanical tool to promote recovery.[9,10] We hypothesize that synchronized pump speed modulation would result in better control of cardiac workload to stimulate heart healing.

The current study aims to use different basic waveforms to modulate the speed of a CentriMag RBP (Levitronix GmbH, Zürich, Switzerland) synchronized with the electrocardiogram (ECG) and investigates its effect on left ventricular (LV) unloading and hemodynamics. We have examined saw tooth, triangle, sine, and square waveforms as the pump modulation patterns, each with 2 different phase shifts with respect to cardiac contraction (comparable to copulsation and counterpulsation). The highlight of synchronization and using different waveforms is the possibility of better control of cardiac workload and valuable new insight into the potential ability of rotary pumps for heart recovery.

MATERIALS AND METHODS

Pulsatile Speed Pattern of Rotary Blood Pump

The CentriMag RBP is a magnetically levitated centrifugal-flow pump composed of a disposable pump head and reusable motor. The device is based on the bearingless motor technology, which results in minimal

Abbreviations and Acronyms

AP = arterial pressure
CF = coronary flow
ECG = electrocardiogram
EDV = end-diastolic volume
krpm = kilo revolutions per minute
LV = left ventricular
PAF = pulmonary artery flow
PF = pump flow
PVA = pressure-volume area
RBP = rotary blood pump
SV = stroke volume
SW = stroke work
VAD = ventricular assist device

friction in the blood path and works with direct drive yielding sturdy control over the speed. A Levitronix industrial controller was modified and tuned to run with the pump. This modified proportional-integral controller yields direct speed control via analog voltage and feedback of the actual speed. The custom-made control program, which has QRS detection and phase shift-tracking algorithms, was written in LabVIEW (National Instruments, Austin, Tex) and communicates in real-time via a data acquisition system (c-RIO-9074, National Instruments). This program detects the QRS complexes in the ECG signal using a peak detector based on the Pan-Tompkins algorithm[11] and then produces the pump control signal in synchrony with the heart rate. The program continuously receives the animal's ECG signal using a patient monitor (model AS/3; Datex-Ohmeda Division, Instrumentarium Corp, Helsinki, Finland). Figure 1, *A* shows a description of the pump speed commands using different waveforms with 2 phase shifts. All the waveforms have the same mean speed (2 kilo revolutions per minute [krpm]) and amplitude (1 krpm); therefore, regardless of the waveform type, the number of pump impeller revolutions per each heart beat is equal. krpm is a measure for rotational speed of the pump impeller. Figure 1, *B*, presents the actual pump speed demonstrating how well the pump can follow the command speed.

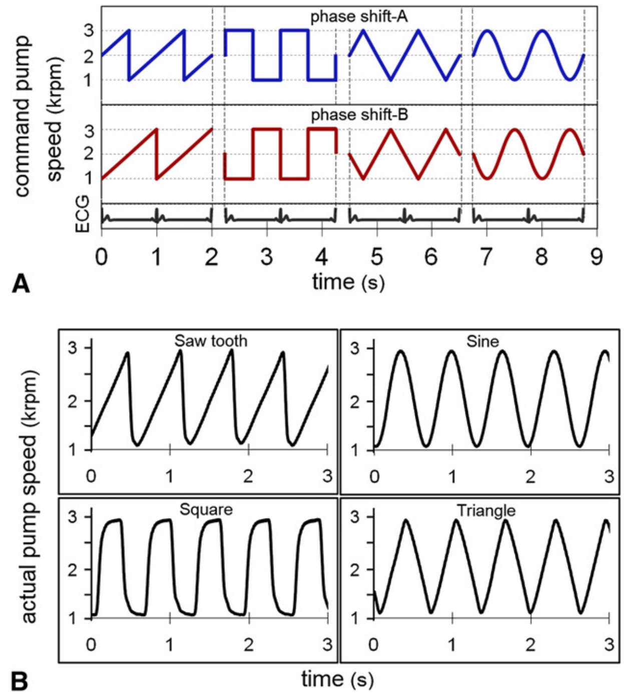

FIGURE 1. A, Various types of waveforms synchronized with electrocardiogram (*ECG*) as pump speed command. Phase shifts A and B have a 180-degree phase difference. krpm is a measure for rotational speed of the pump. B, Actual pump speed derived from the motor's Hall sensors.

Surgical Preparation and Instrumentation

The CentriMag RBP was implanted in 5 healthy female sheep (56–83 kg). This study was approved by the Swiss Federal Veterinary Office and is in compliance with the Guide for the Care and Use of Laboratory Animals (National Academy of Sciences, 1996). All animals received humane care in compliance with the Guide for the Care and Use of Laboratory Animals. After premedication and induction of anesthesia, the animals were intubated and anesthesia was maintained with isoflurane in oxygen (1.6%) and fentanyl (5–10 μg/kg/h). A left thoracotomy was used to enter the thorax and expose the LV apex and descending aorta (used in lieu of a short and inaccessible ascending aorta). The animals were heparinized to maintain the whole blood activated clotting time greater than 400 seconds. For surgical implantation of pump inflow, LV apical cannulation was performed using a modified 32F (1F = 0.33 mm) angled venous cannula (DLP 67532; Medtronic Inc, Minneapolis, Minn), and a 22F arterial cannula (EOPA 77522, Medtronic Inc) was placed in the descending aorta. The cannulation was kept short (35 $\pm$ 5 cm) to simulate implantable VADs and avoid energy losses inside the inlet/outlet cannula. After pump priming and connection of the cannulas to the inlet/outlet ports, pump operation commenced. Pulmonary artery flow (PAF), coronary flow (CF), and pump flow (PF) were measured using ultrasonic flow probes (Transonic Systems Inc, Ithaca, NY) on the pulmonary artery (24PAU), left main coronary artery (8PAU), and outlet cannula of the pump (9PXL), respectively. LV pressure and volume were acquired by a 7F admittance catheter (Scisense Inc, London, Ontario, Canada) in the LV via the right carotid artery. In addition, this catheter includes an extra pressure sensor to obtain arterial pressure (AP) in the ascending aorta. Actual speed of the pump impeller was monitored via an analog output at the pump controller from the motor's Hall sensors. All signals were acquired using iWorx data recorder and LabScribe data acquisition software (iWorx Systems, Inc, Dover, NH) at a sampling rate of 200 Hz. The cRIO-9074 was used to generate analog voltages to command the pump speed. Before recording, all pressure sensors were soaked in warm saline and zeroed to atmosphere and calibrated with a PXCAL medical pressure calibrator (Edwards Lifesciences Inc, Irvine, Calif) over their expected range. Flow sensors also were submerged in water baths and zeroed.

Study Protocol

The study protocol was performed chronologically as follows:

- First, baseline measurements including hemodynamic data (ECG, AP, LV pressure and volume, CF, PF, and PAF) were recorded. Baseline is defined as the condition where the pump is switched off and its inlet cannula is clamped.
- Second, a series of LV pressure-volume loops were measured during inferior vena cava occlusion at baseline. Pressure-volume loops during inferior vena cava occlusion were used to derive volume-axis intercept, V_0 in the PV plane for LV data.
- Third, 4 different waveforms (sine, square, saw tooth, and triangle) with 2 phase shifts (defined as phase shifts A and B in Figure 1, *A*) synchronized with the ECG were prescribed for the pump speed (the order of the waveforms was randomized for all sheep).

Statistical Analysis

One-way analysis of variance was performed to assess the effect of the pump speed on the LV unloading and hemodynamic parameters. In

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