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Thoughts and Progress

Assessment of Right Pump Outflow Banding and Speed Changes on Pulmonary Hemodynamics During Biventricular Support With Two Rotary Left Ventricular Assist Devices

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Abstract: The absence of an effective, easily implantable right ventricular assist device (RVAD) significantly diminishes long-term treatment options for patients with biventricular heart failure. The implantation of a second rotary left ventricular assist device (LVAD) for right heart support is therefore being considered; however, this approach exhibits technical challenges when adapting current devices to produce the lower pressures required of the pulmonary circulation. Hemodynamic adaptation may be achieved by either reducing the rotational speed of the right pump impeller or reducing the diameter of the right outflow cannula by the placement of a restricting band; however, the optimal value and influence of changes to each parameter are not well understood. Hemodynamics were therefore investigated using different banding diameters of the right outflow cannula (3–6.5 mm) and pump speeds (500–4500 rpm), using two identical rotary blood pumps coupled to a pulsatile mock circulation loop. Reducing the speed of the right pump from 4900 rpm (for left ventricle support) to 3500 rpm, or banding the Ø10 mm (area 78.5 mm^2) right outflow graft to Ø5.4 mm (22.9 mm^2) produced suitable hemodynamics. Pulmonary pressures were most sensitive to banding diameters, especially when RVAD flow exceeded LVAD flow. This occurred between Ø5.3 and Ø6.5 mm (22.05–38.5 mm^2) and speeds between 3200 and 4400 rpm, with the flow imbalance potentially leading to pulmonary congestion. Total flow was not affected by banding diameters and speeds below this range, and only increased slightly at higher values. Both right outflow banding or right pump speed reduction were found to be effective techniques to allow a rotary LVAD to be used directly for right heart support. However, the observed sensitivity to diameter and speed indicate that challenges may be presented when setting appropriate values for each patient, and control over these parameters is desirable. **Key Words:** Rotary blood pump—Biventricular heart failure—Left ventricular assist device—Biventricular assist device—Mock circulation loop.

The diagnosis of biventricular heart failure (BHF) among patients with heart failure is not always immediate, as right heart failure (RHF) may not be initially detected. Although some predictors of right ventricular (RV) dysfunction pre- and post-left ventricular assist device (LVAD) implantation have been developed (1), they are neither fully sensitive nor specific, which has resulted in a lack of widespread clinical implementation. RHF has been observed in up to 30% of patients who receive a LVAD. If medical therapy fails to adequately support the RV, the implantation of a right ventricular assist device (RVAD) is the only viable option (2), a procedure observed in almost 50% of mechanically supported patients in one center (3).

Unfortunately, RVAD intervention is frequently delayed until end-organ failure is irreversible (4), which may contribute to the 90% mortality rates reported in these patients (2). Early and planned biventricular assist device (BiVAD) therapy has been shown to improve survival (5). However, the largest obstruction to early RVAD implantation is the absence of a small, clinically evaluated, and long-term implantable RVAD.

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The majority of current BiVAD systems are designed for extra/paracorporeal use only. Recent advances in rotary blood pump (RBP) technology have improved outcomes for left heart failure patients (6); however, their use in a BiVAD arrangement leads to a hybrid situation where the left heart is supported by an implantable RBP and the right heart is supported by an extracorporeal ventricular assist device (VAD). Short-term RBPs are sometimes connected to support the right heart with additional pharmacotherapeutic support to promote weaning from mechanical assistance. Failing this, the subsequent connection of a longer-term (but still limited durability) extracorporeal positive displacement VAD may be undertaken.

It is therefore clear that there is a substantial unmet clinical need for a long-term implantable BiVAD system. Three techniques have evolved as viable options: the specific development of a RVAD to be used in conjunction with an LVAD (7,8); the use of a single rotary BiVAD (9,10); or the adaptation and implantation of a second LVAD as an RVAD (4,11). The latter technique was first attempted clinically by Frazier et al. using two Jarvik 2000 LVADs in 2003 (4). Recently, however, the Heartware HVAD has been used by multiple European centers as both LVAD and RVAD to treat BHF, with acceptable results observed (12,13).

The adaptation of a pump specifically designed as a LVAD to function as a RVAD is attractive commercially but is not without technical challenges: for example, pump size and anatomical fit, adaptation to the lower pressure gradient required across the RVAD due to low pulmonary vascular resistance (PVR) (12), and control techniques to balance left and right pump flows (14). If this latter consideration is not observed, RVAD overpumping may result in pulmonary congestion or RV collapse, while RVAD underpumping may result in multiorgan failure and/or left ventricular collapse.

The small size of some RBP designs enables dual implantation. The outflow pressure can be reduced in pumps that have a mechanically or magnetically suspended impeller by reducing the rotational speed, while a hydrodynamic impeller requires a minimum rotational speed to maintain noncontact suspension. A band (restriction) can instead be placed on the right outflow graft at implantation to increase RVAD afterload. While this technique has proven to be effective clinically, setting the optimal banding diameter for each individual patient remains a challenge, especially when faced with changes in patient PVR (12).

The dynamic balance of left and right total cardiac output is of utmost importance in a BiVAD system, especially given changes in patient hemodynamic states. While the failing heart may have limited reserve to assist in this flow balancing, alterations in pump output will most likely be required. However, the impact and sensitivity of banding diameter or speed alteration to achieve this balance are not completely understood.

The objective of this paper is to discuss the physiological balance between left and right output as well as systemic and pulmonary volumes and pressures when adapting an LVAD to function as an RVAD for biventricular assistance. Particular emphasis was placed on the sensitivity of right pump hemodynamic output with respect to right pump speed changes or right outflow graft banding diameters.

MATERIALS AND METHODS

A mock circulation loop (MCL) was used to evaluate the ability of two identical rotary pumps designed for left ventricular support to support the cardiovascular circulation during a simulated BHF condition. A complete description of the MCL is provided by Timms et al. (15).

Two Deltastream pumps (Deltastream, Medos Medizintechnik GmbH, Stolberg, Germany) were connected to the MCL to support the failing circulation. The Deltastream pump has a mechanical pivot bearing for impeller support. The left pump inflow was cannulated to the left ventricle (LV) and the right pump to the RV. Pump outflow was directed to the aorta and pulmonary artery, respectively. Inflow/outflow cannula lengths and diameters used in this study are listed in Table 1.

The rotational speed of each pump was independently controlled via two speed control boxes. This allowed the rotational speed of the left pump to be increased until a suitable systemic hemodynamic condition of 6 L/min at an aortic pressure of 90 mm Hg was produced. Simultaneous right pump speed adjustments were made to maintain 6 L/min at a pulmonary arterial pressure (PAP) of 15 mm Hg. After recording the relative speeds, the speed of the

TABLE 1. *Nominal cannula dimensions for LVAD and RVAD*

	LVAD	RVAD
Inflow diameter	12.5 mm	12.5 mm
Inflow length	330 mm	330 mm
Outflow diameter	9.6 mm	10 mm
Outflow length	220 mm	220 mm

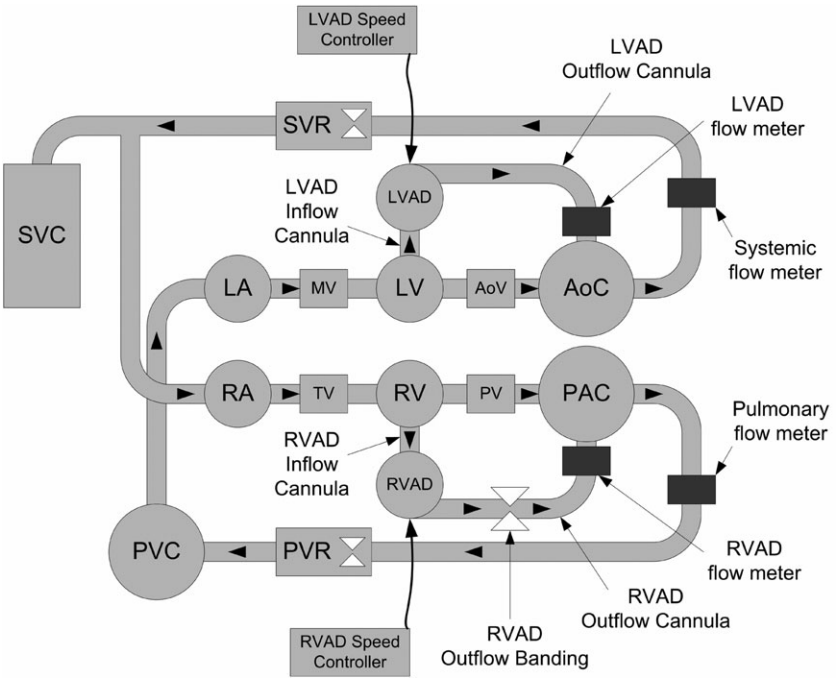

FIG. 1. Schematic of mock circulation loop used for testing biventricular support with two rotary LVADs. Pump speed was adjusted by LVAD and RVAD speed controller boxes. RVAD outflow banding was adjustable with a pinch valve placed on the right pump outflow cannula. LA, left atrium; MV, mitral valve; LV, left ventricle; AoV, aortic valve; AoC, aortic compliance chamber; SVR, systemic vascular resistance valve; SVC, systemic venous compliance chamber; RA, right atrium; TV, tricuspid valve; RV, right ventricle; PV, pulmonary valve; PAC, pulmonary arterial compliance chamber; PVR, pulmonary vascular resistance valve; PVC, pulmonary venous compliance chamber.

right pump was varied in 50 rpm increments in the range 500–4500 rpm in order to evaluate the sensitivity of speed variations on pulmonary pressures and flows.

Evaluation of the right outflow cannula banding technique on RVAD afterload was achieved via diameter variations produced by a proportional controlled pinch valve (ECPV-375B, HASS Manufacturing, Averill Park, NY, USA). In this test, the right pump speed was set to the same value as the left pump speed, at which point the pinch valve was actuated until PAP was 15 mm Hg at a flow rate of 6 L/min. The pinch valve was then activated to reproduce effective banding diameters between Ø3 and Ø6.5 mm in 12 increments. These effective diameters were translated to the pinch valve by an algorithm that determined a comparable area for each step of the pinch valve occluder. These tests were then repeated with an increased PVR, followed by an increase in RV contractility.

In all experiments, left pump/right pump outflow and total systemic and pulmonary flow were detected using two ultrasonic flow probes (TS410-10PXL, Transonic Systems, Ithaca, NY, USA) and two magnetic flow meters (OPTIFLUX 1010C/D, Krohne, Duisburg, Germany), respectively, while pressures (aortic, pulmonary, left and right atrial, left pump inlet/outlet, right pump inlet/outlet) were measured using disposable pressure transducers (NPC-100, GE, Boston, MA, USA). All signals were recorded using a dSPACE 1104 (DS1104, dSPACE Inc., Novi, MI, USA) digital signal processor at a sampling rate of 100 Hz.

A schematic of the MCL experimental setup is shown in Fig. 1.

RESULTS

MCL investigations revealed that circulatory hemodynamics (systemic: 90 mm Hg at 6 L/min, and pulmonary: 15 mm Hg at 6 L/min) were restored with a nominal Ø10 mm (78.5 mm^2) right outflow cannula when the left pump was operated at 4900 rpm and the right pump was operated at 3500 rpm. This condition was reproduced when the effective banding diameter on the right outflow cannula was reduced to Ø5.4 mm (22.9 mm^2) and the right pump was operated at the same speed as the left (4900 rpm).

The effects of right pump speed and right outflow banding diameter variations at a severe level of BHF replicated in the MCL are presented in Fig. 2. It was observed that as speed or banding diameter increased from the lowest setting, right pump outflow increased, while flow through the pulmonary valve decreased. Total cardiac output remained relatively unchanged at 6 L/min up to banding diameters of Ø5.3 mm or speeds of 3200 rpm, whereby a slight increase to 6.5 L/min was observed at higher values in the range. This corresponded to the values at which RVAD outflow exceeded LVAD outflow.

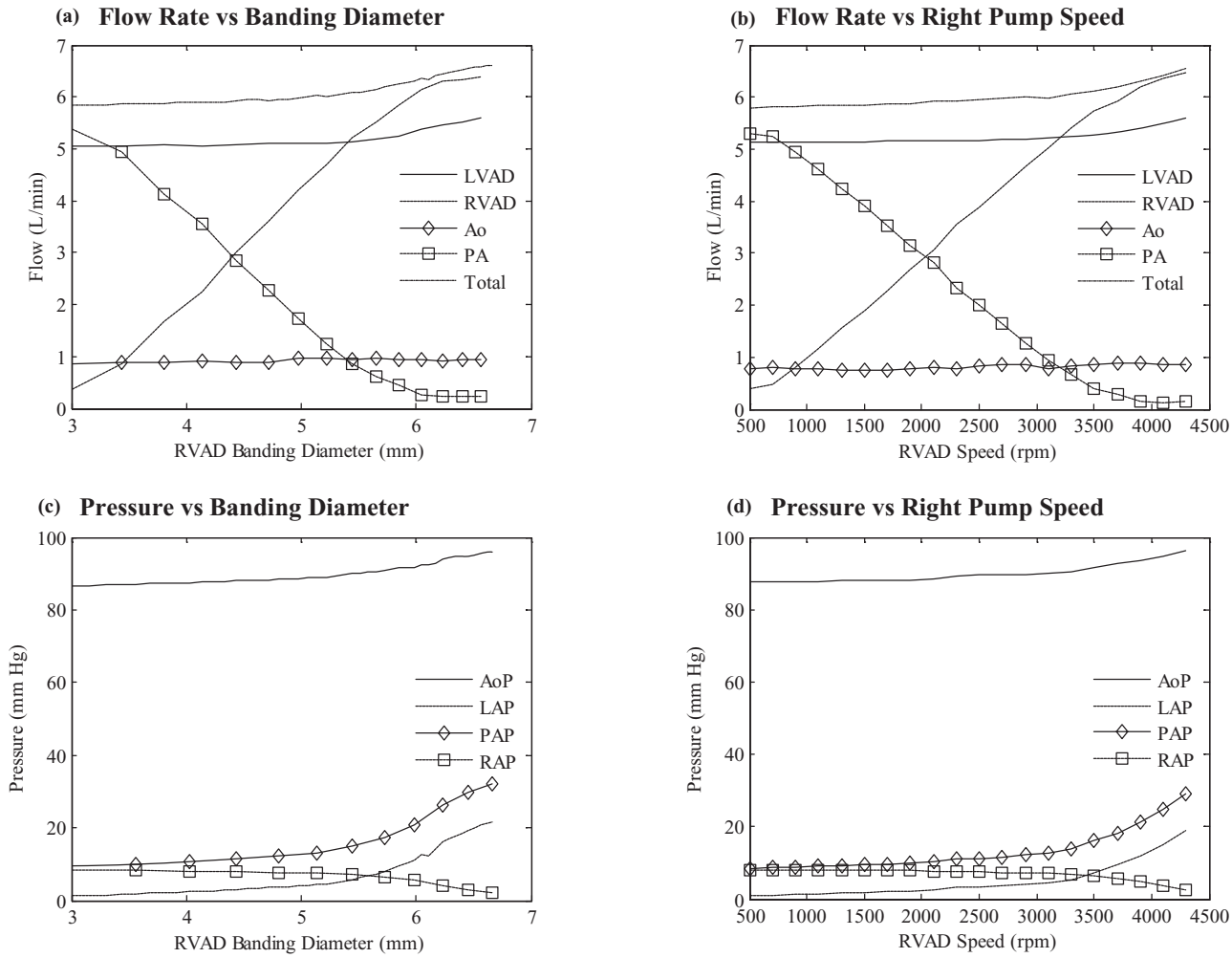

FIG. 2. Effect of alterations in right outflow graft banding diameter on flow (a) and pressure (c), compared to the effect of alterations in right pump speed on flow (b) and pressure (d), when tested in the mock circulation loop.

With low right pump speeds (<2500 rpm) or small banding diameters (<4 mm), left atrial pressures (LAPs) approached 0 mm Hg. Increasing the banding diameter or right pump speed resulted in an increase in PAP and LAP to a maximum of 30 mm Hg and 20 mm Hg, before the corresponding decrease in right atrial pressure (RAP) approached 0 mm Hg. This trend began at a diameter of around 3.5 mm or speed of 1500 rpm, with highest pump output sensitivity to banding diameter observed between Ø5.3–Ø6.5 mm and speed from 3200 to 4400 rpm.

DISCUSSION

The results from this study confirmed that it is possible to adapt to the hemodynamic requirements of the pulmonary system using a rotary LVAD in a right heart assist configuration. This was achieved by reducing the rotational speed of the right pump by 1400 rpm, or restricting the diameter of the right outflow cannula to Ø5.4 mm (22.9 mm^2). These results confirm those observed by Frazier et al. in an animal study that used two rotary axial flow Jarvik 2000 LVADs for biventricular support (2). Similar to our findings, a 1000–2000 rpm speed reduction in the right pump impeller produced normal hemodynamics without any alteration to the right outflow cannula diameter. Nosé et al. also found that a reduction in Baylor Gyro PI601 pump speed by 470–770 rpm adequately provided biventricular assistance in two calves (11). Quantitative discrepancies in actual speed reductions are related to the different performance characteristics of the devices used.

Clinically, Strueber et al. also used left/right speed variations to provide biventricular support in a

patient for at least 180 days using two hydrodynamically suspended Heartware VADs (13). In this case, the speed of the left pump was set at the upper extreme of 3600 rpm, thus allowing a reduced right pump speed at the lower extreme of 2000 rpm to maintain stable hydrodynamic impeller levitation. However, these speeds suggest excessive energy input into both circulations when considering the pump curve of the device (16), which could either elevate arterial pressures or pump flow rates. Furthermore, a limit to the flow variation might exist if a scenario presents that requires either a reduction in RVAD output or increase in LVAD output. Hetzer et al., however, hand operated both Heartware HVAD pumps at a rotational speed more commonly used for LV assistance, clinically producing the reduction in pulmonary pressure by restricting/banding the right outflow cannula (12). A value of Ø5 mm (19.6 mm^2) was recommended in this case, which is slightly lower than the Ø5.4 mm (22.9 mm^2) observed in this study. Many variables can account for the discrepancy, particularly the additional cannula resistance produced by the relatively longer inflow cannula in this study, and connections to the MCL. Furthermore, remaining RV function could compensate for reductions in pump output at smaller banding diameters, while other factors such as PVR and autoregulatory effects of the body may play an important role. The influences of these factors are the target investigated in future studies.

The creation, maintenance, and stability of hemodynamic pressures in the face of changing patient condition is reliant on the balancing of systemic and pulmonary cardiac output (14), and thus circulatory volumes. Patient-specific changes to hemodynamic parameters may therefore have a major influence on setting right pump speeds and right outflow banding diameters.

Understanding the sensitivity to changes of both speed and banding diameter on the balance of circulatory volume is also crucial to effectively fine tune values for each patient. The results showed that small variations in diameter between Ø5.3 and Ø6.5 mm and speed between 3200 and 4400 rpm produced substantial changes in pulmonary pressures. The starting value in each range corresponds to the point at which the RVAD flow exceeds LVAD flow, suggesting that the flow imbalance created may create the pulmonary congestion. Speed changes seemed to produce a smoother transition in pressure over a large range of speeds, signifying that pulmonary pressures are less sensitive to this type of change.

While right pump outflow was also significantly affected by variations in each parameter, total flow was not. This result was also observed by Saeed et al. when altering right pump speed in healthy animals (14), and suggests that the healthy RV has the capacity to compensate for lower output from the right pump. This is a demonstration of the Frank–Starling effect, whereby a reduction in RVAD flow increases right heart end-diastolic volume and thus force of contraction, consequently increasing the flow through the pulmonary valve. However, when maximum RV contractility is limited or PVR is elevated, total flow and LAP would reduce as the RV does not have sufficient capacity to compensate.

The anticipated variation in outflow cannula/graft banding or speed values required to maintain hemodynamics when RV contractility and/or PVR changes, coupled with the observed sensitivity to small variations in these parameters, highlights the need to have control over setting these parameters from patient to patient. Hetzer et al. acknowledged that variations in patient PVR may require the alteration of banding diameter (12). The use of a variable banding system may be beneficial, such as the FloWatch-PAB (FloWatch-PAB, Lehman Medical Technologies SA, Geneva, Switzerland; EndoArt, Lausanne, Switzerland) as first used clinically by the authors. The banding range of the FloWatch-PAB system (17) translates to equivalent diameters of Ø7 mm (38 mm^2)–Ø9 mm (72 mm^2), which seems to cover a higher range than determined by this study, and thus, more variability may be required should the autoregulatory effects of the natural circulation not compensate sufficiently. Additionally, the thrombotic potential of a point restriction must be considered.

Once finely tuned for a patient, further adjustments in either speed or banding diameter may be required to accommodate specific changes in patient hemodynamic condition or physiological state. These are thought to be most apparent in the early postoperative period of up to 2 weeks (18), after which, the native autoregulatory mechanisms of the circulation may adapt. In addition, the same requirement for changes may become apparent during the course of therapy in cases of myocardial recovery.

Although speed or banding changes are sufficient to produce suitable physiological hemodynamics independently, a combination of both techniques may prove advantageous. Adjusting the outflow banding diameter of the right pump until a suitable hemodynamic condition is reached and then accommodating for alterations in that condition via less sensitive speed changes may provide the clinician with greater control over patient hemodynamics.

Finally, the ability to implement changes in speed or banding diameter is influenced by the characteristics of the device used, which may induce additional complications. The reduction in rotational speed afforded in mechanical/magnetic supported pumps may introduce an increase in thrombotic potential in the right pump, as the reduced outlet pressure causes a significant reduction in secondary washout flow through the impeller clearance gaps (19). This complication may be mitigated in hydrodynamically suspended pumps when impeller speed is maintained at the LVAD speed, as the higher pressure at the impeller periphery is maintained due to the banded right pump outflow cannula. Mechanical/magnetically supported impellers can also observe this benefit, should a restrictive band be placed on their right pump outflow cannula, and rotational speed increased. Larger secondary clearances in these pumps may also provide an added benefit. In both cases, however, we observed that this technique increases power consumption up to the range of the LVAD, with up to five times more power needed than if speed alone was reduced.

CONCLUSION

The hemodynamic adaption of a rotary LVAD as a RVAD was successfully demonstrated in both computer simulation and MCL investigations of biventricular assistance.

This study supports current clinical findings that normal pulmonary hemodynamics can be produced at either a reduced right pump rotational speed (by 1400 rpm) or by banding right outflow cannula to Ø5.4 mm (22.9 mm^2). The actual level of speed reduction will depend on the rotary pump used, while the exact banding diameter also depends on other cannula/connection properties. The level of pulmonary resistance and remaining RV contractility are also thought to influence the actual value and their influence will be investigated in the future.

In terms of sensitivity to changes, it was found that banding diameters below 5.3 mm were not so critical on the balance of flow and pressure, especially with a RV that has some remaining contractile function. Banding diameters above Ø5.3 mm, however, caused a sharp rise in PAP and LAP, which could lead to congestion if left unchecked. This diameter also corresponded to the point at which RVAD pump flow exceeded LVAD pump flow. These trends were also observed above and below a rotational speed of 3200 rpm; however, sensitivity to rpm changes was not as significant.

The sensitivity of hemodynamics to patient-specific circulatory parameters and small changes in pump speed/banding diameter values highlights the importance of maintaining control over these values to accommodate for intrapatient and interpatient variation, especially in the postoperative period. It is therefore suggested to make use of a variable banding system in combination with smaller variations in right pump rotational speed to create a suitable hemodynamic condition for each patient. This approach may provide greater control over patient hemodynamic state, as well as reduce the risk of thrombosis formation in the right pump.

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