

Inflammatory modulation during heart surgery: study protocol for randomized trial.

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Background/Aims

Chronic kidney disease (CKD) has consistently been found to be an independent risk factor for the development of cardiovascular disease, increasing the risk of mortality in patients undergoing cardiac surgery. An elevated plasma IL-6 level is commonly observed in CKD patients, which is largely caused by the increased generation resulting from oxidative stress, chronic inflammation and fluid overload. Elevated postoperative plasma concentrations of inflammatory cytokines are associated with an increased mortality and morbidity and plasma IL-6 and IL-10 concentrations predict long-term mortality in adults after cardiac surgery. A novel extracorporeal sorbent haemoadsorption (HA) device (CytoSorb[®]) was recently developed for cytokine removal from the blood and is now approved in the European Union.

In this pilot trial we aim to assess if intraoperative haemoadsorption with CytoSorb[®] can significantly reduce postoperative IL-6 serum levels in patients with CKD undergoing on-pump cardiac surgery.

Methods

This will be a single-centre randomised, two-arm, patient-blinded trial of the effects of intraoperative HA on postoperative inflammatory response and organ dysfunction in patients with chronic kidney disease undergoing on-pump cardiac surgery.

Subjects will be randomly allocated to receive either intraoperative HA during cardiopulmonary bypass (CPB) or standard CPB without HA. The HA device will be included in the CPB circuit between the oxygenator and the venous reservoir. The study will be conducted at University Hospital of Catanzaro (Italy).

The primary outcome is the difference in mean IL-6 serum levels between the two study groups on admission to the ICU.

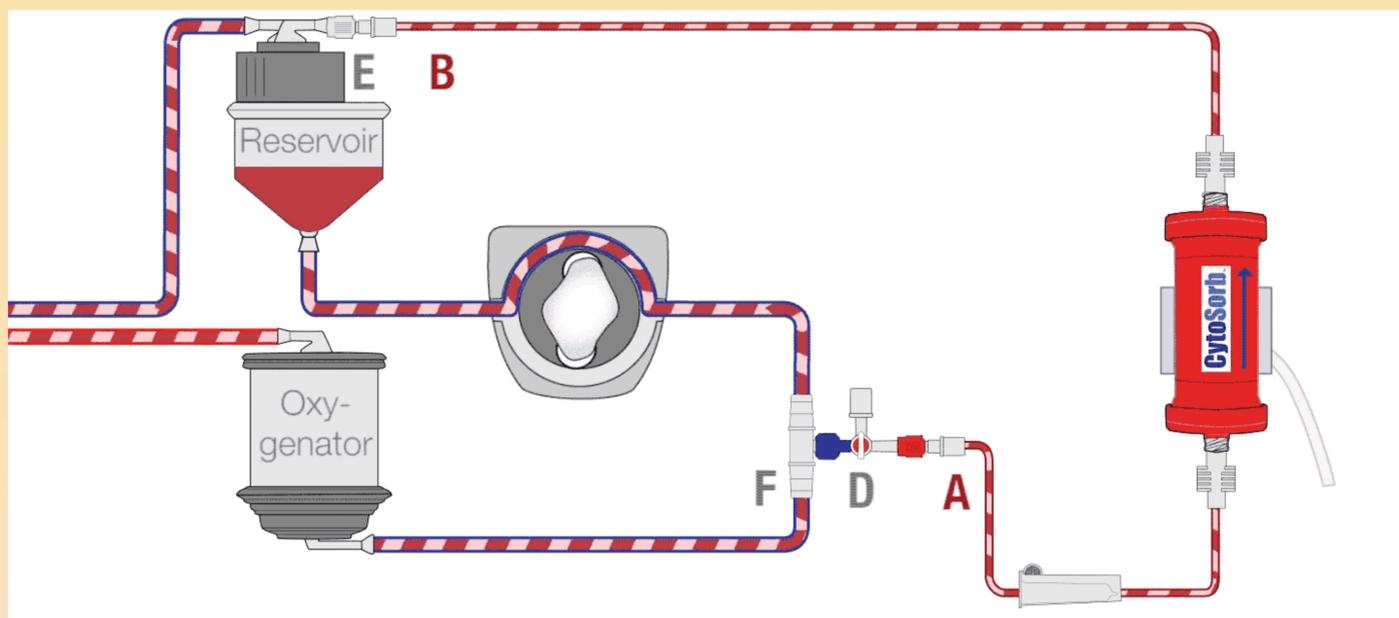


Figure 1: Example of CPB circuit with integrated Cytosorb

Conclusion

We would like to demonstrate the efficacy of intra-operative haemoadsorption with CytoSorb[®] to remove cytokines from circulation for prevention of surgical associated inflammatory response and complications in patients with CKD.