New bidirectional arterial perfusion device

Saad Abdel-Sayed1, Enrico Ferrari2, Phillipe Abdel-Sayed3, Markus Wilhelm4, Maximilian Halbe4, Ludwig Karl von Segesser5, Francesco Maisano6 and Denis Berdajs7

Introduction

In 2009, with the beginning of acute respiratory distress syndrome consecutive to influenza A (H1N1) infection1 extracorporeal membrane oxygenation (ECMO) and extracorporeal life support (ECLS) increased2-3 as stand-alone life-saving technologies.4 In this setting, veno-venous and veno-arterial ECLS are usually applied outside of the operating scene.5 If, in addition to respiratory support also circulatory assistance is required, veno-arterial ECLS is necessary. Peripheral venous drainage and peripheral arterial return are preferred in this case.

Limited arterial access and leg ischemia during ECLS and ECMO with peripheral cannulation is a serious problem, which can be burdened by long-term handicaps including amputation or even death, in prolonged cardiopulmonary bypass (CPB) and ECMO due to obstruction of the access vessel by traditional cannulas. A significant risk of lower limb ischemic complications after prolonged femoral arterial cannulation has been reported. Hendrickson and Glower6 reported an incidence of 11.5% after peripheral CPB. ECMO support is associated with lower limb ischemic complication rates as high as 26%.7,8 The size of the traditional femoral cannula required to maintain a patient on adequate CPB support is often the same diameter as the patient’s own femoral artery, and there is little room around the cannula for distal limb perfusion. Hence, viability of the limb is dependent on collateral blood flow, which can cause limb ischemia if it is poor, resulting in a requirement for fasciotomy or worse amputation. A number of techniques have been proposed to prevent this potentially devastating complication, including the use of an end-to-side femoral artery graft9,10 or a downstream femoral perfusion catheter.6,11-13 These techniques, however, are often cumbersome to perform and not always reliable. They are also associated with bleeding complications and an increased risk of infection.14 Therefore, there is a clinical need for a new type of femoral cannula that will deliver standard retrograde perfusion without compromising distal limb blood flow.

To overcome the problems associated with prolonged cannulation, Smartcanula® LLC (Lausanne, Switzerland) developed an expandable arterial cannula. Unlike the original, flexible, wire wound plastic cannulas, which present the same cross-sectional area over the entire intravascular path, the expandable cannula operates by collapsed insertion and expansion per situm. It automatically adjusts to the diameter of vessel lumen, providing optimal flow and ease of use for both insertion and removal.15 Several proposals have been made in the past for bi-directional perfusion, including lateral orifices and oblique coverage16 providing mitigated acceptance. We propose now, a novel bidirectional femoral arterial cannula design which takes advantage of the performance increase with the virtually wall-less design in comparison to rectilinear traditional percutaneous cannulas and will expand only partially at the point of insertion with reference to the vessel lumen and thus allow for parallel retro-grade flow due to the fact, that the cannula body does not occupy the entire vascular lumen and parallel retrograde flow is still possible. We
hypothesize that this configuration will improve peripheral perfusion and thus, reduce the risk of lower limb ischemia and the resulting complications during ECLS with peripheral cannulation. This study was designed for assessment of the new self-expanding arterial bidirectional cannula allowing for both antegrade and retrograde flow versus commercially available standard percutaneous control with similar diameter at the point of insertion.

Material and methods

Experimental setup

The cannula performance was assessed by measuring the cannula inlet pressure values (P) as a function of pump flow rates (Q) for both the new bidirectional cannula and a commercially available percutaneous control cannula of the same diameter using a computerized flow bench and calibrated sensors with a centrifugal pump. Flow and outlet-pressure were determined at 500, 1000, 1500, 2000, 2500, and 3000 r/min for the new self-expanding design versus control (n = 6).

The in vitro circuit comprised a hard-shell reservoir 65 cm long, 47 cm wide, and 30 cm height (KAISER + KRAFT/ St-Sulpice, Switzerland). The water was pumped from the reservoir to the cannula with a Biomedicus centrifugal pump (Medtronic, Tolochenaz, Switzerland) through a 1 m long silicone ½” tubing (Figure 1). The reservoir was needed to assess the performance of the cannula in this open system with free inflow and free outflow.

Cannulas

The bidirectional arterial cannula (Smartcanula® LLC, Lausanne, Switzerland) shown in Figure 2 is a meshed extra-corporeal 3/8” connecting sleeve leads to the 15F, 90 mm long covered section designed for non-occlusive device insertion. The uncovered section, which can be collapsed for insertion, expands to 24F once it is released in situ and allows for free circulation in all directions (antegrade and retrograde). In a femoral artery, represented in Figure 3 by a transparent tubing there is as a result a free space between the bidirectional cannula and the wall allows for retrograde flow (Figure 3). For the purpose of comparison, a percutaneous Biomedicus arterial cannula (Medtronic, Tolochenaz, Switzerland) of the same diameter was used as a commercially available standard.

Precision and accuracy

Imprecision was defined by the coefficient of variation (CV). Within-assay precision was determined by six repeated measurements within the same assay.

Statistical analyses

Results were presented as means ± SD unless stated otherwise. The unpaired Student t-test was used to compare two cannulas. The standard two-way ANOVA test was used to compare between more than two cannulas. The significance level was p < 0.05.

Results

In vitro evaluation of the bidirectional cannula

The in vitro evaluation of the new arterial bidirectional cannula was characterized by the relationship between P and Q (Figure 4). The six points of each curve were determined at six pump speed: 500, 1000, 1500, 2000, 2500, and 3000 r/min. The results clearly demonstrated that the new bidirectional cannula provide higher Q and lower P
values as compared to the regular design control. The mean retrograde flow was 26% of that of total flow (Figure 5).

Comparison of flow and pressure between bidirectional and control cannula

At 2000 r/min, the mean Q values were $4.52 \pm 0.06$ for bidirectional versus $3.61 \pm 0.01$ control cannula respectively. The corresponding mean outlet pressure values were $101.40 \pm 3.57$ bidirectional versus $129.66 \pm 0.47$ for control (Table 1). The CV ranged between 3% and 6%.

Discussion

The new bidirectional cannula design allows for significantly higher flow rates at lower driving pressures. For a driving pressure typical in the clinical setting, for example, 100 mmHg the corresponding flow rate here is around 4.5 L/min for bidirectional versus 3.2 L/min for control, equivalent to 140%. The advantages shown for the bidirectional design can be reproduced at all pump/flow’s speeds tested (Figure 4) with minimal variations (CV between 3% and 6% for six repeated measures).

In order to reach the same flow rate with the same driving pressure with a traditional rectilinear percutaneous cannula a much larger size would be necessary, thus leaving less or no space for retrograde flow to the limb, a common finding in clinical practice. Practically, for a given target flow rate and a “physiologic” driving pressure, a much smaller cannula diameter can be selected provided it has the bidirectional design.

Figure 5 shows the proportions of antegrade versus retrograde flows in a simulated (femoral) vessel and the bidirectional cannula occupying around 85% of the vessel lumen. In this setting, the retrograde flow in parallel to the antegrade main flow accounts for approximately 26% for the selected minimal afterload. This flow distribution cannot be taken for granted in the clinical setting because of the individual afterload of the two perfusion territories, which may be very different for the central versus the peripheral perfusion.

For the clinical application, there may be concerns about the insertion and the removal of a cannula with fusiform section larger than the cannula diameter at the point of insertion (Figure 3). However, it has to be mentioned here that bidirectional cannula design is based on the “collapsed insertion and expansion in situ principle” which has been proven to be reliable in the clinical setting. This function is achieved by stretching the fusiform cannula section with a mandrel. Likewise, the bidirectional cannula with its fusiform section can be removed easily, because it collapses with simple traction. Access site closure, leg artery compression, or surgical reconstruction similar to other decannulation procedure remains mandatory.

There are some limitations to the findings reported above. These include in addition to the relative resistance of the vascular beds perfused mentioned above, the test medium which was selected here (water) as compared to blood in the clinical setting. We do know from previous studies, that the viscosity of the blood results in approximately 10% lower flow for rectilinear percutaneous cannulas as compared to 6% for virtually wall-less cannulas similar to the bidirectional design presented here (in submission).

Other limitations, like severe atheromatous disease of the access vessel or kinked access vessels may interfere with the self-expanding mechanism of the bidirectional cannula and therefore the flow may also be hindered in one or both directions. However, a traditional rectilinear cannula with a fixed outer diameter may not even be inserted
at all. Hence, the bidirectional cannula cannot solve the underlying atheromatous and other diseases in all cases, but can still be superior to no cannula at all.

A very useful tool in complex situations such as described above is the use of per-procedural ultrasound. The latter is not only helpful for target vessel identification and guide-wire position clarification. For the bidirectional cannula, ultrasound investigation allows in addition for identification of the flow direction by the means of the Duplex Color Doppler function.

We conclude that bidirectional flow for ECLS and ECMO can be achieved on the arterial side with smaller cannulas which do not occupy completely the ECMO can be achieved on the arterial side with smaller cannulas which do not occupy completely the cannulation site. This advantage can be superior to no cannula at all. Hence, the bidirectional cannula cannot solve the underlying atheromatous and other diseases in all cases, but can still be superior to no cannula at all.

A very useful tool in complex situations such as described above is the use of per-procedural ultrasound. The latter is not only helpful for target vessel identification and guide-wire position clarification. For the bidirectional cannula, ultrasound investigation allows in addition for identification of the flow direction by the means of the Duplex Color Doppler function.

We conclude that bidirectional flow for ECLS and ECMO can be achieved on the arterial side with smaller cannulas which do not occupy completely the access vessel provided their performance is sufficiently improved like for the bidirectional cannula design presented here. In-vivo studies are planned next for confirmation of these findings prior to clinical application.

**ORCID iD**

Saad Abdel-Sayed https://orcid.org/0000-0003-0857-1265

**References**