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Project #05: Evaluation of Half-Dose Prothrombin Complex Concentrate in Cardiac Surgery

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Background

- Cardiac surgery inflicts multiple stressors on the coagulation system, sometimes leading to excessive bleeding post-cardiac surgery and requiring blood component transfusions.
- Pre-incision treatment with full-dose four-factor prothrombin complex concentrate (4F-PCC) (25 units/kg) has been used satisfactorily in reversing acute periprocedural bleeding time, volume, and associated costs.
- 4F-PCC poses a substantial cost burden on medical centers, with a cost of approximately \$1085 per 500-unit range vial.

Purpose

To evaluate the effectiveness of half-dose 4F-PCC (12.5 units/kg) use at Henry Ford Hospital and gain insight into optimal dosing and waste prevention strategies in the operating room

Objectives

- Characterize the incidence of half-dose 4F-PCC (~12.5 units/kg) use in cardiac surgery
- Assess the efficacy of half-dose 4F-PCC in patients who underwent cardiac surgery
- Identify patient-specific factors that relate to the use of half-dose 4F-PCC in patients who underwent cardiac surgery
- Elucidate the impact of potential drug waste and opportunity for cost savings

Methods

This is a retrospective chart review designed to evaluate the efficacy of half-dose 4F-PCC in patients undergoing cardiac surgery. Clinical data such as blood transfusion amount used and bleeding rates as well as demographic information will be collected from the electronic medical record (Epic).

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> Patients aged 18 and older Patients admitted to Henry Ford Hospital-Detroit from 7/30/2018 to 7/30/2023 Patients who are undergoing a cardiac surgical procedure Patients who received 12.5 units/kg 4F-PCC during surgery 	<ul style="list-style-type: none"> Special populations such as pregnancy, incarcerated, diminished capacity

Results

Study Population

Figure 1: Patient Enrollment



Table 1: Patient Demographics	
	4F-PCC (n=10)
Age (years), mean (SD)	64 (7.3)
Sex, n (%)	
Male	6 (60)
Race, n (%)	
White	6 (60)
African American	1 (10)
Asian	1 (10)
Not Listed	2 (20)
Scr (mg/dL), mean (SD)	1.25 (0.5)
Weight (kg), median (IQR)	83.7 (79.7, 95.2)
BMI (kg/m ²), mean (SD)	30.32 (3.2)
DM, n (%)	1 (10)
CKD, n (%)	2 (20)
HTN, n (%)	6 (60)
CAD, n (%)	3 (30)
HLD, n (%)	3 (30)
Atrial Fibrillation, n (%)	1 (10)
Liver Disease, n (%)	1 (10)
Active Cancer, n (%)	2 (20)
Risk Factors, n (%)	
Smoker	1 (10)
Alcohol Use	1 (10)
Coagulopathies	0
Outpatient Anti-Platelet, Anticoagulant Use, or NSAID use	0
Type of Surgery, n (%)	
CABG	1 (10)
Heart Transplant	1 (10)
Heart valve repair or replacement	5 (50)
Aortic Repair or replacement	3 (30)

BMI= Body mass index; DM= Diabetes Mellitus; CKD= Chronic kidney disease; HTN= Hypertension; CAD= Coronary artery disease; HLD= Hyperlipidemia; NSAID= Non-Steroidal Anti-Inflammatory Drugs

Efficacy

Figure 2: Hematology Labs

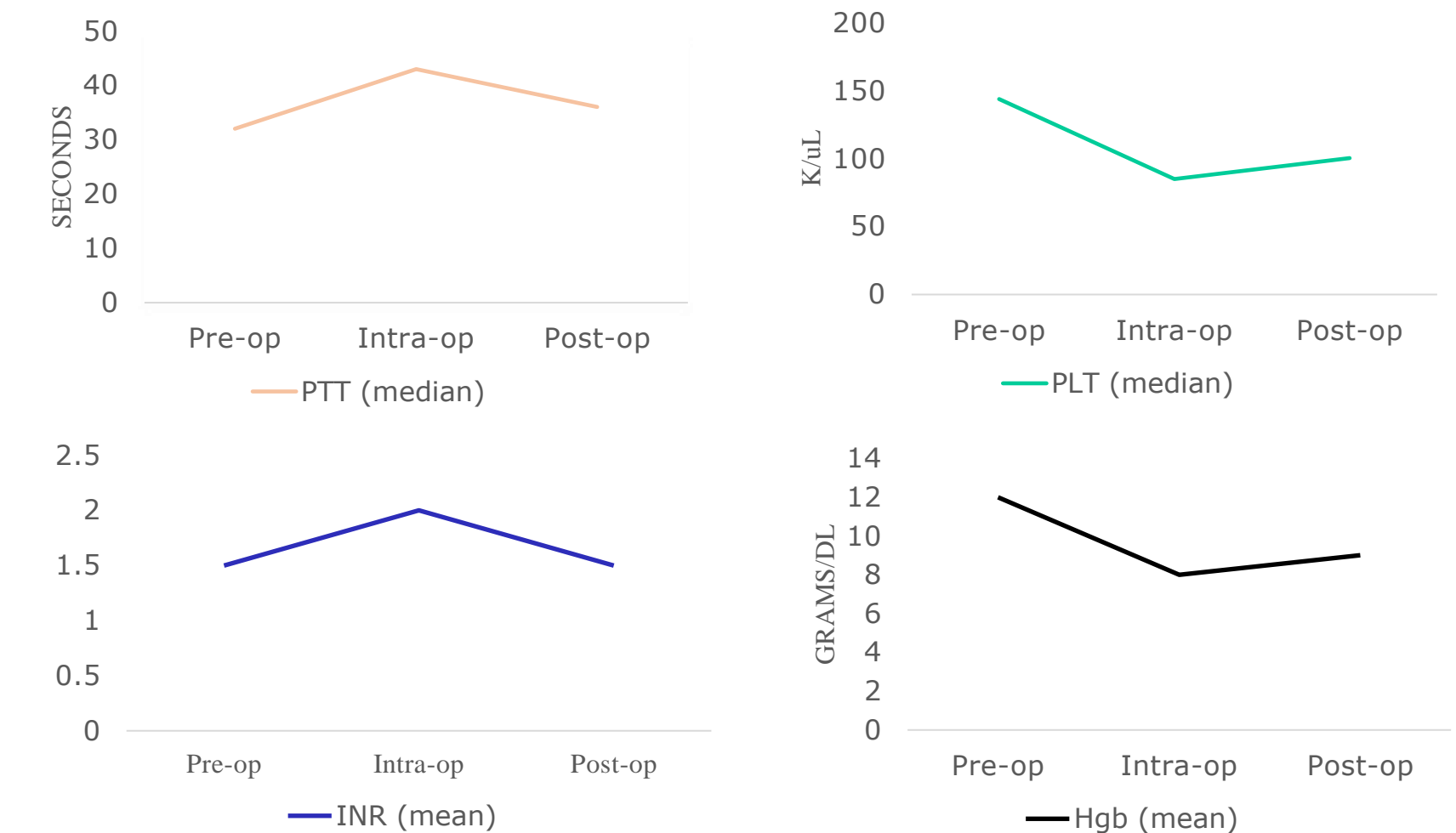
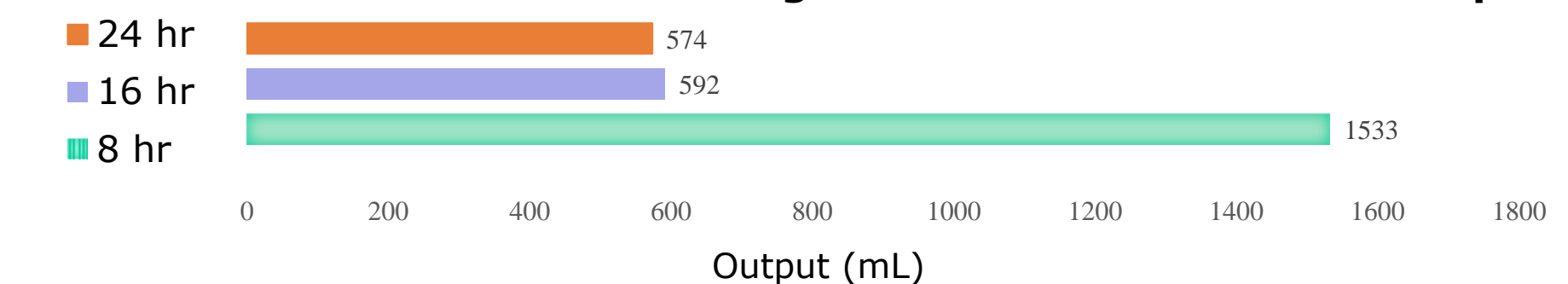


Table 2: 4F-PCC and Output

4F-PCC Dose (units), median (IQR)	1069 (1068,1191)
Estimated Cost (\$), median (IQR)	2319.73 (2318.10, 2584.31)
Time 4F-PCC given intra-op after start time (hrs), mean (SD)	6 (0.1)
BARC Class, n (%)	
3b	1 (10)
3c	1 (10)
4	1 (10)
Chest tube output (mL), median (IQR)	
8 hr	1533 (1039,1607)
16 hr	592 (456,982)
24 hr	574 (397,784)

Figure 3: Median Chest Tube Output



Conclusions

In a small sample of patients undergoing cardiac surgery, half dose 4F-PCC appeared safe and effective when used intraoperatively.

Future Directions

- Additional safety and efficacy studies with a larger sample size are needed to determine the optimal dosing strategy and efficacy of half-dose 4F-PCC during cardiac surgery
- Future studies should examine pharmacoeconomic opportunities using half-dose 4F-PCC