Review of our experience with Recombinant Factor VIIa and FEIBA following cardiac bypass

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Introduction

- Recombinant factor VII (rFVIIa) and prothrombin complex concentrates such as Factor Eight Inhibitor Bypassing Activity (FEIBA) may be used to limit bleeding and allogenic blood product exposure after CPB.
- FEIBA has demonstrated to a similar safety profile for thrombosis as rFVIIa and is less expensive [J Cardiothorac Vasc Anesth 2014; 28: 1221-1226].
- In that adult population FEIBA is associated with correction of coagulopathy, decreased blood product utilization, and chest tube output [Review of Clinical Outcomes. J Cardiac Surg. 2008; 23:614-621].
- The safety and efficacy of FEIBA and rFVIIa use in massive blood transfusion in children undergoing arterial switch procedures has not been fully studied.

Methods

- An IRB-approved retrospective review of patients undergoing arterial switch procedures between January 2016 and September 2017 was preformed. Patient outcomes were compared by administration of FEIBA, rFVIIa, or neither.
- Due to limitations on sample size, the study was not powered for any specific outcome.

Table

Characteristic	Drug received (Median, IQR)			P-value		
	FEIBA (N=4)	rFVIIa (N=7)	Neither (N=9)	FEIBA vs none	rFVIIa vs none	FEIBA vs rFVIIa
OR blood product use (ml/kg)						
PRBCs	97 (84-112)	153 (118- 200)	88 (65-98)	0.537	**0.017**	**0.008**
FFP total	30 (13-43)	47 (40- 82)	23 (0-42)	0.696	**0.044**	0.186
Platelets	42 (38-49)	60 (38-107)	26 (23-46)	0.217	**0.010**	0.298
Cryoprecipitate	14 (9-16)	31 (16-42)	13 (12- 17)	0.440	0.101	**0.023**
CTICU blood product use (ml/kg)						
PRBCs	0 (0-0)	0 (0-45)	0 (0-0)	0.326	0.578	0.262
FFP	0 (0-11)	9 (0-35)	11 (0-11)	0.502	0.868	0.354
Platelets	0 (0-13)	0 (0-9)	5 (0-11)	0.502	0.322	0.904
Cryoprecipitate	0 (0-7)	0 (0-0)	0 (0-0)	0.754	0.816	0.575
Drying time (min)	93 (78-113)	150 (109-155)	95 (79-113)	>0.999	**0.034**	0.059
Chest Tube (CT) output (ml/kg)						
6 hours	5 (2-7)	21 (4-62)	18 (10-23)	**0.021**	0.711	0.131
24 hours	14 (7-19)	33 (15-63)	30 (23-41)	**0.045**	0.791	0.131
Coagulation profile						
Fibrinogen (mg/dL)	314 (56)*	353 (77)*	378 (143)*	0.418	0.345	0.401
PT (sec)	15 (14-16)	11 (10-13)	16 (16-18)	**0.044**	**0.001**	**0.014**
PTT (sec)	68 (64-76)	59 (50-79)	56 (47-74)	0.355	0.958	0.298
Length of Stay						
CTICU LOS (d)	5 (3-13)	6 (6-14)	3 (2-6)	0.257	**0.036**	0.566
Hospital LOS (d)	12 (9-24)	13 (11-19)	6 (6-9)	0.071	**0.009**	0.706

*Mean (Standard Deviation)

Results

- 20 neonates (17 boys & 3 girls) were included. Patient and operative characteristics were similar across groups. Procedural outcomes by product administration are detailed in table 1.
- There were no differences in the complication profile between the groups, including re-exploration (rFVIIa: 1, neither drug: 1) and open sternum (FEIBA: 1, rFVIIa: 4; neither drug: 3). One patient died postoperatively among those who received neither drug.
- PRBC, FFP, and Platelet administration was significantly higher in the rFVIIa vs Neither group.
- Postoperative chest tube output was significantly lower in the FEIBA vs Neither group.

Discussion

- Early administration of FEIBA was associated with reduced post-operative CT output, but had no effect on intra or post-operative blood product use.
- The practice of using rFVIIa as a rescue treatment may explain its association to increased OR blood product use, increased CT output, and increased LOS.
- The small sample size, retrospective nature of the study, and lack of outcome powering limit the ability to reach definitive conclusions.