A Smart Solution for Cannulation Bottlenecks in Mini-invasive Open Heart Surgery

a report by

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Background

About 50 years ago, the first successful open heart operations were performed with cardiopulmonary bypass. To allow for reliable intracardiac repair, a man-made machine was responsible for the work of the patient’s heart and lungs for a limited period of time. Of course, the so-called pump oxygenator, a device maintaining gas exchange (oxygenation and CO₂ removal) and blood pressure, was at the core. A typical heart–lung machine used in the 1950s is shown in Figure 1, and a lot of ancillary equipment has been added since. However, the main basic components, i.e. the artificial lung (at that time excentric rotating drums) and the pump, can still be found in modern machines that now rely on disposable membranes for gas exchange.

Standard Cannulation

In order to fulfil its task, i.e. maintain gas exchange and blood pressure while the heart is arrested for surgical repair, the artificial blood path of the heart–lung machine has to be connected somehow to the blood circulation of the body. The traditional method is to insert specifically designed cannulas into the target vessels of the body, either centrally (for example via vena cava and aorta), or peripherally (for example via common femoral vein and artery), and to connect them to the tubing system of the heart–lung machine.

The original cannula designs, which were often made from stainless steel and were reusable, have been replaced since by disposable plastic models, which nowadays are available in many sizes and configurations. For a 70kg adult patient (target pump oxygenator flow 4–5 litres/min), standard cannulas measure 24 French (F) (= 8mm in diameter) on the arterial side and up to 51F (17mm) on the venous side if the inferior vena cava (see Figure 2) is cannulated with a two-stage design through the right atrium. If the right atrium is to be opened, the two caval veins are usually cannulated separately using two 28F (9mm) venous cannulas. The latter allow for adequate venous drainage by gravity, which is achieved as a result of the height difference between the heart and the venous reservoir of the heart–lung machine (typically around 60cm).

Cannulation for Minimal Access Cardiac Surgery

Major efforts have been made in recent years in order to develop minimal access heart surgery. Sophisticated instruments, including video-endoscopic tools, telemanipulators and robots, have been developed for this purpose. Due to the very limited space for access, remote cannulation is preferred for many of these procedures. Hence, the heart–lung machine is usually connected to the vessels in the groin using thin-walled cannulas. There is a major issue for venous cannulation here, where the diameter of the access vessel (femoral vein in Figure 2 – typically measuring 7–9mm for an adult patient) determines the diameter of the traditional cannulas at both levels, the access vessel and the target vessel (the inferior vena cava measurements in this example are around 20mm in diameter). A femoral vein measuring 9mm in diameter is typically cannulated by a device that is slightly smaller, for example a 24F cannula (8mm). This situation is depicted in Figure 3, where an 8mm cannula is introduced through the femoral and the iliac veins up into the inferior vena cava. At the level of the right atrium, this cannula has exactly the same diameter as at the level of insertion, which is 8mm.

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The only way to achieve full blood flow through such a long thin cannula with a cross-sectional area representing only around 15% of the inferior vena cava is to augment venous blood drainage, either kinetically with a centrifugal pump, or with vacuum applied to a hard shell venous reservoir. However, although both techniques theoretically provide the necessary pressure gradient in order to approach the target blood flow required, the latter is not always met in clinical practice.5

The Smart Cannulation Concept

‘Collapsed insertion and expansion in situ’ is the basic principle of the smart cannulation concept. The smartcanula™ is designed from flexible material with a memory effect in such a fashion that, prior to insertion, it can be stretched over a mandrel and collapsed. Some limitation of its diameter only occurs within the theoretical smaller access vessel (remaining short restriction). Removal of the smartcanula™ is fairly easy, as gentle traction reduces its diameter.

For peripheral cannulation (see Figure 4), it is recommended that the smartcanula™ is slid in its collapsed configuration over a guidewire, through the femoral and iliac veins into the inferior vena cava, where it is released. The mandrel and the guidewire are removed and the cannula position is secured. Due to its design, the smartcanula™ expands over the majority of its entire length to a diameter well above the access vessel and much closer to the diameter of the target vessel, thus reducing the resistance to venous drainage.6

Mathematical calculations using computational fluid dynamics predicted for the smartcanula™ show a drastic reduction of the cannula-induced pressure drop and therefore increased blood flow. In vivo evaluations have shown that the flow increased for smartcanula™ in comparison with standard cannulas by 34% for an access limited to 28F, 72% for an access limited to 24F and 170% for an access limited to 20F. Meanwhile, the superior venous drainage capacity of the smartcanula™ has been demonstrated clinically in nine patients participating in a prospective study.6

Advantages of Smart Central Cannulation

The advantages of ‘collapsed insertion and expansion in situ’, as described for the smartcanula™ in

Figure 1: A Melrose Pump Oxygenator Built in the 1950s at the Hammersmith Hospital in London Exposing the Basic Principles of Function

Figure 2: Inferior Vena Cava and Main Peripheral Affluent Veins Including, on Right and Left Sides, Superficial and Deep Femoral Veins, Common Femoral Veins, External and Internal Iliac Veins

<table>
<thead>
<tr>
<th>Position</th>
<th>Diameter</th>
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<tbody>
<tr>
<td>Inferior vena cava</td>
<td>10mm</td>
</tr>
<tr>
<td>Common iliac vein</td>
<td>12mm</td>
</tr>
<tr>
<td>External iliac vein</td>
<td>10mm</td>
</tr>
<tr>
<td>Common femoral vein</td>
<td>9mm</td>
</tr>
<tr>
<td>Superficial femoral</td>
<td>7mm</td>
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Not shown are the renal and hepatic veins, which drain directly into the inferior vena cava.

Cardiothoracic Surgery

peripheral cannulation, are also of interest for central cannulation (see Figure 5). The most apparent benefit, of course, is the fact that full blood flow can be achieved through a relatively small access hole. As a matter of fact, four-litre/min can be achieved with a 20F orifice for access, which is a fraction of the traditional orifice sizes for right atrial central cannulation. Cannulation of a small right atrium, a so-called ‘crowded’ right atrium and a previously operated right atrium are just a few examples where access orifice size matters. The self-expansion capability is also an advantage during cardiac surgical procedures requiring significant mobilisation of the heart, where the smartcanula™ has proved to be relatively kink-resistant for both the experimental and the clinical set-up. It is the same material memory effect of the smartcanula™ that limits the possibility of the venous wall collapsing (resulting in temporary interruption of the venous flow). The latter is well known during cardiopulmonary bypass with traditional cannulas and is known as ‘atrial chatter’ – a quite disturbing phenomenon.

Figure 3: Peripheral Venous Cannulation

A purse string suture (*-*-*--) placed on the right atrium is snared and tied together with the cannula in optimal position. As shown here, the smartcanula™can also be used for central cannulation. In contrast to standard right atrial two-stage cannula, which measures up to 21F; a smaller access orifice (around 24F or less than 50%) is sufficient for optimised venous drainage and reduced atrial chatter.

Figure 5: smartcanula™ in Action

Although the access vein diameter is the same as in Figures 2 and 3, the smartcanula™ expands over its entire length within the host vessel. As a matter of fact, only a relatively short portion of the smartcanula™ (within the access vessel) remains in partial expansion and thus the blood flow required for cardiopulmonary bypass can be achieved easily by gravity drainage. Augmentation of venous return by an additional pump or vacuum is no longer necessary.

Figure 4: smartcanula™

In addition to complex cardiac surgical procedures and unstable haemodynamic situations, peripheral venous cannulation has gained renewed interest for minimally invasive cardiac surgery using small access for exposure, endoscopic visualisation or robotic instrumentation. However, the diameter of a traditional venous cannula (standard and percutaneous) is determined over its entire length by the diameter of the access vessel (e.g. the femoral vein): 8mm = 24F at the cannula inlet as well as 8mm = 24F at the cannulation site.

Outlook

Devices for venous cannulation have seen significant progress over time. Until today, the original, rigid steel cannulas have evolved towards flexible plastic cannulas with wire support that prevent kinking, very thin walled wire wound cannulas allowing for percutaneous application and all sorts of combinations. In contrast to all these rectilinear venous cannula designs exposing the same cross-sectional area over the entire intravascular path, the smartcanula™ concept of ‘collapsed insertion and expansion in situ’ is the logical next step for venous access combining flexible cross-sectional area for optimised flow and ease of use for both insertion and removal. Reduced atrial chatter, kink resistance in situ and improved blood drainage despite smaller access orifice size are some of the most evident advantages of this new device. The fact that flexible, self-expanding venous cannulas of a given size cover various dimensions of cannula with traditional design will certainly reduce the number of cannulas that have to be kept in stock, and this will have an impact on warehouse cost and thus reduce another bottleneck.

For the surgeon, however, the most intriguing aspect of cannulation with the smartcanula™ device might be the fact that this technology allows for intracardiac surgery and a fully open right atrium without the need to snare the vena cava – a totally new and very promising perspective.