

Category :**Hematology: bleeding\transfusion**

A288 - Comparison of coagulation parameters associated with fibrinogen concentrate and cryoprecipitate in the treatment of bleeding in pseudomyxoma peritonei surgery: results from the prospective, randomized, controlled phase 2 forma-05 study

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Introduction:

The FORMA-05 study compared hemostatic efficacy and safety of human fibrinogen concentrate (HFC) vs cryoprecipitate for bleeding patients with acquired fibrinogen deficiency undergoing cytoreductive surgery (CRS) for pseudomyxoma peritonei (PMP). Maintaining adequate levels of coagulation proteins, including plasma fibrinogen concentration, during CRS are important to help control hemostasis.

Methods:

FORMA-05 was a single-center, prospective, randomized, controlled Phase 2 study. Patients undergoing PMP surgery with predicted intraoperative blood loss ≥ 2 L received HFC (4 g) or cryoprecipitate (2 pools of 5 units, approximately 4.0–4.6g fibrinogen), repeated as needed. Plasma fibrinogen concentration (measured using Clauss assay) and FIBTEM A20 (measured using thromboelastometry) were measured hourly intraoperatively, while Factor (F) XIII, FVIII, von Willebrand Factor (VWF) levels, standard laboratory tests and endogenous thrombin potential (ETP) were measured every two hours. Post-surgery, all parameters were measured at 6, 12, 24, and 28 hours, and 10 days.

Results:

The full analysis included 45 patients on either HFC (n=22) or cryoprecipitate (n=23). The intraoperative and postoperative changes in ETP and fibrinogen concentration are shown in **Table 1**. For FIBTEM A20 (intraoperatively) and fibrinogen concentration (intraoperatively and postoperatively), the mean numerical values appeared higher with HFC than cryoprecipitate. FXIII (HFC: 121.86%, 66.85%; cryoprecipitate: 115.55%, 68.68%, at baseline and 4hr after surgery start), FVIII and VWF were maintained throughout surgery in both treatment groups. This was also the case for laboratory tests activated partial thromboplastin time, prothrombin time and platelet count.

Conclusion:

The FORMA-05 coagulation parameters analyses showed broad overlaps between HFC and cryoprecipitate, with satisfactory maintenance of the clot quality parameters, FXIII concentrations and thrombin generation parameters.

Table:

Parameter	Endogenous thrombin potential (nmol/L/min)	Endogenous thrombin potential (nmol/L/min)	Plasma fibrinogen concentration (g/L)	Plasma fibrinogen concentration (g/L)
Treatment group	HFC	Cryoprecipitate	HFC	Cryoprecipitate
Baseline mean	1514.5 (430.6)	1639.1 (339.1)	4.79 (1.316)	4.50 (1.497)
Interoperative, 2hr after surgery start, mean (SD)	1673.5 (340.1)	1690.2 (320.2)	3.20 (0.722)	2.67 (0.984)

Interoperative, 6hr after surgery start, mean (SD)	1310.7 (171.2)	1260.7 (342.2)	2.34 (0.610)	1.91 (0.543)
Postoperative end-of- surgery, mean (SD)	1225.4 (220.7)	1346.4 (243.6)	2.21 (0.515)	2.08 (0.562)
2 days after surgery end, mean (SD)	1263.44 (176.9)	1385.6 (301.6)	5.47 (0.832)	5.24 (0.818)
10 days after surgery end, mean (SD)	1426.16 (260.4)	1357.0 (349.5)	6.62 (1.484)	6.48 (1.685)

HFC, human fibrinogen concentrate; SD, standard deviation