

FARES-II Trial

A New Standard in Cardiac Surgery Bleeding Management

Octaplex® (4F-PCC) vs. Frozen Plasma (FP):

Evidence from a Landmark Phase III Study

(JAMA 2025 | Multicenter RCT in Canada & US)

The Problem: Bleeding in Cardiac Surgery



15% of patients undergoing cardiac surgery experience **excessive bleeding**

FP has long been the **standard** for bleeding management, despite **safety risks** (TRALI, TACO, anaphylaxis) and **limited robust data**

The FARES-II Study: What we did



12 Hospitals: 420 patients

4F-PCC: n = 213

FP: n = 207

Goal: Compare **4F-PCC vs. FP** for hemostatic efficacy and safety



Key Findings: Octaplex® (4F-PCC) Delivers Superior Results

4F-PCC significantly outperforms **FP** across multiple endpoints



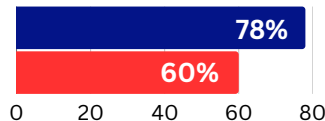
Efficacy Outcomes

Hemostatic Effectiveness

+17.6% improvement vs. FP

FP

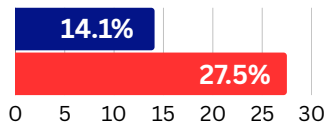
$P < 0.001$



Severe to Massive Bleeding

49% reduction vs. FP

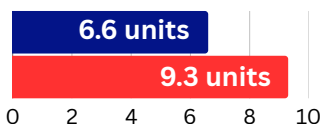
$P = 0.001$



Transfusion Needs

29% fewer blood transfusions vs. FP

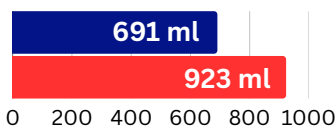
$P = 0.002$



24-hour blood loss

25% less chest tube drainage vs. FP

$P < 0.001$



4F-PCC **FP**

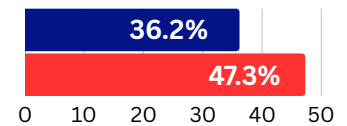


Safety Outcomes

Any Serious Adverse Events

23% lower incidence vs. FP

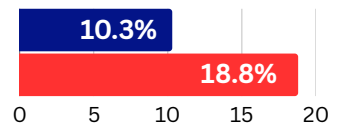
$P = 0.02$



Acute Kidney Injury

45% lower incidence vs. FP

$P = 0.02$



Why does this matter?

The data is clear, **now is the time to act.**

Octaplex® (4F-PCC) should be the **new standard**, presenting a significant step for **patient blood management**:

- **Optimize** blood product use
- **Minimize** unnecessary blood transfusions
- **Enhance** patient safety

4F-PCC, four-factor prothrombin complex concentrate; **FP**, frozen plasma; **n**, number of patients

Karkouti K, Callum JL, Bartoszko J, et al. Prothrombin Complex Concentrate vs Frozen Plasma for Coagulopathic Bleeding in Cardiac Surgery: The FARES-II Multicenter Randomized Clinical Trial. JAMA. Published online March 29, 2025. doi:10.1001/jama.2025.3501

Multicenter randomized clinical trial supported by:

octapharma