LIMITATIONS

- Selection and performance bias may be present because of the unblinded nature of the study.
- No control group.
- Time on cardiopulmonary bypass was relatively short, particularly when compared with patients undergoing venoarterial extracorporeal membrane oxygenation, where peripheral ischemia is more common.
- Further research on a larger scale and in different patient populations is now warranted.

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A Phase 1 Study of a Novel Bidirectional Perfusion Cannula in Patients Undergoing Femoral Cannulation for Cardiac Surgery

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ORIGINAL ARTICLE

OPEN

A Phase 1 Study of a Novel Bidirectional Perfusion Cannula in Patients Undergoing Femoral Cannulation for Cardiac Surgery

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Objective: Leg ischemia is a serious complication of femoral artery cannulation. The primary aim of this study was to assess the safety and efficacy of a novel bidirectional femoral arterial cannula (Sorin Group USA, a wholly owned subsidiary of LivaNova PLC, Arvada, CO USA) that provides both antegrade and retrograde flow, in patients undergoing peripheral cannulation for cardiopulmonary bypass during cardiac surgery.
Methods: Patients undergoing routine cardiac surgery requiring femoral artery cannulation for cardiopulmonary bypass were identified preoperatively. Informed written consent was obtained in all cases. Bidirectional cannula insertion used either a surgical cut-down and wire through needle approach or a percutaneous technique. Flow in the superficial femoral artery was assessed using Doppler ultrasound after commencement of cardiopulmonary bypass. Lower limb perfusion was assessed using reflectance near-infrared spectroscopy to measure regional oxygen saturations in the cannulated limb during cardiopulmonary bypass.
Results: Fifteen patients (median age = 61.3 years, range = 26–79 years, 10 males, 5 females) underwent femoral arterial cannulation using the novel bidirectional femoral cannula between August 2016 and May 2017. Fourteen cannulae were inserted directly into the femoral artery via a surgical cut-down and wire through needle technique. One bidirectional cannula was inserted using a percutaneous insertion technique. Indications included minimally invasive mitral and aortic valve surgery, thoracic aortic aneurysm repair, and redo cardiac surgery. The median duration of cardiopulmonary bypass was 129 minutes (range = 53–228 minutes). The cannula was inserted and positioned without difficulty in 14 of 15 patients. Incorrect sizing and arterial spasm prevented correct cannula positioning in one patient. Antegrade flow in the superficial femoral artery was observed on Doppler ultrasound in 12 of 12 patients in which this was performed. Continuous stable distal perfusion was demonstrated in the cannulated limb in 14 of 15 patients. No procedural complications occurred in the immediate or convalescent postoperative period.

VIDEO CLIP *Video clip is available online.*

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CENTRAL MESSAGE

The use of a novel bidirectional cannula is safe and provides stable distal perfusion of the cannulated limb in patients undergoing femoral arterial cannulation for CPB during cardiac surgery.

STUDY OUTLINE

- Phase 1, open-label, non comparative, single-center, device study of the novel bidirectional cannula.
- Aim: assess the safety and efficacy of a novel bidirectional femoral arterial cannula that provides both antegrade and retrograde flow, in patients with peripheral cannulation for CPB.
- 19F bidirectional cannula
  - Patient was deemed ineligible if the internal diameter of the femoral artery < 7.5 mm.
- Follow-up visit at 24 hours after the cannula removal.
- Lower limb perfusion assessed using reflectance near-infrared spectroscopy (NIRS) as a measure of regional oxygen saturation (rSO2) every 15 minutes
  - A drop in oxygen saturation level of more than 20% in the cannulated limb in comparison with baseline triggered a clinical review.
- Doppler ultrasound of the superficial femoral artery (SFA) in the cannulated limb.

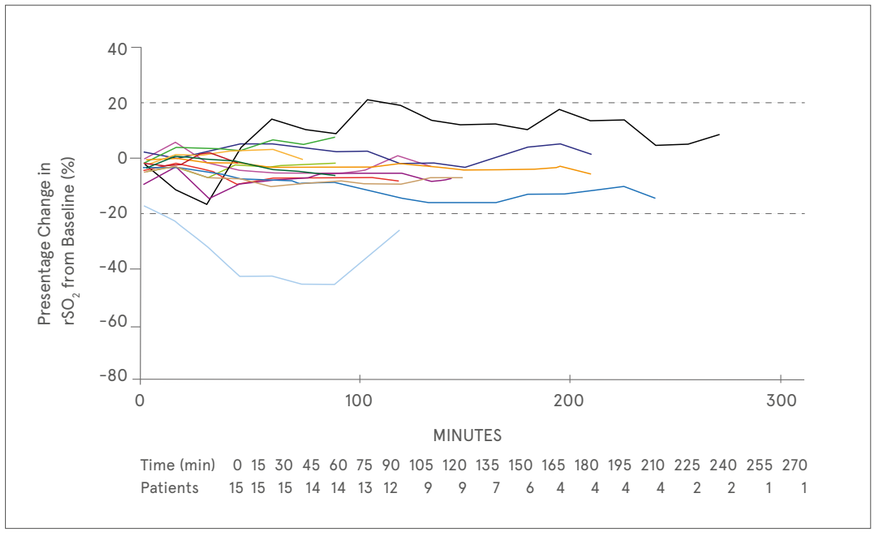
RESULTS

- 15 patients between August 2016 and May 2017, median age = 61.3 years.
- Indications: minimally invasive mitral and aortic valve surgery, thoracic aortic aneurysm repair, and redo cardiac surgery.
- Mean duration of cannulation was 151.9 min, mean CPB duration 129 min.
- Mean internal diameter of femoral artery measured on ultrasound was 9.3 mm (range = 7.5–11 mm).
- Bidirectional cannula inserted directly into a surgically exposed femoral artery using a wire through needle technique in 14 patients. In one patient inserted using a percutaneous insertion technique.
- Bidirectional cannula was **inserted and positioned without difficulty in 14 of 15 patients**
  - In one patient with a 7.5 mm femoral artery, the operator had difficulty inserting the body of the bidirectional cannula into the artery.
- **No bleeding issues or excess trauma to the vessel during insertion and CPB support in any patient.**
- **Antegrade flow in the SFA observed on Doppler ultrasound in 12 of 12 patients.**
- **Continuous stable distal perfusion demonstrated using NIRS in 14 of 15 patients** (Figure)
  - In one patient where the operator had difficulty positioning the cannula due to size mismatch with the femoral artery, poor distal perfusion was present, but satisfactory flows and line pressures through the CPB circuit were achieved.
- In 100% of the cases, mean arterial pressure was deemed sufficient to ensure adequate organ perfusion.
- Line pressures were in a satisfactory range for a 19F cannula in all patients throughout the period on CPB.
- **The cannula was removed without difficulty in all cases, and there were no reported procedural complications.**
- At 24-hour follow-up no evidence of infection, active bleeding, significant hematoma formation (>5 cm diameter), or leg ischemia in any patient.
- 13 patients (87%) completed outpatient follow-up visit (mean time to follow-up 49 days)
  - All had well-healed vascular access sites, no clinical evidence of hematoma, infection, or pseudo-aneurysm formation.
  - One serious adverse (cerebrovascular accident) was reported as possibly but highly unlikely to be related to the bidirectional cannula.

KEY TAKE-AWAYS

- "Leg ischemia remains a serious and morbid complication of femoral artery cannulation, particularly in patients undergoing prolonged support on cardiopulmonary bypass."
- "All participants were supported on CPB with adequate bypass flows, satisfactory line pressures, and mean arterial pressures that were sufficient to support organ perfusion."
- "**Continuous stable distal perfusion** of the cannulated limb was demonstrated in more than 90% of participants (n = 14), as evidenced by stable regional oxygen saturation levels recorded every 15 minutes during CPB."
- "In these cases, **the bidirectional cannula was inserted and positioned without difficulty**. The cannula glided freely within the femoral artery, and there was **excellent tactile feedback** with positioning of the bidirectional cannula shoulder."
- "No events relating to the safety of the cannula occurred during the study. Specifically, **there was no dislodgement of the cannula and no significant bleeding around the insertion point**. The cannula was removed without difficulty in all cases, and there were no reported procedural complications."
- The use of NIRS to quantify regional oxygenation in the cannulated limb represents a unique strength
  - NIRS has been validated as a measure of regional oxygen saturation and was highly sensitive to changes in distal perfusion.

Figure. Percentage change in regional oxygen saturation (rSO_2): A reduction in rSO_2 of more than 20% from baseline is considered to be significant and an indicator of local ischemia.



CONCLUSION

"This study demonstrates that in patients undergoing femoral arterial cannulation for CPB during cardiac surgery, the use of a novel bidirectional cannula is safe and easy to insert and provides stable distal perfusion of the cannulated limb.

"Use of the device should largely obviate the need to insert a separate downstream perfusion cannula or use other techniques to protect against lower limb ischemia.