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Development of a Double Lumen Cannula for a Percutaneous RVAD

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Abstract

The objectives were to design/fabricate a double lumen cannula (DLC) for a percutaneous RVAD (pRVAD), and to test the feasibility/performance of this pRVAD system. A 27 Fr DLC prototype was made and tested in 6 adult sheep. The pRVAD DLC was inserted into the right jugular vein, advanced through the superior vena cava (SVC)-right atrium (RA)-right ventricle (RV), and ended in the pulmonary artery (PA). A CentriMag pump and optional gas exchanger were connected to the DLC. Blood was withdrawn from RA, pumped through gas exchanger, and perfused PA. Maximal pumping flow was maintained for 2 hours. The pRVAD DLC was successfully deployed in all 6 sheep. In first 3 sheep, maximal average pumping flow was below 3 l/min because the DLC was advanced too far with drainage opening against RA side wall. In last 3 sheep with well positioned DLC, average maximal flow was above 3.5 l/min. The gas exchanger provided up to 230 ml/min CO₂ removal and 174 ml/min O₂ transfer. Our DLC-based pRVAD system is feasible for percutaneous right heart and respiratory assistance through a single cannulation. The pRVAD DLC can easily be placed prophylactically during LVAD implantation and removed as needed without additional open chest procedures.

Keywords

right ventricular assist device; double lumen cannula; percutaneous; sheep

Introduction

Left ventricular assist devices (LVADs) are increasingly used to treat advanced heart failure as a bridge to recovery, transplant, or destination therapy, improving patient outcomes and quality of life¹⁻⁸. Right heart failure (RHF) affects up to 40% of LVAD patients and is associated with a higher early mortality rate, greater ICU length of stay, higher rates of re-operation for bleeding and renal failure, and a lower bridge-to-transplantation rate⁹⁻¹².

About 10% of these LVAD patients need a RVAD, which is difficult to predict before/during LVAD surgery. When a RVAD requirement is identified¹²⁻¹⁵, a second open chest procedure

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is needed for RVAD installation. In most cases, RHF can recover in about two weeks, and a third open chest procedure is required to remove the RVAD. These two additional major surgical procedures add extra risk to LVAD patients. Moreover, RVAD installation after LVAD surgery has worse outcomes than planned RVAD installation during LVAD surgery¹⁶.

We are developing a convenient and minimally invasive RVAD system based on a percutaneous double lumen cannula (DLC). This DLC-based percutaneous RVAD (pRVAD) system can be easily placed prophylactically during LVAD implantation and easily removed after RHF resolution without additional open chest surgeries. Our pRVAD system could also be used to treat RHF after heart transplant, myocardial infarction, or cardiomyopathy.¹⁷

The objectives of this study were to design, fabricate, and test the first DLC prototype for its *in vivo* feasibility/performance as a DLC-based pRVAD system. An optional gas exchanger was also included for concomitant lung function compromise.

Methods and Materials

pRVAD DLC Design and Prototype Fabrication

The pRVAD system consists of a specially designed DLC, a centrifugal pump and an optional gas exchanger. The critical component of this pRVAD system is the specially designed DLC. This pRVAD DLC is designed to be inserted from the right jugular vein (RJV) into the superior vena cava (SVC)-right atrium (RA)-right ventricle (RV)-pulmonary artery (PA). Coupled with a pump, the blood is withdrawn from the RA and delivered to the PA, bypassing the RV for right heart assistance (Fig 1).

The pRVAD DLC consists of a main DLC body and a pre-curved extension infusion cannula (EIC) with stainless steel wire wound reinforced polyurethane construction (Fig 2A). The cross sectional area ratio was 2 (drainage):1 (infusion) in this prototype. The reinforcement coil was made from flat stainless steel wire (0.25 mm thick), which was wound on a smooth mandrel through a wire winding machine. Polyurethane was coated on the stainless steel coil through a proprietary dip molding process, resulting in a flexible yet kink resistant one-piece (0.7 mm thick) wire. The infusion lumen was an ultrathin polyurethane non-distensible membrane sleeve (0.3 mm thick). The infusion lumen was molded onto the inner sidewall of the DLC outer lumen to form an eccentric configuration, with one end connected to the reinforced EIC and the other end to the infusion connection tubing. Thermoforming was used to curve the EIC to fit the sharp angle of the RV inflow and outflow tract. A rigid introducer was placed in the infusion lumen to straighten the curved EIC to facilitate percutaneous cannulation (Fig 2).

When the pRVAD DLC is placed correctly, the end openings of the drainage lumen are located in the RA for blood drainage, and the curved EIC ends in the PA for blood delivery. The first DLC prototype was 27 Fr with 0.7 mm outer wall thickness. The infusion lumen was an eccentric thin membrane sleeve (0.3 mm thickness), maximizing cross-sectional area of each DLC lumen for low blood resistance (Fig 1). The cylindrical shape of the membrane sleeve infusion lumen is very stable.¹⁸⁻²⁰ In a traditional DLC, the straight septum is designed to divide a cylinder cannula into two semi-cylinders as infusion and drainage

lumens. When blood flow pumps through a traditional DLC, the pressure difference between the infusion and drainage lumens makes the septum curve toward the negative pressure side (drainage lumen), making the infusion lumen bigger and the drainage lumen smaller. In our DLC design, this pressure difference would not affect infusion membrane sleeve geometry, and the cross-sectional area of both lumens will be the same at any pressure difference.

The pRVAD DLC Prototype Bench Testing

The pRVAD DLC was bench tested for performance (flow-pressure). The bench test circuit included a CentriMag blood pump (Thoratec Corporation, Pleasanton, CA) connected to the pRVAD DLC by 20 cm of Tygon tubing (3/8 in). The DLC was hooked to a reservoir. This circuit and reservoir were primed with 37% glycerin to mimic human blood viscosity. Two pressure sensors (Transpac®, ICU medical, San Clemente, CA) were placed in inlet and outlet connectors of the pRVAD DLC for drainage and infusion pressures. The flow sensor (9XL, Transonic Inc, Ithaca, NY) was placed on the circuit tubing for pump flow measurement. The data acquisition system (cDAQ9172, National Instruments, Austin, TX) with a pressure module (NI 9237), a flow module (NI 9215), and a flow meter (HT110, Transonic Inc, Ithaca, NY) was used to monitor/record pressure and circuit flow. The pump was adjusted to target flow at 1, 2, 3, 4, and 4.5 l/min, with the corresponding drainage and infusion pressures recorded.

The pRVAD DLC Prototype Animal Testing

All animal studies were approved by the University of Kentucky Institutional Animal Care and Use Committee (IACUC) and were conducted in accordance with the Principles of Laboratory Animal Care (National Society of Medical Research) and the “Guide for the Care and Use of Laboratory Animals (National Institutes of Health publication no. 85-23, revised 1996)”. The pRVAD system included the DLC, the CentriMag blood pump, and an optional gas exchanger (Affinity™, Medtronic, Minneapolis, MN). The blood pump and gas exchanger were connected and primed with Ringer’s solution.

Animal Anesthesia, Instrumentation and Surgical Procedure—Six crossbred adult sheep (40-60 kg) were used to test the pRVAD system. After anesthesia induction with ketamine and diazepam, all sheep were intubated and connected to the anesthesia machine (Narkomed 2B, DRAGER, Telford, PA). Anesthesia was maintained with 1-3% isoflurane, titrating a normal range of heart rate (HR) and arterial blood pressure (ABP). Arterial/venous catheters (BD Medical Inc, Sandy, UT) were placed into right femoral artery/vein for pressure monitoring and fluid administration. A right lateral thoracotomy was performed through the 5th intercostal space. The pericardium was opened to expose the SVC and the RA. A rigid introducer was placed inside the DLC infusion lumen, straightening the curved EIC. A bolus of heparin (200 U/kg) was administered intravenously for systemic heparinization, maintaining an ACT of 300-400 sec. A 2 cm cut down was made on the right neck to expose the RJV for cannulation. A veinotomy was made on the RJV. The DLC along with the rigid introducer was inserted through the veinotomy into the RJV-SVC. As the DLC tip reached the RA (identified by finger palpation), the introducer was held and no longer moved forward while the DLC was continuously advanced. Losing the support of the rigid introducer, the EIC tip curved to cross the tricuspid valve to the RV. The EIC was

progressively moved over the introducer tip, increasing curvature. This curved EIC crossed the RV outflow tract and the pulmonary valve to end in the PA. The DLC drainage lumen openings at the end of the main DLC body were located in the RA, and the end of the EIC was located in the PA. After introducer removal, the DLC was connected to a primed CentriMag pump – Affinity oxygenator circuit. Venous blood was withdrawn from the RA, went through the oxygenator for gas exchange, and was pumped into the PA, bypassing the RV for right heart and pulmonary assistance. The RA is a low pressure flexible chamber. Excessive pumping speed will cause negative RA pressure and RA collapse. The collapsed RA wall will obstruct the drainage opening and dramatically decrease RVAD flow. Therefore, maximal pumping blood flow was obtained by adjusting the pump speed until central venous pressure (CVP) was > 1 mm Hg to prevent RA collapse. This maximal pumping flow was maintained for 2 hours. The sweep gas (100% oxygen at 5 l/min) was connected to the gas exchanger.

Monitoring and Data Collection—Arterial blood pressure and CVP were continuously monitored by a IntelliVue MP 50 patient monitor (Philips Healthcare, Andover, MA). The maximal pump flow was recorded every 45 minutes. Outlet sweep gas was monitored for CO₂ concentration by a Philips Capnography Extension. The pre and post gas exchanger blood was sampled for blood gas analysis. The CO₂ removal was calculated by multiplying the sweep gas flow rate and the outlet CO₂ concentration. The O₂ transfer was calculated according to the following formula²¹:

$$O_2 \text{ transfer} = 1.34 \times \text{hemoglobin} \times 10 \times \Delta O_2 \text{ sat} \times Qb + 0.003 \times \Delta PO_2 \times Q.$$

Where O₂ sat and PO₂ were the change in blood O₂ saturation and in oxygen pressure across the gas exchange device, respectively.

Results

The pRVAD DLC prototype was successfully made. The main DLC body was 27 Fr, and the EIC was 21 Fr. In our bench testing with 37% glycerin solution, 4 l/min pumped through the DLC against a 217 mm Hg pressure in the infusion lumen and a –105 mm Hg pressure in the drainage lumen (Fig 3). When the pump was turned up to 5.0 l/min flow, the DLC remained intact without deforming.

In the animal testing, the pRVAD DLC was inserted into the RJV and deployed into the RA with the help of manual guide over the RA and RV in all 6 adult sheep. Maximal pumping flow was maintained for 2 hrs. In the first 3 sheep, the maximal average RVAD pumping flow was 1.8-2.6 l/min because the DLC was advanced too far with the drainage opening sucked against the RA side wall. In the last 3 sheep with a well-positioned DLC, the average flow was 3.8-4.4 l/min (Table 1). Tachycardia arrhythmia was found in two sheep.

All venous blood was completely arterialized through the gas exchanger with the post gas exchanger O₂ saturation at 100%, and PCO₂ = 40 mmHg. The O₂ transfers were 68, 76 and 85 mL/min in the first three sheep, and 127, 174, and 206 ml/min in the 4th, 5th and 6th sheep. The CO₂ removal was up to 246 ml/min (Table 1).

At autopsy, all 6 pRVAD DLCs fit the contour of the RA-RV-PA, with the drainage lumen openings in the RA and the EIC end in the main PA (Fig 4). No damage was observed in the RA, RV, PA, tricuspid valve, and pulmonary valve. No thrombosis was found in the RA, RV, PA, and inside/outside the DLC. The DLC was easily removed from the sheep.

Discussion

Our preliminary *in vivo* study shows the feasible percutaneous insertion/placement, good performance, and easy removal of our pRVAD DLC prototype. This DLC-based pRVAD system can pump over 4 l/min blood flow for RV and lung support in 50 kg healthy sheep. This technology could be prophylactically placed during LVAD surgery to support post LVAD right heart failure, eliminating two additional open chest surgeries for RVAD installation and removal.

A RVAD is needed in 10% of LVAD patients for right heart failure complication. This RVAD requirement is usually identified after LVAD surgery.¹²⁻¹⁵ Although several compact pumps have been specifically developed for RVAD application,^{10,22-24} they all require open chest surgeries to connect and remove from the pulmonary circulation. A pRVAD system would be advantageous over a traditional RVAD system to avoid two open chest surgeries and associated trauma.

Percutaneous LV support (IABP and Impella Pump) has already been developed for temporary LV assist through percutaneous femoral artery insertion. Compared to femoral artery-aorta blood path for pLVAD, the RVAD is much more amenable for percutaneous access since the RJV-SVC-RV is a very low pressure blood path with very limited potential bleeding complication. The large RJV in the adult can accommodate up to a 31 Fr cannula for a pRVAD system, allowing sufficient blood flow for RV support.

The existing pRVAD with two separate cannulations is an off label application of the TandemHeart percutaneous LVAD (CardiacAssist, Inc, Pittsburgh, PA). The TandemHeart transseptal cannula, originally designed as a LVAD left atrium drainage cannula, is used as a PA infusion cannula in RVAD application. An additional cannula is required for drainage from the vena cava. Extracorporeal centrifugal pumps such as the Tandem Heart Pump and the CentriMag (Thoratec Corporation, Pleasanton, CA) are used to withdraw the blood from the vena cava and to infuse blood into the PA. This technology has been applied in 101 patients with refractory RHF, proving the feasibility of a pRVAD.²⁵ The CentriMag was also used in this percutaneous configuration in 8 patients for short-term RV support as a bridge to recovery and BiVAD.^{17,26} However, this technology requires two separate cannulations, long connection tubing, and complicated circuit, preventing patient mobility.

The Impella RP (Abiomed, Danvers, MA) is a catheter-based microaxial pump designed for up to 4.8 L/min pumping flow and up to 2 weeks of support. Successful application of the Impella RP in four RHF patients has been reported.^{27,28,29} The results of the recently finished Canadian/European clinical trial was presented at the 2012 American College of Cardiology meeting,³⁰ but the data has not been formally published yet. A U.S. clinical trial

is currently ongoing to test the Impella RP device.²⁸ However, this device is placed through the femoral vein, which greatly limits patient mobility.

Our pRVAD DLC specifically addresses the problems of long circuit, high circuit blood resistance, and lack of patient mobility. This DLC, through a single RJV cannulation, leads to a pRVAD system with very short circuit, less resistance, and good potential for patient ambulation. Our previous patented ECMO DLC (Avalon Elite™, Rancho Dominguez, CA) has successfully proved this concept.²¹ The AvalonElite DLC-ECMO circuit is much shorter with much lower resistance than the ECMO circuit with two single lumen cannulas. The AvalonElite DLC spares the femoral vein, enabling patient ambulation.

In DLC design, too much negative pressure in the drainage lumen is believed to be unsafe and should be avoided. Usually, 1/3 of the pressure gradient is distributed to the drainage lumen and 2/3 to the infusion lumen. In order to achieve this pressure gradient distribution, the lumen cross sectional area ratio is set at 2 (drainage):1 (infusion). Therefore, the cross sectional area ratio was 2 (drainage):1 (infusion) in this prototype, which originated from AvalonElite. However, in this pRVAD DLC, the length of the drainage lumen is much shorter than the infusion lumen and the 2:1 ratio is not suitable. Therefore, a computational fluid dynamics (CFD) investigation is needed to optimize the geometry of the cannula to target a 2 (drainage):1 (infusion) pressure gradient.

The challenge of developing a percutaneous DLC for a RVAD system is the positioning of the infusion cannula into the PA through the sharp angle between the RV inflow and outflow tracts. We designed the pRVAD DLC with a curved EIC to fit this sharp angle. The rigid introducer inside the DLC infusion lumen straightens the curved EIC for easy percutaneous insertion from the RJV. When the introducer tip enters the RA, the DLC is continuously advanced while the introducer is held still. The EIC then loses the support of the rigid introducer, curving into the RV and PA. This study demonstrated the feasibility of percutaneous DLC placement in adult sheep. The RVAD performance was compromised in the first three sheep because deep cannula placement caused drainage opening suction against RA wall. While this problem was resolved by less advancement of the pRVAD DLC into the RA, we will redesign the pRVAD DLC to completely resolve this position-induced drainage obstruction. We will also embed a catheter inside the introducer to aide pRVAD DLC placement.

Lung function compromise may coexist with right heart failure, due to cardiogenic lung edema, inflammatory reaction to cardiopulmonary bypass, or lung infection. Our DLC-based pRVAD system has the flexibility to connect an optional gas exchanger to provide total respiratory support for concurrent compromised lung function.

Limitations

Although our current pRVAD DLC placement through open chest surgery is justified by the proposed cannula placement during open chest LVAD implantation surgery, we did not test percutaneous DLC placement due to the lack of image guidance equipment. Another limitation of the current study is that cardiac output was not measured. In our pRVAD system, the blood was withdrawn from the RA outside the body and delivered back to the

PA. This extracorporeal circuit results in blood heat loss. Therefore, the thermodilution method through a Swan-Ganz catheter is no longer suitable for cardiac output measurement. However, we plan to place an ultrasound flow sensor in aortic root to measure cardiac output in future animal studies. In the current feasibility study, the pRVAD was evaluated for only 2 hours. Long-term studies are needed to fully evaluate the performance of the cannula. Also, the potential for valve damage could not be evaluated in this short *in vivo* study. A long-term animal study is required to assess whether there is any potential for valve damage. Thrombosis in the RJV after use of the Avalon Elite has been reported³¹. Although this thrombosis may be removed by a minor surgery during DLC withdrawal³¹, this potential drawback may dampen enthusiasm for the pRVAD DLC since the RJV is a frequent site for endomyocardial biopsies following heart transplant.

Conclusion

Our DLC-based pRVAD system is feasible for percutaneous right heart assistance through a single site RJV cannulation. This pRVAD DLC can be easily placed prophylactically during LVAD implantation and removed as needed, eliminating two open chest procedures.

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Figure 1.

The pRVAD DLC-Based Right Heart Assist System. The double lumen cannula (DLC) is inserted from the right jugular vein, through the superior vena cava (SVC)-right atrium (RA)-right ventricle (RV), ending in the pulmonary artery (PA). The blood pump withdraws venous blood through the drainage opening in the RA and perfuses the pulmonary circulation through the infusion opening in the PA. An optional gas exchanger provides lung assistance. The inset is a cross-section of the DLC, showing good separation of the drainage and infusion lumens.

Figure 2.

The pRVAD DLC Prototype. **A:** The pRVAD DLC with pre-curved extension infusion cannula (EIC) and rigid introducer. **B:** Rigid introducer placed inside infusion lumen straightens EIC for easy insertion. **C:** When DLC tip reaches RA, the introducer is held to advance only the DLC. The EIC tip curves to facilitate entry into the tricuspid valve and the RV inlet track. **D:** As the DLC is further advanced, the EIC curves more into the RV outlet track and the PA.

Figure 3.
The pRVAD DLC Performance in Bench Test Study. The flow-pressure chart shows that the infusion lumen pressure was 217 mm Hg and the drainage lumen pressure was -105 mm Hg at 4 l/min flow.

Figure 4. Necropsy Confirmed Correct Positioning of pRVAD DLC. The pRVAD DLC (n=6) fit well in the RA-RV-PA tract. The drainage lumen openings were in the RA and the EIC was in the main PA.

Table 1

In Vivo Performance of pRVAD System.

	Sheep 1	Sheep 2	Sheep 3	Sheep 4	Sheep 5	Sheep 6
Pump Flow (L/min)	1.9±0.1	1.8 ± 0.1	2.6 ± 0.1	4.2 ± 0.1	4.4 ± 0.1	3.8 ± 0.07
Pre PO₂ (mm Hg)	46±1.2	37±14.8	47±6.9	58±7.7	51±3.6	38±12.2
Pre Sat O₂ (%)	64 ± 0.1	57 ± 0.1	65±0.1	78± 0.1	69 ± 0.1	67 ± 0.2
Post PO₂ (mm Hg)	445±60	461±47	432±0.4	443±63	386±25	449±48
Post Sat O₂ (%)	100±0	100 ± 0	100 ± 0	100 ± 0	100 ± 0	100±0
O₂ Transfer (ml/min)	68 ± 1.5	76 ± 9.6	85 ± 20.0	127 ± 39.3	174 ± 12.5	206 ± 132.5
Pre CO₂ (mm Hg)	40.5±1.4	42 ± 1.4	45± 5.6	50 ± 3.6	52± 7.6	51.45 ± 8.8
Post CO₂ (mm Hg)	25±1.7	29 ± 7.9	35 ± 10.1	39.5 ± 1.1	39 ± 7.5	48.1 ± 6.2
CO₂ Removal (ml/min)	141 ± 3.7	145 ± 7.5	153 ± 41.5	175 ± 12.5	235 ± 39.2	246 ± 22.2

The flows were under 3 l/min in the first 3 sheep, due to inlet opening obstruction. In last three sheep, the flows were above 3.5 l/min. N= 6 sheep.