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Use of Fibrinogen Concentrate in Surgical and Bleeding Trauma Patients

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Abstract: Fibrinogen concentrate has emerged as a key agent in the management of acquired hypofibrinogenemia in both surgical and bleeding trauma settings. Evidence suggests it can reduce transfusion requirements, improve clot stability, and support hemostasis when used promptly and guided by point-of-care viscoelastic testing. This review examines the pharmacological background, clinical applications, efficacy, safety, and evolving protocols for fibrinogen concentrate in surgical and trauma patients, with data visualizations to highlight key findings.

Keywords: Fibrinogen concentrate, Hypofibrinogenemia, Hemostasis, Trauma surgery, Viscoelastic testing.

INTRODUCTION

Acquired hypofibrinogenemia, characterized by a fall in plasma fibrinogen below critical thresholds, critically impairs clot formation in major bleeding related to surgery or trauma. Traditional therapies such as fresh frozen plasma (FFP) and cryoprecipitate have limitations including slow administration, non-standardized dosing, and risk of transfusion reactions. Human fibrinogen concentrate (FC) is an increasingly adopted alternative offering rapid administration and consistent dosing. Its role, however, remains a topic of active investigation due to variable results and ongoing questions about cost-effectiveness and safety.

BACKGROUND AND MECHANISM

- **Fibrinogen** is the first coagulation factor to fall to critical levels in severe bleeding.
- **FC** is a lyophilized plasma-derived product standardized to deliver precise doses, quickly reconstituted and administered intravenously.
- **Mechanism:** FC directly replenishes depleted fibrinogen, restoring thrombin-mediated polymerization and supporting robust clot formation. Its efficacy can be monitored by assays such as FIBTEM (ROTEM) or Clauss fibrinogen[1][2].

Indications for Use

- **Guidelines suggest FC** for acquired hypofibrinogenemia—most commonly defined as fibrinogen <1.5–2.0g/L—in major bleeding (including cardiac, hepatic, obstetric, or trauma surgery)[1][3].
- In trauma, FC may be given pre-emptively when massive hemorrhage or traumatic coagulopathy is suspected or confirmed[3][4][5].
- European trauma and anesthesia societies endorse FC as a first-line therapy in bleeding patients when viscoelastic signs of fibrinogen deficit are present.

Efficacy in Surgical Patients

A meta-analysis of 14 randomized controlled trials (RCTs) (1,035 patients, mostly in cardiac surgery) found:

- **Mortality:** Lower in fibrinogen group (0.9% vs 3.5%, risk ratio 0.26, p=0.02)[2].
- **Blood loss:** Reduction of 127mL mean in patients given FC compared to controls.
- **Red blood cell transfusion:** Decrease in units transfused (mean difference −0.9 units).
- **Thrombotic events:** No significant difference in major complications[2][1].

Table 1. Clinical Outcome in Surgical Patients Receiving Fibrinogen Concentrate[2][1]

Outcome	Fibrinogen Group	Control Group	p-value
Mortality (%)	0.9	3.5	0.02
Blood Loss (mL)	Decreased by 127	—	0.002
RBC Units Transfused	Decreased by 0.9	—	<0.001

Efficacy in Bleeding Trauma Patients

Early Administration

- Early use of FC in trauma patients protects against fibrinogen depletion, improves clot stability, and is feasible even in prehospital settings[5].
- A multicentre pilot RCT found that within 1 hour of arrival, patients receiving FC had increased FIBTEM maximum clot firmness (MCF), maintained plasma fibrinogen above 2.0g/L, and avoided the significant decrease seen in placebo[5].
- Observational and propensity-matched studies report improved in-hospital survival among severe trauma patients who received FC early after admission, though data are still emerging[4][6].

Table 2. Selected CT and Survival (Trauma Patients)[4][5][7]

Outcome	Fibrinogen Group	Control Group	p-value
FIBTEM Clot Firmness (MCF)	Increased	Decreased	<0.0001
Plasma Fibrinogen level	Maintained >2.0	Fallen <1.5	—
In-hospital Survival (%)	Higher	Lower	0.013

Safety and Adverse Effects

- Rates of thromboembolic events and myocardial infarction are not increased in current RCTs or cohort studies[2][1].
- FC is pathogen-inactivated and has a strong safety track record over decades[1].
- Infusion reactions are rare; the key risks remain overcorrection (thrombosis) and cost.
- Limited data are available on long-term complications in highly comorbid populations.

Practical Approaches to Dosing

- **Weight-based dosing:** Common initial dose is 2–4g IV, titrated to effect and guided by fibrinogen measurement or viscoelastic testing[3].
- Repeat dosing may be needed in persistent or ongoing bleeding, guided by labs or clinical effect.

Advantages Versus Traditional Products

- **Cryoprecipitate/FFP:** Slower to administer, risk of viral and allergic reactions, inconsistent fibrinogen content[1].

- **FC:** Rapid, standardized, low-volume preparation, no risk of ABO incompatibility, and pathogen inactivation[1][2].

Limitations of Current Evidence

- Most data are derived from cardiac and trauma surgery; conclusive results for other surgical areas or universal survival benefit are lacking[2][1].
- Many RCTs are small, heterogenous, and sometimes underpowered for hard outcomes such as mortality or thromboembolic complications[2].

Future Directions

- Additional large-scale, well-powered trials are needed to clarify optimal patient selection, dosing regimens, cost-effectiveness, and clinical outcome impact[1][2].
- Personalized protocols factoring in point-of-care coagulation monitoring (e.g., ROTEM/TEG) show promise in refining FC use.

Data Visualization

Figure 1. Effect of Fibrinogen Concentrate on Blood Loss and RBC Transfusion in Surgical Patients

A bar graph would illustrate the average reduction in blood loss (−127mL) and red cell units (−0.9 units) in FC groups versus controls, with error bars for confidence intervals.

Figure 2. Survival Rate of Trauma Patients After Early Fibrinogen Concentrate Administration

A Kaplan-Meier curve could depict higher in-hospital survival in FC-receiving trauma patients versus matched controls (p=0.013).

CONCLUSION

Fibrinogen concentrate has established itself as a valuable evidence-based therapy for the correction of hypofibrinogenemia in both surgical and severely bleeding trauma patients. Applied early and in targeted fashion—often using viscoelastic monitoring—it reduces transfusion need, supports clot formation, and may improve survival in select populations. Its safety profile is reassuring, but further data on long-term outcomes, broader indications, and cost-effectiveness are still needed to cement its place in hemostatic management.

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