First-In-Human Study of a Dual-Lumen Femoral Artery Cannula for Peripheral Cardio-Pulmonary Bypass in Minimally Invasive Cardiac Surgery

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1 Objective

Femoral artery cannulation is increasingly used to initiate peripheral cardiopulmonary bypass (pCPB) or veno-arterial extracorporeal membrane oxygenation (pVA-ECMO). Nevertheless, as a direct consequence of the arterial obstruction, up to 30% of patients undergoing femoral artery cannulation for pCPB or pVA-ECMO are experiencing some degree of leg hypoperfusion [1].
A dual-lumen femoral artery cannula has been designed to perfuse both the upper body and the cannulated leg and to alleviate the risk of leg hypoperfusion. The aim of this first-in-human study was to evaluate the safety and preliminary performance of the novel dual-lumen femoral artery cannula in patients undergoing minimally invasive cardiac surgery (MICS) with pCPB.

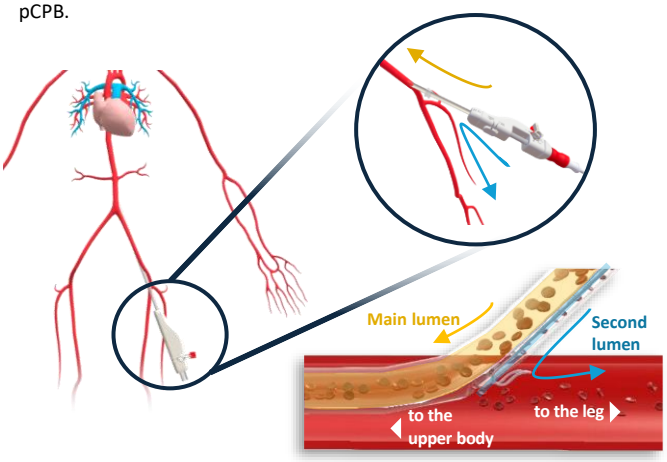


Fig. 1 Illustration of the placement of the cannula in the artery

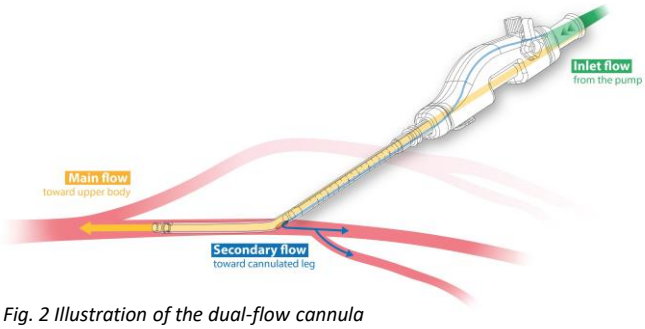


Fig. 2 Illustration of the dual-flow cannula

2 Methods

A prospective monocentric study included 15 patients undergoing MICS with pCPB with the dual-lumen femoral artery cannula. The study was performed at private hospital Jacques Cartier (Massy, France). The clinical trial was registered on ClinicalTrial.gouv (NCT07163234) and approval was received from the French ethical committee CPP Sud-Est II.

The primary outcome was the safety evaluation with the record of intraoperative and late adverse events up to 30 days after the procedure. Secondary outcomes included the perfusion of the canulated leg measured by Near Infrared Spectroscopy (NIRS) every 15 minutes and the evaluation of cannula usability.

3 Results

Among the 15 patients, surgical procedure was mitral valve repair in 6, aortic valve replacement in 5, mitral and tricuspid valve repair in 2, mitral valve replacement in 1, and Tirone-David procedure in 1.

The insertion of the dual-lumen femoral artery cannula was performed through open approach in all cases. The mean duration of the pCPB was 92.8 ± 17 min with a minimum of 56 min and a maximum of 119 min. CPB flows were stable during the procedures with a mean pCPB flow rate of 4.3 ± 0.7L/min and a mean pressure drop of 250 ± 78mmHg. No serious adverse device effect were reported by the site during procedures or during follow-up. Surgeon satisfaction was achieved in all cases.

No significant drop of NIRS was observed in the cannulated leg during procedures. NIRS values were similar between legs before cannulation (cannulated vs. non cannulated, 71% ± 11% vs. 72% ± 9%) and these values remained stable during the procedures (cannulated vs. non cannulated, 68% ± 12% vs. 68% ± 8%) (Figure 3). No clinical sign of limb ischemia was observed during procedures and follow-up.

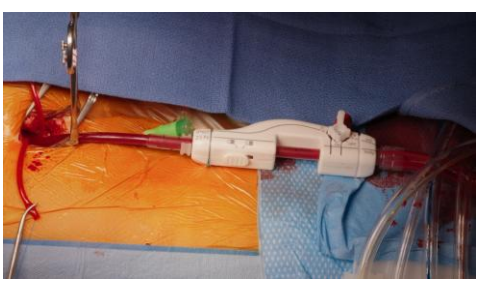
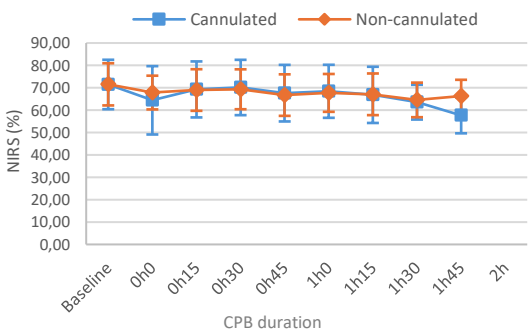


Fig. 3 Photo of the cannula inserted in the femoral artery



Number of patients	15	15	15	15	15	14	12	7	3	0

Fig. 4 NIRS of the cannulated and contralateral leg (mean ± sd)

4 Conclusion

In this first-in-human study, the dual-lumen femoral artery cannula was successfully used during pCPB, with no serious adverse device effects reported by the site, providing preliminary evidence supporting the safety of the device. Preliminary efficacy data also showed comparable intraoperative NIRS values between the cannulated and non-cannulated legs, with no relevant asymmetry observed. Additional studies will be performed to further assess the efficacy of the dual-lumen femoral artery cannula in the prevention of leg hypoperfusion and leg ischemia during peripheral femoral artery cannulation.

[1] Ceulemans A et al., Incidence, predictors and vascular sequelae of distal limb ischemia in minimally invasive cardiac surgery with femoral artery cannulation: an observational cohort study. 2023 Heart and Vessels

Conflict of interest: PM is the co-founder and shareholder of IPERF