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Superior flow for bridge to life with self-expanding venous cannulas

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Abstract

Background: Recently, a compact cardiopulmonary support (CPS) system designed for quick set-up for example, during emergency cannulation, has been introduced. Traditional rectilinear percutaneous cannulas are standard for remote vascular access with the original design. The present study was designed to assess the potential of performance increase by the introduction of next-generation, self-expanding venous cannulas, which can take advantage of the luminal width of the venous vasculature despite a relatively small access orifice. **Methods:** Veno-arterial bypass was established in three bovine experiments (69 ± 10 kg). The Lifebridge® (Lifebridge GmbH, Munich, Germany) system was connected to the right atrium in a trans-jugular fashion with various venous cannulas; and the oxygenated blood was returned through the carotid artery with a 17 F percutaneous cannula. Two different venous cannulas were studied, and the correlation between the centrifugal pump speed (1500—3900 RPM), flow and the required negative pressure on the venous side was established: (A) Biomedicus 19 F (Medtronic, Tolochenaz, Switzerland); (B) Smart canula 18 F/36 F (Smartcanula LLC, Lausanne, Switzerland). **Results:** At 1500 RPM, the blood flow was 0.44 ± 0.26 l min^{-1} for the 19 F rectilinear cannula versus 0.73 ± 0.34 l min^{-1} for the 18/36 F self-expanding cannula. At 2500 RPM the blood flow was 1.63 ± 0.62 l min^{-1} for the 19 F rectilinear cannula versus 2.13 ± 0.34 l min^{-1} for the 18/36 F self-expanding cannula. At 3500 RPM, the blood flow was 2.78 ± 0.47 l min^{-1} for the 19 F rectilinear cannula versus 3.64 ± 0.39 l min^{-1} for the 18/36 F self-expanding cannula ($p < 0.01$ for 18/36 F vs 19 F). At 1500 RPM, the venous line pressure was 18 ± 8 mmHg for the 19 F rectilinear cannula versus 19 ± 5 mmHg for the 18/36 F self-expanding cannula. At 2500 RPM the venous line pressure accounted for -22 ± 32 mmHg for the 19 F rectilinear cannula versus 2 ± 5 mmHg for the 18/36 F self-expanding cannula. At 3500 RPM, the venous line pressure was -112 ± 42 mmHg for the rectilinear cannula versus 28 ± 7 mmHg for the 18/36 F self-expanding cannula ($p < 0.01$ for 18 F/36 F vs 19 F). **Conclusions:** The negative pressure required to achieve adequate venous drainage with the self-expanding venous cannula accounts for approximately 31% of the pressure necessary with the 19 F rectilinear cannula. In addition, a pump flow of more than 4 l min^{-1} can be achieved with the self-expanding design and a well-accepted negative inlet pressure for minimal blood trauma of less than 50 mmHg.

Keywords: Cardiopulmonary support; ECMO; Cardiopulmonary bypass; Emergency bypass; Cannulation

1. Introduction

Cardiopulmonary support (CPS) or extracorporeal membrane oxygenation (ECMO) have the potential for both, cardiac as well as pulmonary support, for various indications [1—3] including emergency applications for cardiopulmonary resuscitation as well as temporary support for planned surgical procedures on the heart and the tracheo-bronchial tree as well as high-risk interventional procedures.

Recently, a compact CPS system designed for simplified application [4—6] has been introduced with a menu-guided set-up and priming procedure. This systematic system is particularly suited for emergency CPS where quick device readiness and safety are of prime importance. Connection of this device to the circulatory system of the patient is usually performed by remote cannulation of a peripheral artery and vein, respectively, typically a common femoral artery and vein by the means of traditional, rectilinear, percutaneous cannulas (catheters over the wire). However, there is a conflict of interest in remote access perfusion as the operator's preference goes to relatively small cannula diameters, whereas larger cannula diameters are necessary to achieve high blood flows.

The present study was designed to assess the potential performance increase by the introduction of next-generation, self-expanding venous cannulas [7—10] which can take advantage of the luminal width of the venous vasculature

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despite a relatively small access orifice. In contrast to the previous reports about the self-expanding cannula, a ready-for-use centrifugal pump is an integral part of this set-up, hence providing, by definition, augmentation of venous drainage.

2. Methods

Following approval of the veterinary office of the State of Vaud, Lausanne, Switzerland, for the experimental evaluation of new cardio-pulmonary bypass equipment, veno-arterial bypass was established in three bovine experiments (mean bodyweight 69 $\pm$ 10 kg) using the recently introduced Lifebridge® system (Lifebridge GmbH, Munich, Germany).

2.1. Pump set-up

The Lifebridge® system (Fig. 1) is basically a very compact heart–lung machine with three pre-assembled modules:

- the base station;
- the drive module; and
- the patient module.

The base station weighs 18 kg, has a small footprint and can be folded for ease of storage and transportation. A touch screen allows for menu-guided set-up and provides back-up power for 120 min on batteries.

The drive module weighs 18 kg, and can be snapped into the base station described above, where it is interfaced automatically. It holds the basic electronics for driving the pump as well as the electromechanical tubing clamp, the bubble detector, the venting pump, etc., provides 20-min power back-up for emergencies and can be refurbished for the next application.

The patient module is basically a disposable cube (Fig. 1), which holds all the liquid-carrying components of the system, including venous reservoir/bubble trap, a centrifugal pump, an integrated hollow-fibre/heat exchanger structure, an arterial filter, a bubble detector, a flow sensor, the necessary tubing as well as electromechanical clamps for the arterial line and the *A–V* shunt.

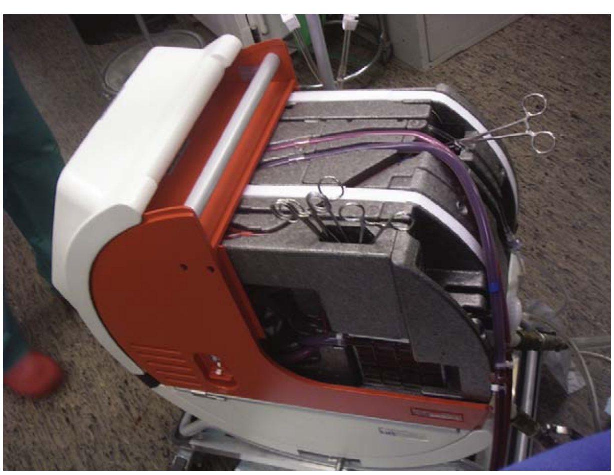

Fig. 1. The Lifebridge® system is a very compact heart–lung machine with three pre-assembled modules: the base station, the drive module, and the patient module. The latter (upper-right) holds all the liquid carrying components of the system including venous reservoir/bubble trap, a centrifugal pump, an integrated hollow-fibre/heat exchanger structure, an arterial filter, a bubble detector, a flow sensor, the necessary tubing as well as electromechanical clamps for the arterial line and the *A–V* shunt.

Once the three modules are connected, the pump set-up is realised semi-automatically in a menu-driven fashion, including systematic testing of the flow sensor, the level sensor, the pressure sensors, the bubble detectors, the RAM and flash memory modules, the electromechanical clamps, the drives of the systemic pump and the venting pump as well as all the interfaces and controls. The total priming volume including a 3/8 in. $\times$ –3/8 in. table set accounts for approximately 1400 ml.

2.2. Cardiopulmonary bypass

Following general anaesthesia with volatile anaesthetics, the animals were instrumented in standard fashion (EKG, central venous pressure, arterial pressure) and fully heparinised (Liquemin, Roche, Basel, Switzerland: 300 IU kg^{-1} bodyweight) with 480 s as the target for the activated coagulation time (ACT, International Technidyne Corporation, Edison, NJ, USA).

The Lifebridge® system was connected to the right atrium in trans-jugular fashion with venous cannulas to be assessed and the oxygenated blood was returned through the carotid artery with a 17 F percutaneous cannula.

Two different venous cannulas were studied and the correlation between the centrifugal pump speed (1500–3900 RPM), the flow achieved and the required negative pressure on the venous side was established:

(A) A 19 F rectilinear wire-wound percutaneous Biomedicus cannula (Medtronic, Tolochenaz, Switzerland)
(B) A Smart canula 18 F/36 F (Smartcanula LLC, Lausanne, Switzerland) as shown in Fig. 2 is inserted percutaneously in collapsed fashion (<18 F) and expands *in situ* (up to 36 F or the available vessel lumen, respectively).

We have previously reported the functional principles of the self-expanding venous cannulas mainly for applications with gravity drainage that is, open heart surgery and mini-invasive cardiac surgery [7–10]. Briefly, the self-expanding cannula can be stretched and collapsed with a hollow mandrel, inserted into the venous vasculature, for example, through a femoral vein, over a guide wire in open, semi-open or percutaneous fashion [11]. Once the cannula tip is located in the target zone by trans-oesophageal echocardiogram (TEE), for example, in the right atrium and the superior vena cava, the guide wire is removed first, and the mandrel second. As a result, the next-generation design cannula expands spontaneously up to its nominal diameter of 36 F or the available vessel lumen, respectively. The resulting increase in luminal width is the main reason for improved drainage and reduced pressure drop.

These venous cannulas were tested in a random fashion after insertion through a percutaneous orifice prepared with an 18 F dilator, and at least three measurements were made for each pump speed level (increments of 500 RPM from 1500 RPM up to the maximum motor speed of 3900 RPM).

Fig. 2. The self-expanding venous cannula (Smartcanula LLC, Lausanne, Switzerland) for adults is stretched and collapsed with a mandrel to 18 F and inserted over a guide wire, e.g., through the femoral vein. Once the cannula tip has reached the target region, e.g., the right atrium or the superior vena cava, the guide wire is removed first, the mandrel second and the smartcanula® expands up to 36 F or the available vessel lumen respectively.

2.3. Statistics

Continuous variables are expressed as mean $\pm$ standard deviation and displayed after linear regression analyses where applicable. Analysis of variance (ANOVA) for repeated measures is used for comparison between the groups.

3. Results

Blood flow was successfully assessed with the Lifebridge® system in all animals as a function of the pump speed (stepwise increase from 1500 RPM to 2000, 2500, 3000, 3500 and 3900 RPM) using the 19 F rectilinear wire-wound percutaneous Biomedicus cannula in a random fashion versus the 18 F/36 F self-expanding Smart canula.

Fig. 3 depicts the blood flows achieved at various pump speeds for the two cannulas tested. At 1500 RPM, the blood flow was 0.44 ± 0.26 l min^{-1} for the 19 F rectilinear cannula versus 0.73 ± 0.34 l min^{-1} for the 18/36 F self-expanding cannula. At 2500 RPM, blood flow was 1.63 ± 0.62 l min^{-1} for the 19 F rectilinear cannula versus 2.13 ± 0.34 for the 18/36 F self-expanding cannula. At 3500 RPM, the blood flow was 2.78 ± 0.47 l min^{-1} for the 19 F rectilinear cannula versus 3.64 ± 0.39 l min^{-1} for the 18/36 F self-expanding cannula ($p < 0.01$ for 18/36 F vs 19 F).

Fig. 4 shows the venous line pressure at the various pump speeds for the two cannulas tested. At 1500 RPM, the venous line pressure was 18 ± 8 mmHg for the 19 F rectilinear cannula versus 19 ± 5 mmHg for the 18/36 F self-expanding cannula. At 2500 RPM the venous line pressure accounted for -22 ± 32 mmHg for the 19 F rectilinear cannula versus 2 ± 5 mmHg for the 18/36 F self-expanding cannula. At 3500 RPM, the venous line pressure was -112 ± 42 mmHg for the rectilinear cannula versus -28 ± 7 mmHg for the 18/36 F self-expanding cannula ($p < 0.01$ for 18/36 F vs 19 F).

The venous line pressure as a function of pump flow is plotted in Fig. 5. It can be easily recognised that the venous line pressure measured for the 18/36 F self-expanding cannula stays above -50 mmHg even for blood flows as high as 4.7 l min^{-1}, whereas the maximal blood flow reached with the 19 F rectilinear cannula in the same setting, not more than 3.7 l at a negative pressure of up to -230 mmHg. The results of the linear regression analysis confirm the superior performance expressed by the venous line pressure as a function of blood flow for the self-expanding cannula over the entire test range.

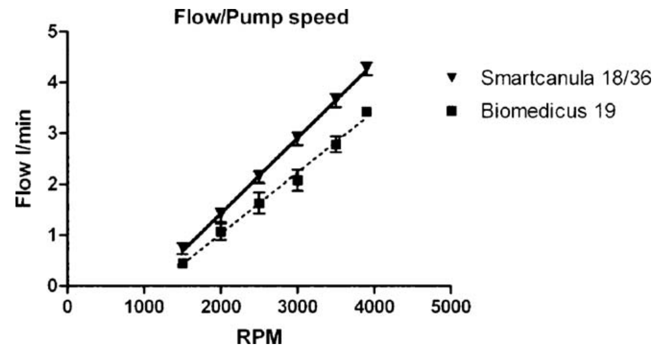

Fig. 3. Flow achieved as a function of RPM (revolutions per minute) with the 19 F rectilinear wire-wound percutaneous Biomedicus cannula versus the 18 F/36 F self-expanding Smart cannula (mean $\pm$ SD and linear regression analysis).

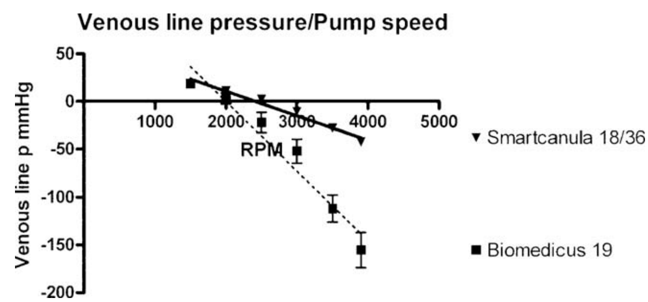

Fig. 4. Venous line pressure as a function of RPM (revolutions per minute) with the 19 F rectilinear wire-wound percutaneous Biomedicus cannula versus the 18 F/36 F self-expanding Smart cannula (mean $\pm$ SD and linear regression analysis).

4. Discussion

The Lifebridge® system achieves up to 27% higher pump flows in conjunction with the self-expanding venous Smart canula®, which can be collapsed to 18 F for insertion and

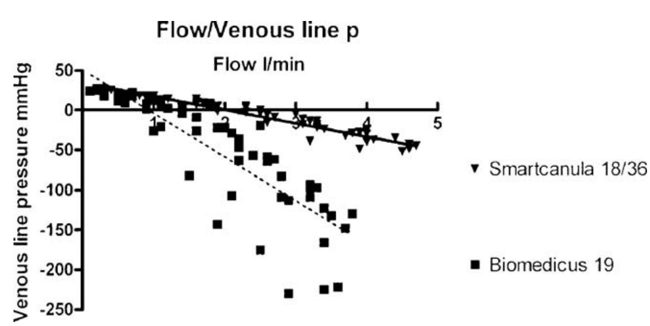

Fig. 5. Flow and inlet line pressure with the 19 F rectilinear wire-wound percutaneous Biomedicus cannula versus the 18 F/36 F self-expanding Smart cannula (scatter plot and linear regression analysis).

expanded *in situ* to 36 F or the luminal width of the access vein, respectively. Simultaneously, the venous line pressure, which is also the pump inlet pressure, can be kept for the self-expanding cannula at less than −50 mmHg for flows up to 4.7 l min whereas negative pressures well beyond 200 mmHg are observed with rectilinear cannulas for flows up to a maximum of 3.7 l min^{-1}.

Obviously, the man–machine interface, in this setting, the cannula that connects the extracorporeal circulation to the venous system of the patient, is of prime importance. As a matter of fact, the cannula performance is more of an issue with remote cannulation, the preferred access in the emergency setting [1–3], than for central cannulation. There are a number of reasons including the relatively small dimensions of the peripheral veins, typically the femoral vein, as compared to the caval veins, which bring the de-saturated blood naturally back to the heart. In addition, the veins are thin walled, not suitable for important negative pressures which induce them to collapse, a phenomenon that during perfusion can shut off venous drainage completely.

The self-expanding cannula assessed here allows for addressing both these issues. As reported previously, the self-expanding venous cannulas [7–10] can be stretched and collapsed with a hollow mandrel, inserted into the venous vasculature over a guide wire through an access orifice similar to the size of the peripheral vein or even smaller [11] and expanded to its nominal diameter of 36 F within the vena cava (typical diameter in adults is >20 mm or 60 F) or to the available luminal width of the access vessel (typical diameter of the femoral vein is 8 mm or 24 F). Already at the iliac level, the vein diameter increases, and, therefore, the narrow segment of a well-positioned self-expanding cannula is relatively short. It has to be mentioned here that a cross-sectional area of 1 cm^2 (equivalent to <34 F) is sufficient to carry up to 6 l min^{-1} with a 200-cm-long venous line relying on gravity alone [12].

The underlying physics provides further understanding regarding the improved flow achieved with the self-expanding cannulas as the resistance to flow within a rectilinear tube increases with its length in linear fashion whereas the flow increases with the diameter at the fourth power. The superiority of the self-expanding cannula design resulting in a short reduction of its diameter at the point of insertion has also been demonstrated by both computation fluid dynamics [7,13] and bench tests [14]. For the set-up presented here, the negative pressure required to achieve adequate venous drainage with the self-expanding venous cannula accounts for approximately 31% of the 19 F standard rectilinear design at negative pressures reaching 200 mmHg and more. This explains also why a pump flow well above 4 l min can be achieved with the self-expanding design despite a negative inlet pressure for minimal blood trauma of less than 50 mmHg.

The second advantage of the self-expanding venous cannula is its ability to support the venous wall. We have termed this phenomenon temporary caval stenting as it allows the cannulated vein to stay open and prevents it from collapsing [15]. In contrast to cardiopulmonary bypass for open heart surgery, where gravity drainage is sufficient for achieving the target flow in conjunction with the self-expanding cannula [10], temporary caval stenting is even more helpful, when higher negative pressures in the venous cannula can be expected similar to augmentation using centrifugal pumps or vacuum. The term 'temporary' refers here to the fact that the caval stenting is reversible as the self-expanding cannula can be re-collapsed by simple traction and therefore easily removed at the end of the extracorporeal circulation.

Additional design improvements coming with the self-expanding venous cannula evaluated here include the extremely thin cannula wall, which is practically non-existent over a major proportion of the cannula length due to its open wall design. The uncovered grid structure allows for drainage of the venous affluent from collaterals directly into the cannula lumen, an effect that further enhances the flow.

Finally, there is the option of positioning a self-expanding venous cannula in trans-atrial fashion into the pulmonary artery tree [16]. This procedure allows, at least in the experimental set-up, not only for efficient decompression of the left ventricle during veno-arterial bypass (e.g., in prolonged ventricular fibrillation), but also for recovery of large blood volumes from pulmonary vasculature, which in turn improves haemodynamics.

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