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A novel technique using echocardiography to evaluate venous cannula performance perioperatively in CPB cardiac surgery

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Abstract

Objective: Transthoracic echocardiography (TTE) has been used clinically to disobstruct venous drainage cannula and to optimise placement of venous cannulae in the vena cava but it has never been used to evaluate performance capabilities. Also, little progress has been made in venous cannula design in order to optimise venous return to the heart lung machine. We designed a self-expandable Smartcanula® (SC) and analysed its performance capability using echocardiography. **Methods:** An epicardial echocardiography probe was placed over the SC or control cannula (CTRL) and a Doppler image was obtained. Mean (V_m) and maximum (V_{max}) velocities, flow and diameter were obtained. Also, pressure drop (ΔP_{CPB}) was obtained between the central venous pressure and inlet to venous reservoir. LDH and Free Hb were also compared in 30 patients. Comparison was made between the two groups using the student's *t*-test with statistical significance established when $p < 0.05$. **Results:** Age for the SC and CC groups were 61.6 ± 17.6 years and 64.6 ± 13.1 years, respectively. Weight was 70.3 ± 11.6 kg and 72.8 ± 14.4 kg, respectively. BSA was 1.80 ± 0.2 m^2 and 1.82 ± 0.2 m^2, respectively. CPB times were 114 ± 53 min and 108 ± 44 min, respectively. Cross-clamp time was 59 ± 15 min and 76 ± 29 min, respectively (p = NS). Free-Hb was 568 ± 142 U/l versus 549 ± 271U/l post-CPB for the SC and CC, respectively (p = NS). LDH was 335 ± 73 mg/l versus 354 ± 116 mg/l for the SC and CC, respectively (p = NS). V_m was 89 ± 10cm/s (SC) versus 63 ± 3 cm/s (CC), V_{max} was 139 ± 23 cm/s (SC) versus 93 ± 11 cm/s (CC) (both $p < 0.01$). ΔP_{CPB} was 30 ± 10 mmHg (SC) versus 43 ± 13 mmHg (CC) ($p < 0.05$). A Bland—Altman test showed good agreement between the two devices used concerning flow rate calculations between CPB and TTE (bias 300 ml ± 700 ml standard deviation). **Conclusions:** This novel Smartcanula design, due to its self-expanding principle, provides superior flow characteristics compared to classic two stage venous cannula used for adult CPB surgery. No detrimental effects were observed concerning blood damage. Echocardiography was effective in analysing venous cannula performance and velocity patterns.

Keywords: Cardiopulmonary bypass; Cardiotomy suction; Haemolysis; Blood

1. Introduction

The use of ultrasound techniques has become routine in cardiac surgery in order to help the clinicians in optimising diagnosis preoperatively (transthoracic echocardiography (TTE)) and perioperatively (transoesophageal echocardiography (TOE)) by validating surgical techniques such as mitral valvuloplasties, identifying dyskinetic myocardial zones postcoronary artery bypass graft (CABG) procedures and assuring the absence of paravalvular leaks postvalve replacement.

Recently, its usefulness has been reviewed and demonstrated in off-pump coronary artery bypass (OPCAB) [1] and during on-pump cardiopulmonary bypass (CPB) procedures [2].

Novel applications for TTE or TOE was already introduced several years ago such as evaluating the correct positioning of femoral CPB cannulae, ventricular assist device (VAD) and the intra aortic balloon pump catheter (IABP) [3,4]. With the inception of minimally invasive procedures such as Port-access, TOE was also utilised with success [5,6].

Recently, diverse applications such as placement of umbilical venous catheter, haemodialysis and jugular vein cannulation have been reported with TOE [7—9]. Specific to cardiac applications, TOE has been used to disobstruct venous drainage cannula and to optimise placement of venous cannulae in the inferior vena cava (IVC) [10—12].

Since the inception of CPB, little progress has been made in the design of venous cannula except for minimally invasive applications [13] and three-stage venous cannula [14]. However, a self-expanding cannula, Smartcanula® (SC), was developed and tested using computational fluid dynamics (CFD) [15], in vitro [16] and in in vivo animal settings [17]. During all of the above tests, it was found to be

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Table 1
Patient demographics and operative data of the study population

	Group CTRL ($n = 6$)	Group SC ($n = 7$)
Age (years)	64.6 ± 13.1	61.6 ± 17.6
Gender (male/female ratio)	6/0	4/3*
Body surface area (m^2)	1.82 ± 0.2	1.80 ± 0.2
Ejection fraction (%)	58.4 ± 8.6	55.0 ± 10.4
CPB time (min)	108 ± 44	114 ± 53
Cross-clamp time (min)	76 ± 29	59 ± 15
Weight (kg)	72.8 ± 14.4	70.3 ± 11.6
CABG (*n* and %)	2 (33%)	2 (29%)
Valve (*n* and %)	1 (17%)	4 (57%)*
Combined (*n* and %)	2 (33%)	0 (0%)*
Other (*n* and %)	1 (17%)	1 (14%)

CTRL: control group versus SC: smartcanula group; CPB: cardiopulmonary bypass; CABG: coronary artery bypass graft.

* Statistical significance found between the two groups when $p < 0.05$.

superior compared to classic venous cannula used for CPB applications.

Therefore, the aim of this study was twofold: (1) to establish the feasibility of using echocardiography (E) to evaluate the performance of venous cannula; and (2) to compare the SC with a control one to establish which is superior.

2. Materials and methods

The study design was approved by the Institutional review board and the patient demographics are presented in Table 1. Block randomisation was carried out and divided into a treated group (SC, $n = 7$) and a control group (CTRL, $n = 6$). However, only selected surgeons were implicated in the study due to the novelty of the device and the need for adaptive learning. Block randomisation was previously defined [18]. Briefly, it randomises *n* individuals into *k* treatments, in blocks of size *m*. Randomisation reduces opportunities for bias and confounding in experimental designs, and leads to treatment groups, which are random samples of the population sampled, thus helping to meet assumptions of subsequent statistical analysis. Random allocation can be made in blocks in order to keep the sizes of treatment groups similar. In order to do this, you must specify a sample size that is divisible by the block size you choose. In turn you must choose a block size that is divisible by the number of treatment groups you specify. An advantage of small block sizes is that treatment group sizes are very similar. A disadvantage of small block sizes is that it is possible to guess some allocations, thus reducing blinding in the trial. An alternative to using large block sizes is to use random sequences of block sizes. The random block size option selects block sizes of 2, 3, 4 or 5 at random. The randomisation proceeds by allocating random permutations of treatments within each block.

2.1. Anaesthesia technique

All patients received midazolam for premedication. Anaesthesia was induced in all patients with propofol or etomidate, opioids including fentanyl, and the muscle relaxants pancuronium or vecuronium. All necessary monitoring lines were then inserted, and anaesthesia was maintained with propofol infusion or with anaesthetic gas (isoflurane or sevoflurane), continuous infusion or repeated doses of opioids, and pancuronium or vecuronium administration as required.

2.2. Echocardiography technique

After rewarming but before weaning, a sterile sheath (Raucodrape®, Lohmann & Rauscher International GmbH & Co, Rengsdorf, Germany) was passed to the surgeon into which the epicardial TTE probe (model 15-6L, Philips, Böblingen, Germany) was inserted together with transonic gel. The probe was placed on the venous cannula at the outlet of the right atrium. Echocardiographic longitudinal and cross-sectional images are shown of the SC in situ (Fig. 1). A Hewlett-Packard TTE machine (Sonos 5500, Philips, Böblingen, Germany) was used to perform the imaging with a frame rate of 50 Hz. Once visualisation of flow inside the cannula was possible, continual doppler imaging was performed to obtain the maximum velocity (V_{max} in cm/s) and mean velocity (V_m in cm/s)(Fig. 2). The diameter of the cannula was calculated by using the pointer on the TTE machine thereby making the calculation of flow rate (Q_E and Q_{CPB}, subscript E denotes echocardiography and subscript CPB denotes cardiopulmonary bypass, respectively) possible from the following formula: VTI (velocity time integral using $V_m \times 60$) $\times$ CSA (cannula surface area). Simultaneously, the pressure drop ($\Delta P_{CPB} = P_{in} - P_{out}$) between the right atrium and the inlet of the CPB venous reservoir was calculated by placing a DLP pressure transducer at the inlet to the venous reservoir (DLP 60000, Grand Rapids, MI, USA). The P_{in} was the central venous

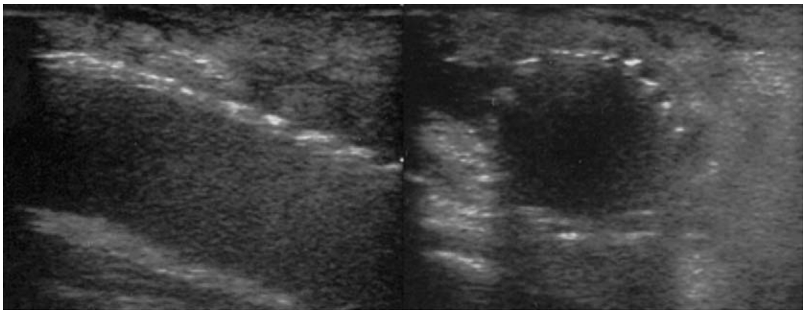

Fig. 1. TTE longitudinal image (left) of the SC inserted with its proximal end inside the IVC and a cross-sectional view in situ (right).

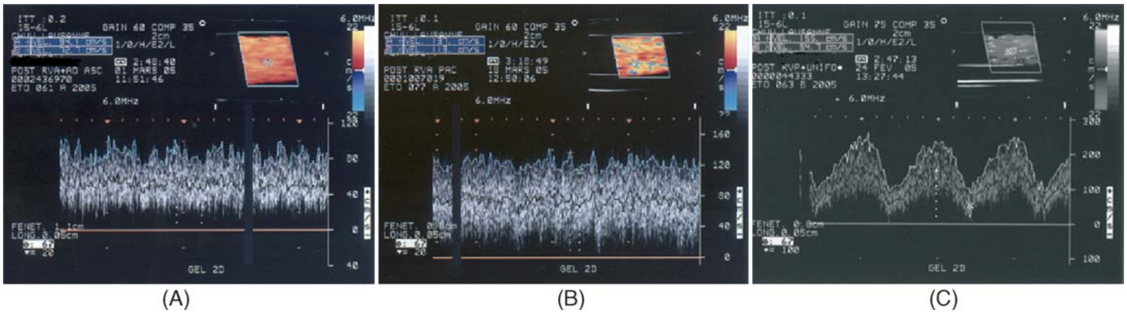
(A) (B) (C)

Fig. 2. Echocardiography images for the CTRL (A) and SC (B) showing velocity (mean and max) profile using continual Doppler imaging. Upper right hand image reflects the cannula's wall section, while the bottom image reflects the velocity over time. Notice the greater velocities obtained with the SC. (C) The chattering phenomenon often encountered during the running of the CPB procedure. Notice how the excess negative pressure in the venous line provokes velocity variations over time.

pressure value (CVP) while the P_{out} was the value indicated on the DLP pressure transducer.

2.3. The SC device

The Smartcanula® (Smartcanula Ltd, Fribourg, Switzerland) is made of interlaced wires having memory shape properties. The one end is moulded into a plastic tip, the other end is siliconised to a 3/8-in. connector (Fig. 3). To insert the cannula in a vessel, a guide wire is placed to assure proper placement. The guide wire is inserted into the cannula's tip and through an introducer used to flatten the cannula because of the cannula's ability to change shape when placed under stress. Once the cannula is in place, the guide wire and introducer are removed, and it expands to a larger diameter value due to the fact that the stress is removed from the cannula's structure. The circuit is now connected to the cannula's outlet which is manufactured with a 3/8- or 1/2-in. connector.

2.4. Perfusion technique

A heart lung machine (Stockert Medizintechnik AG, Munich, Germany), a hollow fibre membrane oxygenator (D903 Dideco®, Mirandola, Italy or Quadrox® Jostra Medizintechnik AG, Hirrlingen, Germany), a conventional tubing circuit (Dideco, Mirandola, Italy or Jostra Medizintechnik AG, Hirrlingen, Germany) and an air—oxygen blender (Sechrist Industries, Inc., Anaheim, CA, USA) were used in all of the procedures. The extracorporeal circuit is primed with 1000 ml Ringer lactate, 500 ml Haes, 100 mg Heparin (Liquemin, Hoffmann-La Roche, Basel, Switzerland), an antibiotic and 1 million IU Aprotinin (Trasylol, Bayer, Zürich, Switzerland) following the departmental protocol.

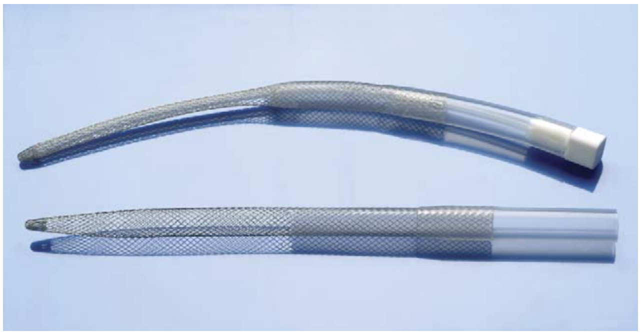

Fig. 3. SC before insertion with a mandrel inside (top) and deployment when the mandrel is removed (bottom). The SC expands to take the shape of the inside lumen of the native vessel, i.e. the IVC (proximal end in this case).

2.5. Surgical technique

A midline sternotomy was performed. The pericardium opened anteriorly to the phrenic nerve to expose the right atrium and both venae cavae. Simultaneously, the arterial site was prepared to expose the aorta. The patient was anticoagulated with 3 mg/kg heparin (Liquemin, Hoffmann-La Roche, Basel, Switzerland) before cannulation of the aorta. Subsequent superior vena cava (SVC) and inferior vena cava (IVC) cannulation occurs or direct cannulation of the right atrium depending on the surgical procedure. CPB was initiated with passive venous drainage. The cardiac procedure was performed under direct vision. After rewarming and careful deairing manoeuvres by way of a vent placed in the ascending aorta, the aorta was unclamped. The weaning process was started once the patient was ventilated and cardiac rhythm reinitiated.

2.6. Measurements

Age, weight, body surface area (BSA), CPB and cross-clamp times were recorded. V_{max} (cm/s), V_m (cm/s), ΔP_{CPB} (mmHg), diameter, CSA of analysed section (mm) and Q_E (l/min) were also recorded. Free Hb and LDH values were also compared between the two groups.

2.7. Data analysis

(1) Mean and standard deviation were derived for each parameter analysed. An unpaired Student's *t*-test and analysis of variance for repeated measures were used for determination of statistical significance between the two groups ($p < 0.05$).
(2) We performed a Bland—Altman analysis between Q_{CPB} and Q_E rate (l/min) using GraphPad Prism version 4.00 for Windows (GraphPad Software, San Diego, CA, USA) [19].

Table 2
Free Hb (mg/l) and LDH (U/l), performance parameters compared between the two groups: V_{max} (cm/s), V_m (cm/s), ΔP_{CPB} (mmHg), diameter of analysed section (cm) and CSA (cm^2)

	Free Hb (mg/l)	LDH (U/l)	V_m (cm/s)
CTRL	549 ± 271	354 ± 116	63 ± 3
SC	568 ± 142	335 ± 73	$89 \pm 10^{\dagger}$
	Diameter (cm)	CSA (cm^2)	V_{max} (cm/s)
CTRL	1.27	1.27	93 ± 11
SC	0.95	0.71	$139 \pm 23^{\dagger}$
	Q_E (ml/min)	Q_{CPB} (ml/min)	ΔP_{CPB} (mmHg)
CTRL	4800 ± 200	4500 ± 550	43 ± 13
SC	$3800 \pm 400^{\dagger}$	4400 ± 540	$30 \pm 10^{*}$

Parameters indexed: V_m indexed to flow rate; V_m and Q_{CPB} indexed to diameter and CSA.

* Statistical significance found between the two groups when $p < 0.05$.

† Statistical significance found between the two groups when $p < 0.01$.

3. Results

The patient demographics are presented in Table 1. Significant differences in patient demographics were observed between the two groups for gender, valve and combined procedures.

In order to exclude any detrimental effects of the wire-interlaced design on the intimal vessel wall, Free Hb and LDH values were both comparable between the two groups (Table 2). The SC expressed 30% greater V_m values and 33% greater V_{max} values compared to the CTRL ($p < 0.001$, Table 2). When ΔP_{CPB} was analysed, lower values of 30 ± 10 mmHg versus 43 ± 13 mmHg were observed for the SC and CTRL, respectively ($p < 0.05$, Table 2). Q_{CPB} was comparable between the two groups. However, Q_E was significantly different when compared between the two groups.

A Bland–Altman analysis showed good agreement between the two devices used concerning flow rate calculations between CPB and echocardiography (bias 300 ± 700 ml standard deviation). This means that echocardiography slightly underestimated actual flow rates (Fig. 4).

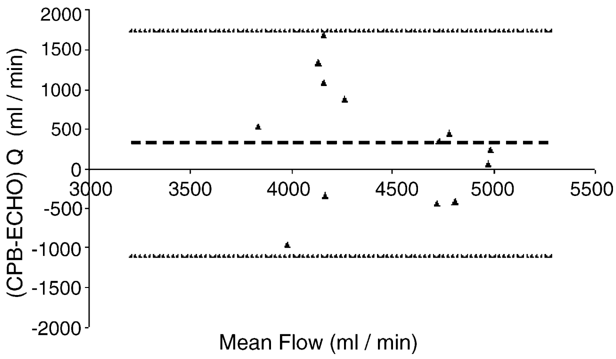

Fig. 4. Bland–Altman analysis of Q_E and Q_{CPB}; subscript E denotes echocardiography and subscript CPB denotes cardiopulmonary bypass, respectively. The y-axis presents the differences between the two measuring techniques. The x-axis represents the mean values of the two measuring techniques. Dashed lines indicate mean differences; dotted lines indicate boundaries of two standard deviations of the differences.

All patients underwent successful CPB weaning with minimal inotropic support and were transferred to the intensive care unit in a stable condition. There were no complications reported: neither postoperative organ dysfunction nor any other complication related to this technique. Echocardiographic control at day 7 was normal in every patient. The mortality of the patients were zero in both groups; also the median hospital stay was 11 days for both groups.

4. Discussion

We were successfully able to evaluate venous cannula performance with the use of echocardiography. Moreover, the SC significantly outperformed the CTRL cannula with respect to all flow dynamic variables measured. No haemolysis was observed by the SC during the study period.

During a numerical analysis using CFD, Mueller et al. [15] established lower pressure gradients across the SC which we can advocate and validate in our study performed in a clinical setting with a 30% lower ΔP_{CPB} observed (Table 2). Moreover, significantly greater mean and maximum velocities were attained for the SC for an equivalent flow rate when compared to the CTRL (Table 2). Due to the fact that higher velocities are measured within the SC, greater resistance to blood flow is encountered outside the patient or in the venous line. However, the ΔP_{CPB} is lower; thus, resistance to blood flow inside the patient (CVP) is lower which supports the superiority of the SC by showing its ability to reduce the CVP when compared to the CTRL cannula. Jegger et al. [16,17], also showed superiority of the SC in an in vitro setting demonstrating 14–19% greater flow rates depending on the preload used. This phenomenon was complemented by performing in vivo animal testing with the SC exhibiting a 20% greater flow rate capacity during passive and active venous drainage techniques [20]. Similar findings were encountered by Mueller et al. [21] in a parallel bovine experiment. Undertaking clinical comparisons is difficult as once theoretical flow is attained, it is also maintained. Nevertheless, comparable flow rates of 4.8 ± 0.2 l/min and 4.4 ± 0.5 l/min for the CTRL and SC, respectively, were obtained. In our study, no additional haemolysis was associated with the use of the SC compared to the CTRL as LDH and Free Hb values were comparable (Table 2). In addition, after each CPB procedure with the smartcannula, the cannula was examined macroscopically with no deposits being found. Also, the cannulae were rinsed and visually inspected again in the absence of any thrombotic material in or around the cannulae.

TTE has previously been reported by Grooters et al. [22] in a clinical setting analysing the velocities at the outlet of several commercially available arterial CPB cannula. The intention was to evaluate whether cannula design influenced velocities and thus reduced the tendency of atherosclerotic emboli being a major cause of morbidity and mortality in the cardiac surgical community. Also, TTE has already been utilised to improve outcome when used to guide aortic cannula during on-pump CABG procedures. The use of this technique significantly reduced perioperative stroke and death [2]. Recently, the use of intraoperative epiaortic ultrasonography (EAUS) has been reported to delineate aortic atheroma. A correlation was established between atheromatous finding in the ascending aorta detected by EAUS and the presence of peripheral vascular disease. Additionally, surgical technique was altered in 24% of the population due to atheromatous finding. The changes in surgical technique included conversion from on-pump to OPCAB, change in cannulation, aortic cross-clamping or saphenous vein graft proximal anastomosis site. More importantly, no cerebral vascular accidents were observed in the patients with a pathologic aorta who were converted to off-pump CABG surgery [23].

This novel analysis has not been performed with venous cannula. However, TTE was used to determine the position of the cannula relative to the IVC or right hepatic vein (RHV). It was observed that malposition of the venous cannula into the RHV was observed in 10% of the study population. When analysing the data, it was also observed that the incidence was greater with single stage compared to two-stage cannula. It is speculated that position of the cannula deep inside the IVC is more deleterious than the positioning of it in the RHV [11].

Upon the onset of CPB or during vital manipulations during the surgical procedure, Q_{CPB} can often take several seconds or minutes to stabilise, which are represented by a constant level of blood in the venous reservoir. However, when Q_E is utilised, it is performed instantaneously or in real time and the waiting period for stabilisation of blood in the venous reservoir is substantially reduced. This is advantageous as not only instantaneous flow is measured but also change in flow patterns, such as chattering (Fig. 3C), can be identified and corrected. This improves patient safety as venous drainage is optimised, maintained and assured during the CPB procedure.

The TTE technique can be considered a valid one due to the fact that the Bland–Altman analysis depicts small bias values when comparing the two methods. Also, the standard deviation is less than 10% of the theoretical flow rates often observed during CPB.

In conclusion, this study emphasises the benefit of using TTE in evaluating venous cannula performance and at the same time could be used to visualise correct placement of it in the right atrium. More so, the SC outperforms the CTRL one using this novel technique. This unique Smartcanula design, due to its self-expanding principle, provides superior flow characteristics compared to classic two stage venous cannula used for adult CPB surgery. Additionally, no haemolysis was observed in this clinical setting.

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