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Original Research Article

Percutaneous double lumen cannula for right ventricle assist device system: A computational fluid dynamics study

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ABSTRACT

Objectives: Our goal is to develop a double lumen cannula (DLC) for a percutaneous right ventricular assist device (pRVAD) in order to eliminate two open chest surgeries for RVAD installation and removal. The objective of this study was to evaluate the performance, flow pattern, blood hemolysis, and thrombosis potential of the pRVAD DLC.

Methods: Computational fluid dynamics (CFD), using the finite volume method, was performed on the pRVAD DLC. For Reynolds numbers <4000, the laminar model was used to describe the blood flow behavior, while shear-stress transport k–ω model was used for Reynolds numbers >4000. Bench testing with a 27 Fr prototype was performed to validate the CFD calculations.

Results: There was <1.3% difference between the CFD and experimental pressure drop results. The Lagrangian approach revealed a low index of hemolysis (0.012% in drainage lumen and 0.0073% in infusion lumen) at 5 l/min flow rate. Blood stagnancy and recirculation regions were found in the CFD analysis, indicating a potential risk for thrombosis.

Conclusions: The pRVAD DLC can handle up to 5 l/min flow with limited potential hemolysis. Further modification of the pRVAD DLC is needed to address blood stagnancy and recirculation.

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1. Introduction

Left ventricular assist devices (LVADs) are increasingly used to treat advanced heart failure with improved outcomes. About 40% of these patients develop right heart failure [1–3], which is difficult to predict before LVAD placement and typically manifests after LVAD installation [2,4,5]. One third of these right heart failure patients need a right ventricular assist device (RVAD), requiring a second open chest procedure for its installation [2]. Usually, the need for right ventricle (RV) support is temporary, and a third open chest procedure is required to remove the RVAD. These two procedures for RVAD installation and removal add additional risks, significantly contributing to LVAD morbidity and mortality.

A percutaneous RVAD (pRVAD) system eliminates two open chest procedures for RVAD installation and removal, decreasing the overall morbidity/mortality of post-LVAD right heart failure. Current pRVAD application is based on the off-label use of two TandemHeart™ cannulas for right atrium (RA) drainage and pulmonary artery (PA) infusion [6,7]. However, this percutaneous technique is rarely used for RVAD application. The two separate venous cannulations require a long circuit to connect the blood pump, resulting in a large artificial surface-blood contact area and high blood resistance, which compromises RVAD performance. Furthermore, the femoral cannulation prevents ambulation. The A-Med was another two cannula RVAD system with the infusion cannula inside the drainage cannula. This system was designed for short-term (hours) support in off-pump coronary artery bypass surgery and was contraindicated for ambulation [8,9]. The Impella RP is a single cannula system that has been used for RVAD application in Canada. However, the integration of the pump prevents guide wire usage. Therefore, the Impella RP can only be inserted from the femoral vein, which limits patient mobility [10,11].

We are developing a double lumen cannula (DLC) for a pRVAD system that can be easily placed in the right jugular vein (RJV) during LVAD implantation and easily removed without surgery when right heart failure resolves. Compared to femoral vein access, right jugular vein cannulation has a much shorter route to the PA, can accommodate a much larger cannula for higher performance, and allows moderate ambulation.

This paper presents the numerical analysis of a pRVAD DLC model using computational fluid dynamics (CFD). The CFD results were used to predict the DLC performance and the potential for blood hemolysis/thrombosis. The CFD pressure drop results were validated by bench data from a 27 Fr pRVAD DLC prototype with <1.3% error.

2. Materials and methods

2.1. *pRVAD DLC design*

The pRVAD DLC is designed for one site cannulation from the RJV. The infusion tip is advanced through the superior vena cava to the PA via the RA and RV, with the drainage opening positioned in the RA. This DLC is coupled with a blood pump to establish a pRVAD system (Fig. 1A). This system withdraws blood from the RA and delivers it to the PA, bypassing the RV for right heart support.

The pRVAD DLC consists of a main body and an extension infusion cannula (EIC) (Fig. 1B). This DLC is made of thin-walled polyurethane with stainless steel flat wire reinforcement which allows for greater flow rates and kink resistance. The infusion lumen within the main body is an eccentric membrane sleeve, maximizing the cross-sectional area of each DLC lumen. Under a pressure difference between the drainage and infusion lumens, the cylinder shape of the membrane sleeve is very stable and does not collapse [12,13]. The infusion membrane sleeve extends out of the DLC main body to become an EIC. The EIC is curved to fit the sharp angle between the RA-RV and the RV-PA. A rigid introducer is placed inside the infusion lumen and EIC, which straightens the curved EIC for easy DLC insertion from the RJV (Fig. 1C). When the EIC tip reaches the RV, the introducer is held stationary and only the DLC is advanced until the infusion tip enters the PA, while the drainage lumen resides in the RA.

2.2. *Numerical analysis*

Using a commercial CFD software package (Fluent v14.5, ANSYS Inc.), the numerical analysis was carried out separately for the two different fluid domains (drainage and infusion DLC lumens) for blood flow rates of 1–5 l/min. To analyze blood flow in laminar regions (Reynolds number, $R_e < 2000$), the laminar model was used. Flow rates with the $R_e > 4000$ were modeled using the shear-stress transport (SST) k–ω model [14]. The Menter SST k–ω model is a hybrid model which solves the fully turbulent regions far from the wall using the k–ε model and the blood regions near the wall, transforming the k–ε to the k–ω model [15]. Fraser et al. [15,16] highlighted the dubious accuracy of the turbulent models to describe transitional flow, since the turbulent models can describe the behavior of the fluid only if a turbulent boundary layer exists next to the wall and a fully turbulent flow is developed far from the wall. Therefore, the transitional flows ($2000 < R_e < 4000$) were modeled using the laminar model. The drainage lumen model was solved using the semi-implicit method for pressure-linked equations (SIMPLE). The SIMPLE method is used to iteratively solve steady state problems. First, an approximation of the velocity field is obtained by solving the momentum equation. The pressure gradient is calculated from the pressure distribution of a previous iteration or from an initial guess. Then, the equation for the pressure correction (Poisson equation) is solved to calculate the new pressure distribution, and the velocity is corrected [14]. The infusion lumen model was solved using the coupled pressure-velocity solver. The second-order upwind scheme was set for all simulations.

Computational domain: The three-dimensional geometry of both domains was constructed using commercial computer aided design software (Rhinoceros 2.0, Fig. 1D). The main DLC OD (section R) is 27 Fr (9 mm), and the EIC OD is 20 Fr (6.7 mm). The length of the DLC main body is 188 mm, and the length of the EIC is 151.8 mm. The infusion lumen diameter of main DLC body (section E) is 4 mm, and the EIC lumen diameter (section C) is 5.8 mm. For the drainage lumen, the inlet hydraulic