The effect of retrograde autologous priming on transfusion requirements after cardiac surgery (TheRAPy)

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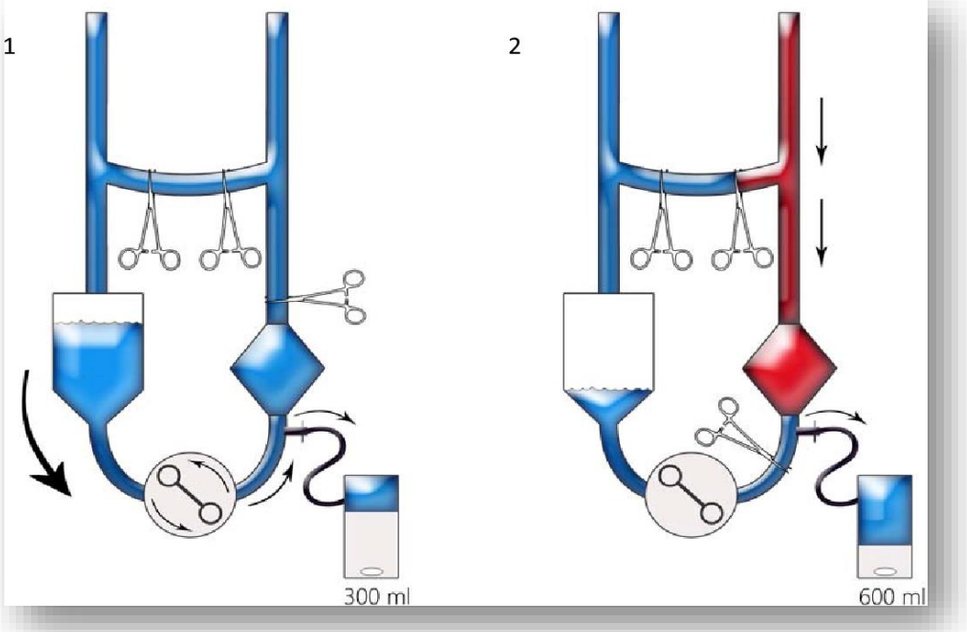
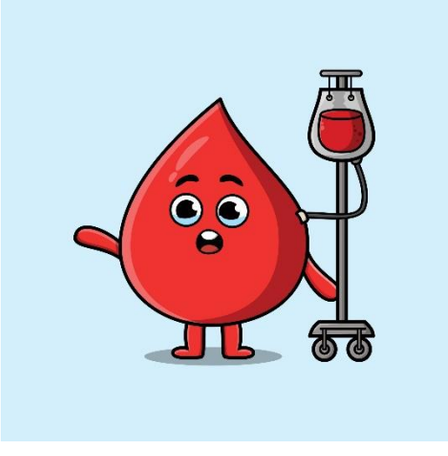
Background of Retrograde Autologous Priming (RAP)

- RAP is a simple and low-cost technique, whereby the patient's own blood, rather than crystalloid fluid, is used to prime the cardiopulmonary bypass (CPB) circuit



Background of Retrograde Autologous Priming (RAP)

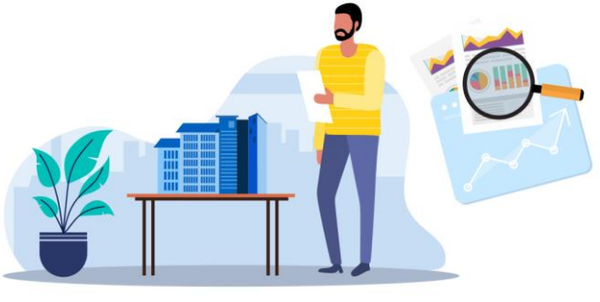
- RAP may minimize hemodilution during cardiac surgery, a potentially modifiable contributor to red blood cell (RBC) transfusion
  - Lowering blood transfusions can decrease costs and resource use at the level of the healthcare system, and morbidity and mortality at the level of the individual patient
- There is a large variation in the clinical uptake of RAP, which reflects the limitations in existing evidence



Study Summary

Vanguard Objective: to assess the feasibility of a full-scale trial to determine whether an institutional policy of routine RAP versus a policy of crystalloid priming reduces intra- and post-operative RBC transfusion up to 72 hours after cardiac surgery

Study Design: Multi-centre, multiple period, cluster randomized crossover trial



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Study Summary (cont.)

Intervention: 2 hospital-based policies for the initiation of CPB during cardiac surgery

1. RAP
2. Crystalloid Priming

Duration

- 12 x 4-week crossover periods

Sample Size

- Vanguard: 4,500 patients across 4 sites
- Full Trial: 16,800 patients across 20 sites

Description of the Policies

Routine RAP Policy (intervention)	Crystalloid Priming Policy (control)
I. Use of arterial and venous autologous CPB priming in all adult patients undergoing cardiac surgery (minimum 300mL) II. Crystalloid priming acceptable for patients with a contraindication to RAP (≤ 10% expected; hemodynamic instability, need for emergency implementation of CPB) according to clinician discretion.	I. Use of crystalloid priming in all patients undergoing cardiac surgery II. RAP acceptable in patients with a contraindication to crystalloid priming (≤ 10% expected); refusal to receive transfusion, patients with rare blood types) according to clinician discretion

Primary and Secondary Outcomes

Phase	Primary Outcome(s)	Secondary Outcome(s)
Vanguard	• Feasibility of the trial protocol, defined as adherence ≥90% to both institutional policies applied in random sequence	• To collect data about critical parameters that affect the design and implementation of the full-scale trial
Full Trial	• The mean number of RBC units transfused within 72 hours of cardiac surgery per patient in each centre	• The mean number of RBC units transfused in-hospital up to 30-days • Incidence of transfusion at 72 hours and in-hospital up to 30-days • Incidence of acute kidney injury (AKI) at 72 hours and in-hospital up to 30-days • ICU and hospital length-of-stay • In-hospital mortality • Healthcare costs