Comparison of Fresh Frozen Plasma (FFP) and Plasmalyte® for priming cardiopulmonary bypass in infants and children undergoing open-heart surgery : A double-blinded, randomised study.

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Background and goal of the study

Few studies in infants have investigated whether the addition of FFP to the cardiopulmonary bypass (CPB) priming shows advantages in terms of bleeding and transfusion.^{1,2} We hypothesized that adding FFP to CPB priming is superior when compared with Plasmalyte®.

Material and methods

This prospective double-blinded randomised trial (NCT02567786) included children of all age weighing between 7-15 kg undergoing surgery with CPB. Exclusion criteria were coagulation abnormalities, renal and hepatic dysfunction. Primary endpoint is that adding 15 mL/kg FFP to CPB prime decreases bleeding and/or exposure to blood products up to 6h postoperatively when compared with 15 mL/kg Plasmalyte®. Secondary endpoint is the volume of transfused blood products. RBC was used in the CPB prime to prevent haemodilution and unblinding. The perfusionist was unblinded. Blood was drawn for thromboelastometry (ROTEM®) and platelet aggregometry (Multiplate®) after the induction of anaesthesia, at the end of CPB and at PICU arrival to help in deciding to transfuse in case of bleeding. In total, 60 children will be included. A Student's t-test, Mann-Whitney or Chi-square tests were used as appropriate.

Results and discussion

After informed parental consent 30 children were included. One patient in the Plasmalyte® group was excluded after inclusion because of refusal to continue.

Table 1: Baseline and intraoperative data

	FFP (N=16)	Plasmalyte (N=13)	p
Age (months)	25 ± 17	23 ± 14	0.66
Weight (kg)	10.4 ± 2.8	10.6 ± 2.4	0.82
Cyanotic heart disease	8 (50%)	6 (46%)	0.84
Baseline Hb (mg/dL)	13.7 ± 2.7	13.0 ± 2.6	0.47
Baseline platelets (*10 ³ /mm ³)	414 ± 113	304 ± 105	0.01
Baseline fibrinogen (mg/dL)	311 ± 91	331 ± 69	0.52
CPB time (min)	142 ± 57	158 ± 68	0.52
Redo surgery	7 (44%)	1 (8%)	0.03
Platelet count end of CPB (*10 ³ /mm ³)	192 ± 84	133 ± 57	0.04

Data are expressed as mean ± SD

Table 3: Post-operative data

	FFP (N=16)	Plasmalyte (N=13)	p
Blood loss 6h post-op (mL/kg)	6.4 (4.2 - 10.9)	6.0 (5.4 - 8.5)	0.79
Duration PICU stay	4 (2 - 6)	4 (3 - 5)	0.87
Duration of intubation (h)	5 (3-12)	4 (2 - 28)	1.0
Hospital stay (d)	11 (10-14)	12 (11-17)	0.36

*Data are expressed as median (P25 – P75)

Conclusions

- The preliminary results of this first double-blinded study show that in small infants priming CPB with FFP does not show beneficial effects in terms of bleeding and transfusion requirements and can be avoided.
- Our results need to be interpreted with caution as the baseline characteristics of the groups were not totally comparable.

References

1. Miao X. Perfusion 2015;
2. Bianchi P. BJA 2017

Table 2: Transfusion data

	FFP (N=16)	Plasmalyte (N=13)	p
N patients transfused (OR & PICU)	6 (38%)	8 (62%)	0.20
N blood products transfused (OR & PICU)	0 (0 - 1)	1 (0 - 2)	0.13
Volume blood products transfused (OR & PICU) (mL/kg)	21 (0 - 64)	38 (10 - 68)	0.29
Volume blood products transfused OR* (mL/kg)	7 (0 - 25)	19 (5 - 34)	0.12
N blood products transfused OR*	0 (0 - 1)	1 (0 - 2)	0.05
RBC (OR) (mL/kg)	7 (0 - 26)	15 (0 - 21)	0.44
RBC (PICU) (mL/kg)	0 (0 - 0)	0 (0 - 0)	0.68
FFP (OR) * (mL/kg)	0 (0 - 0)	0 (0 - 16)	0.08
FFP (PICU) (mL/kg)	0 (0 - 0)	0 (0 - 0)	0.37
Platelet concentrate OR (mL/kg)	0 (0 - 0)	0 (0 - 8)	0.10
Platelet concentrate PICU (mL/kg)	0 (0 - 0)	0 (0 - 0)	0.43

Data are expressed as median (P25 – P75)

* excluding the priming volume

OR: Operating Room; PICU: Paediatric Intensive Care Unit