

# **Significant merits of a fibrin sealant in the presence of coagulopathy following paediatric cardiac surgery: Randomised controlled trial.**

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## **Abstract:**

**Objectives:** The efficacy of a fibrin sealant in paediatric cardiac surgery has been demonstrated. However, its effectiveness in the presence of significant untreated coagulopathy has not been addressed. This study was designed to investigate the role of the topical application of a fibrin sealant, Beriplast P (BP), in the presence of coagulopathy following paediatric cardiac surgery.

**Methods:** After confirming the presence of significant post-bypass coagulopathy, patients undergoing repair of congenital heart defects using cardiopulmonary bypass were randomised to the use of BP (group BP) or no intervention (group C). BP was applied over suture lines and microvascular bleeding sites. Criteria for transfusion of blood and blood products were standardised for both groups. Outcome variables were: (1) post-operative bleeding; (2) transfusion of blood and blood products; (3) theatre time to achieve haemostasis; (4) ventilation time, intensive therapy unit (ITU) and hospital stay.

**Results:** Fifty-two patients (n=26 in each group), aged 3 days to 17.4 years were recruited. There were no hospital deaths and no significant differences in demographic or intraoperative variables that might have affected the chosen endpoints. After protamine, all patients in both groups had significant coagulopathy ( $P \leq 0.05$  versus baseline). There were fewer patients receiving transfusions of fresh frozen plasma (FPP) in the intervention group, when compared to the control group ( $P \leq 0.05$ ). Patients receiving BP spent less time in theatre to achieve haemostasis ( $P \leq 0.05$ ), had a lesser amount of bleeding intraoperatively ( $P \leq 0.01$ ), at 4h ( $P \leq 0.05$ ) and at 24h ( $P \leq 0.05$ ), required a lower amount of transfusions of red cells ( $P \leq 0.01$ ), FPP ( $P \leq 0.05$ ) and platelets ( $P \leq 0.05$ ). There were no differences in ventilation time, length of stay in ITU or in hospital.

Conclusions: Even in the presence of significant coagulopathy, intraoperative use of fibrin sealant in paediatric cardiac surgery reduces the amount of bleeding and need for transfusions of blood and blood products. The theatre time necessary to achieve haemostasis is also significantly reduced. These findings have a potential to improve clinical outcomes and enhance cost benefits. © 2002 Elsevier Science B.V. All rights reserved.