A paired membrane umbrella double-lumen cannula ensures consistent cavopulmonary assistance in a Fontan sheep model

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Objectives: The Avalon Elite (Macquet, Rastatt, Germany) double-lumen cannula can provide effective cavopulmonary assistance in a Fontan (total cavopulmonary connection) sheep model, but it requires strict alignment. The objective was to fabricate and test a newly designed paired umbrella double-lumen cannula without alignment requirement.

Methods: The paired membrane umbrellas were designed on the double-lumen cannula to bracket infusion blood flow toward the pulmonary artery. Two umbrellas were attached, one 4 cm above and one 4 cm below the infusion opening. Umbrellas were temporarily wrapped and glued to the double-lumen cannula body to facilitate insertion. A total cavopulmonary connection mock loop was used to test cavopulmonary assistance performance and reliability with double-lumen cannula rotation and displacement. The paired umbrella double-lumen cannula also was tested in a total cavopulmonary connection adult sheep model (n = 6).

Results: The bench test showed up to 4.5 L/min pumping flow and approximately 90% pumping flow efficiency at 360° rotation and 8-cm displacement of double-lumen cannula. The total cavopulmonary connection model with compromised hemodynamics was successfully created in all 6 sheep. The cavopulmonary assistance double-lumen cannula with paired umbrellas was smoothly inserted into the superior vena cava and extracardiac conduit in all sheep. At 3.5 to 4.0 L/min pump flow, the systolic arterial blood pressure and central venous pressure returned to normal baseline and remained stable throughout the 90-minute experiment, demonstrating effective cavopulmonary assistance support. Double-lumen cannula rotation and displacement did not affect performance. Autopsy revealed well-opened and positioned paired umbrellas, and double-lumen cannulas were easily removed from the right jugular vein.

Conclusions: Our double-lumen cannula with paired umbrellas is easy to insert and remove. The paired umbrellas eliminated the strict alignment requirement and ensured consistent cavopulmonary assistance performance. (J Thorac Cardiovasc Surg 2014;148:1041-7)

The Fontan or total cavopulmonary connection (TCPC) procedure has been used to palliate the univentricular heart for more than 40 years.[1] After decades of modification and improvement, TCPC provides excellent short-term outcome with less than 2% early mortality.[2,3] However, long-term outcome is poor with as high as 30% mortality at 25 years after the procedure.[4,5] Fontan patients exhibit hypercoagulability due to venous stasis along with an imbalance in procoagulant and anticoagulant factors, resulting in chronic pulmonary embolism.[6,7] The combination of pulmonary embolism and systemic to pulmonary collateral formation[8] increases pulmonary vascular resistance and elevates central venous pressure (CVP) to an undesired level. This causes low cardiac output, peripheral tissue fluid accumulation (edema), protein-losing enteropathies, pleural effusions, ascites, and systemic congestion, compromising systemic/pulmonary organ function. A cavopulmonary assistance (CPA) device is needed to actively move blood from the superior vena cava (SVC)/inferior vena cava (IVC) through the TCPC connection to the pulmonary artery (PA), decreasing CVP, increasing cardiac output, and reversing pathophysiology of the failing Fontan circulation.

Our patented Avalon Elite (Macquet, Rastatt, Germany) double-lumen cannula (DLC) can fit in the Fontan anastomosis in a special TCPC sheep model[9] through percutaneous right jugular vein (RJV) cannulation, providing effective CPA. However, this CPA system is not clinically practical because of the (1) requirement of strict DLC outlet alignment to single pulmonary anastomosis to prevent significant recirculation and (2) perfusion of only 1 lung.[10]

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Abbreviations and Acronyms

CPA	= cavopulmonary assistance
CVP	= central venous pressure
DLC	= double-lumen cannula
ECC	= extracardiac conduit
IVC	= inferior vena cava
LPA	= left pulmonary artery
PA	= pulmonary artery
RA	= right atrium
RJV	= right jugular vein
RPA	= right pulmonary artery
sABP	= systolic arterial blood pressure
SVC	= superior vena cava
TCPC	= total cavopulmonary connection
VAD	= ventricular assist device

We modified the Avalon Elite DLC by adding a pair of membrane umbrellas on both sides of the infusion outlet of DLC. These paired umbrellas generate a higher pressure zone and prevent recirculation, eliminating the requirement of strict DLC alignment and perfusing both lungs. We tested the feasibility and CPA performance of this CPA DLC in both a mock loop simulation and a TCPC sheep model.

METHODS

Paired Membrane Umbrella Cavopulmonary Assist Double-Lumen Cannula Design

The paired membrane umbrella CPA DLC is based on our patented Avalon Elite DLC, which is inserted from the RJV into the SVC-Fontan anastomoses-IVC. One drainage lumen has 2 openings for blood drainage from both the SVC and the IVC. The infusion lumen outlet is located between the 2 drainage openings for blood delivery to pulmonary arteries. Each membrane umbrella is positioned between the infusion opening and the drainage opening, with one umbrella above and one umbrella below the infusion opening (Figure 1, *A*).

The paired membrane umbrellas are directional. They block backward blood flow from the infusion opening to the drainage openings, eliminating recirculation. The paired membrane umbrellas are safe in terms of CPA system failure events. When the CPA system malfunctions, the paired membrane umbrellas close to allow blood flow from the SVC/IVC to the PA as unassisted TCPC (Figure 1, *B*).

ET/BS

How the Paired Membrane Umbrella Cavopulmonary Assist Double-Lumen Cannula Works

The paired membrane umbrellas were wrapped and temporarily glued to the DLC with saturated dextrose, facilitating percutaneous insertion (Figure 2). The dextrose is easily dissolved in blood after the CPA DLC is positioned inside the SVC/IVC. When the pump initiates, the venous blood in SVC/IVC is withdrawn, generating lower pressure beyond the paired membrane umbrellas, and blood from the pump is delivered into the area between the paired membrane umbrellas, generating higher pressure and perfusing both the left pulmonary artery (LPA) and the right pulmonary artery (RPA). This pressure gradient across the paired umbrellas expends/deploys the membrane umbrellas, preventing blood recirculation from the PA (within the membrane umbrella) to the DLC drainage opening in the SVC/IVC (beyond the paired membrane umbrellas). Therefore, there is a higher pressure zone between the paired membrane umbrellas to perfuse the PA. As long as the Fontan anastomoses are within this zone, the CPA system will work well. DLC rotation/disorientation does not affect CPA performance. This design eliminates the strict alignment requirement, allowing limited patient ambulation.

Fabrication

The membrane umbrellas were made by dip molding polyurethane with a thickness of 0.15 mm. The outer diameter of the umbrella edge was 2.0 cm. The paired membrane umbrella was attached to a 27F commercial Avalon Elite DLC (Figure 2, *A* and *B*). The 4-0 Ethicon sutures were used to secure umbrellas, preventing umbrella reversal under pressure. The distance between the umbrellas was 8 cm.

Bench Test

The bench test was performed in a Fontan simulation loop. A polycarbonate tube (internal diameter 20 mm) was used to mimic the SVC and IVC; both were connected to a venous reservoir. Two polyvinyl chloride tubes (internal diameter of 9.5 mm) were perpendicularly attached to polycarbonate tubing to mimic the LPA and RPA in TCPC and connected to a pulmonary reservoir. The bench circuit was filled with 37% glycerin to mimic blood viscosity. The CPA DLC with the paired umbrella was placed from the SVC into the IVC and connected to a CentriMag pump (Thoratec Corp, Pleasanton, Calif). When the pump started, fluid was withdrawn from both the SVC and IVC outside the umbrellas and perfused between the umbrellas, generating a pressure gradient across membrane umbrellas. This pressure gradient deployed (opened) the membrane umbrellas. During the bench testing, the pumping flow was set from 1.0 to 4.5 L/min. The fluid levels of the venous reservoir were adjusted to 13.6 cm above the DLC to mimic 10 mm Hg CVP, and the fluid levels of the pulmonary reservoir were adjusted to 34 cm above the DLC to mimic 25 mm Hg PA pressure. Therefore, fluid was pumped from the low-pressure venous reservoir to the high-pressure pulmonary reservoir through the CPA DLC. Three flow sensors were placed on the RPA, LPA, and CPA DLC infusion cannula tubing.

To test whether CPA DLC rotation and displacement affect CPA performance, flow efficiencies were measured/calculated when the cannula was rotated 180 degrees or moved up/down 4 cm. The flow efficiency was calculated as the percentage of total flow through the LPA and RPA compared with total pumping flow through the DLC infusion lumen.

In Vivo Test in Failing Fontan Circulation Sheep Model

All animal studies were approved by the University of Kentucky Institutional Animal Care and Use Committee and 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). Six adult female cross-bred sheep (35-45 kg) were used in this study.

Animal Preparation, Instrumentation, and Surgical Procedure

After induction with ketamine (5 mg/kg, intravenously) and diazepam (0.25 mg/kg, intravenously), all sheep were intubated and connected to the anesthesia machine (Narkomed 2B, DRAGER, Telford, Pa). Anesthesia was maintained with 1% to 3% isoflurane, titrating a normal range of heart rate and arterial blood pressure. Arterial/venous catheters (BD Medical Inc, Sandy, Utah) were placed into the right femoral artery/vein to monitor pressure and administer fluid.

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