



Real-World Utilization of Human Fibrinogen Concentrate in Managing Bleeding in Adult and Pediatric Patients: A Retrospective Study

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INTRODUCTION

- Fibrinogen is an essential component of clot formation, clot strength, and clot integrity.¹
- Fibrinogen deficiency can be either congenital, due to genetic mutations, or acquired.²
- Acquired fibrinogen deficiency is more common and can present due to certain diseases, trauma, excessive surgical bleeding, or post-partum hemorrhage as a result of increased coagulation factor consumption and/or reduced factor production.²
- Transfusion of human fibrinogen concentrate can potentially correct this deficiency, limiting, or even preventing hemorrhage, excessive blood loss, and transfusion.³
- Human fibrinogen concentrate is provided as a freeze-dried, pathogen-reduced substance that is often available in the operating room and can be administered immediately without the need for thawing or blood bank management.²⁻⁴

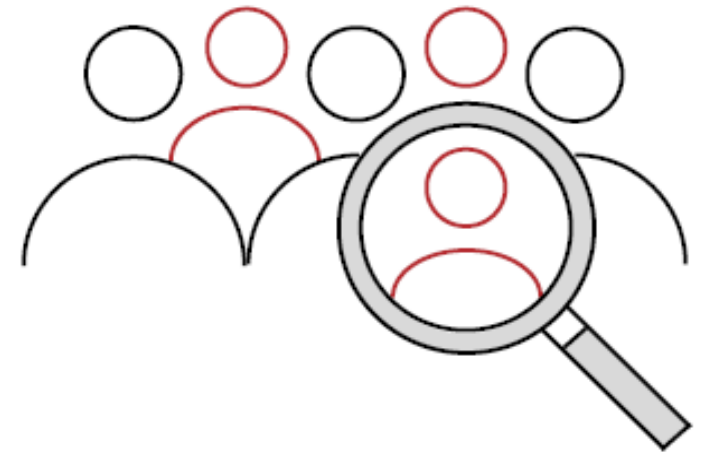


AIM

This observational, retrospective study assessed the use and efficacy of human fibrinogen concentrate at a single institution.

METHODS

- A retrospective investigation of acquired fibrinogen deficiency was conducted at Vanderbilt University Medical Center.
- The main objective of the study was to determine the specific circumstances of human fibrinogen concentrate [Fibryga] use in this real-world setting.
- The secondary objective was to assess the success of treatment, defined as the ability to effectively control or prevent bleeding.
- Data were gathered regarding the characteristics of the patients, indications for human fibrinogen concentrate use, and pre-dose and post-dose laboratory evaluations (including hemoglobin and fibrinogen activity), and the resulting clinical outcomes.
- Treatment efficacy was assessed based on the management of bleeding and maintenance of hemoglobin levels with hemostatic success defined as a <20% decrease in hemoglobin from initial values.

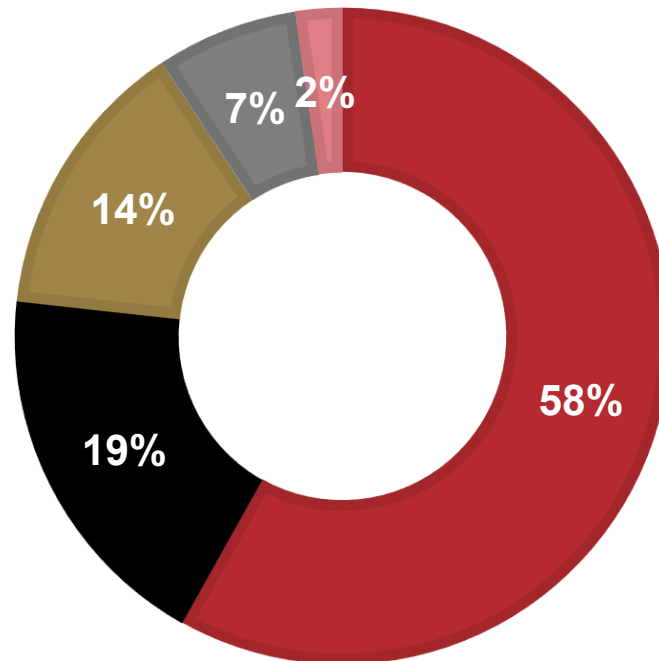


RESULTS

Study Population

The study population (N=43) was comprised of adults (n=40 [93.0%]) and children (n=3 [7.1%]) with acquired fibrinogen deficiency.

- Postpartum Hemorrhage
- Liver Disease
- Pulmonary
- Cardiac Surgery
- Trauma



RESULTS (continued)

Study Population

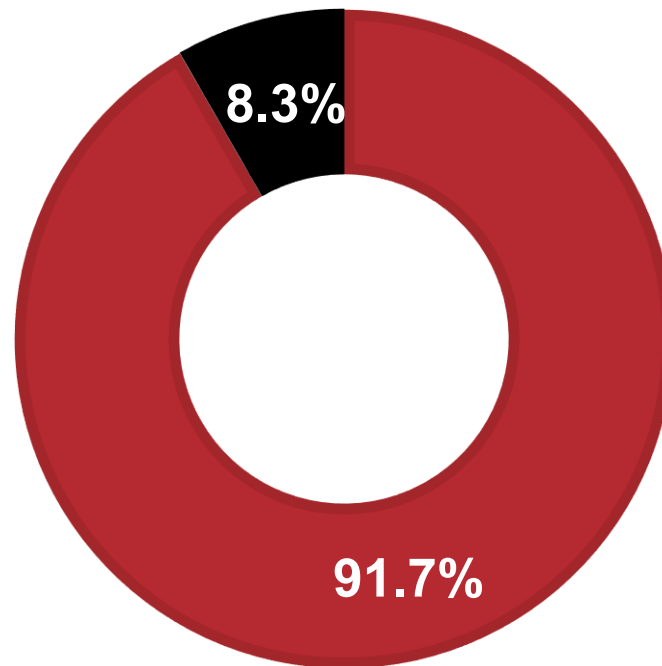
Patient Characteristics	Total Patients	Pediatric Patients <18 years	Adult Patients ≥18 years
N, %	43 100.0%	3 7.1%	40 93.0%
Age [years]			
Mean (SD)	35.7 (16.5)	6.2 (9.4)	37.9 (14.7)
Median (range)	33 (0.5-72)	1 (0.5-17)	34 (19-72)
Sex n (%)			
Female	30 (69.8%)	2 (66.6%)	28 (70.0%)
Male	13 (30.2%)	1 (33.3%)	12 (30.0%)
Past Medical History, n (%)			
Coronary heart disease	7 (16.3%)	0 (0.0%)	7 (17.5%)
Myocardial infarction	6 (13.9%)	0 (0.0%)	6 (15.0%)
Thromboembolic events	6 (13.9%)	1 (33.3%)	5 (12.5%)
Concomitant Medications, n (%)			
Tranexamic acid	27 (62.7%)	2 (66.6%)	25 (62.5%)
Acquire Fibrinogen Deficiency, n (%)			
Cardiac surgery	8 (18.6%)	1 (33.3%)	7 (17.5%)
Liver disease	6 (13.9%)	0 (0.0%)	6 (15.0%)
Post-partum hemorrhage	25 (58.1%)	0 (0.0%)	25 (62.5%)
Pulmonary	1 (2.3%)	1 (33.3%)	0 (0.0%)
Trauma	3 (6.9%)	1 (33.3%)	2 (5.0%)
Surgical vs. Nonsurgical, n (%)			
Surgical	11 (25.6%)	1 (33.3%)	10 (25.0%)
Nonsurgical	32 (74.4%)	2 (66.7%)	30 (75.0%)

RESULTS *(continued)*

Hemostatic Success

Hemostatic success was achieved in 91.7% of patients (n=36; patients with pre- and post-dose hemoglobin levels), resulting in effective bleeding control.

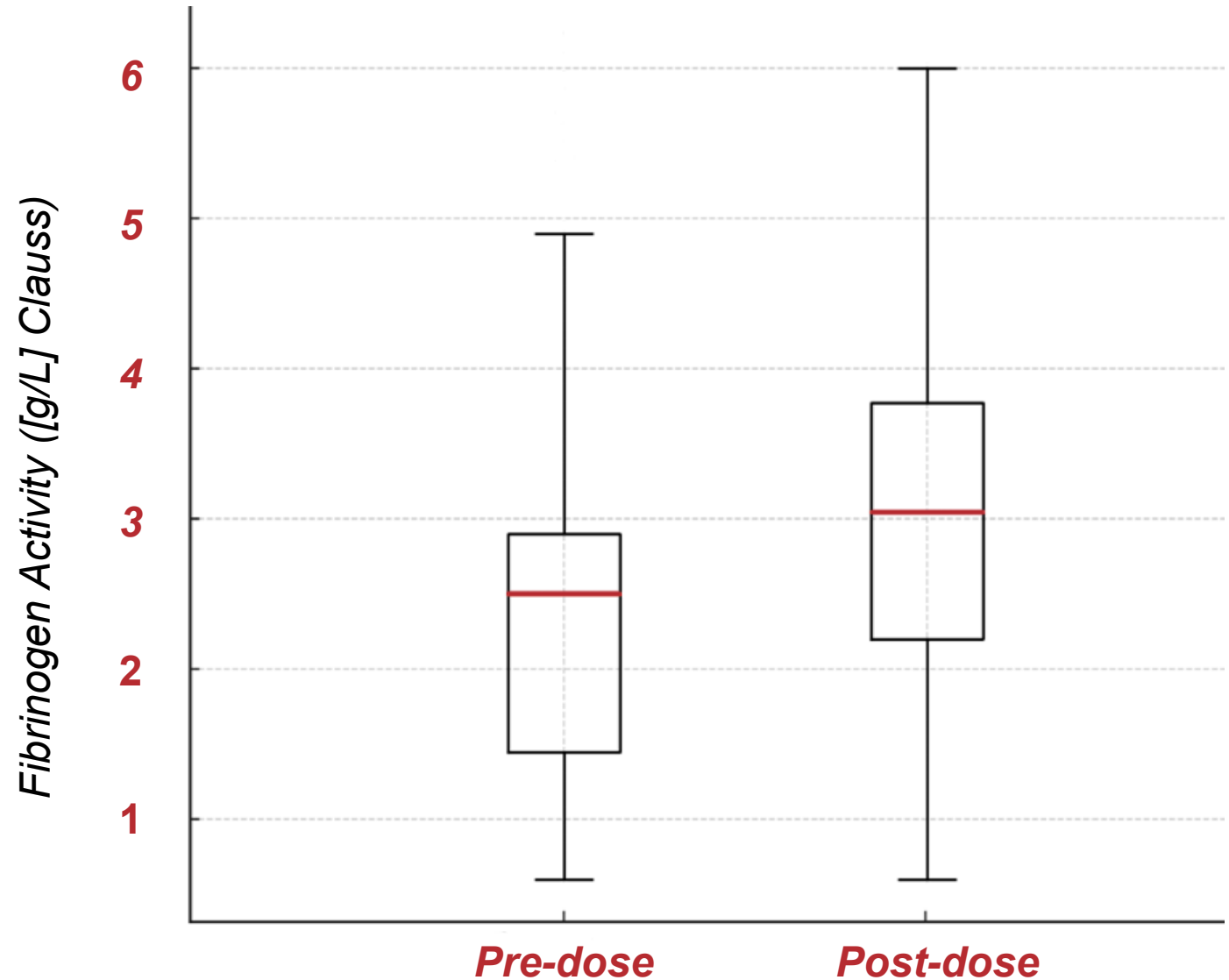
Hemostatic success was defined as a <20% decrease in hemoglobin from initial values (n=36).



RESULTS *(continued)*

Fibrinogen Levels

- There was an increase-in fibrinogen levels following administration of human fibrinogen concentrate, with mean pre-dose levels of 2.4 g/L and mean post-dose levels of 3.1 g/L after the first infusion (n=38 [88.4%]; patients with pre- and post-dose fibrinogen levels [Clauss]).



CONCLUSIONS

- Human fibrinogen concentrate can successfully manage bleeding in patients with acquired fibrinogen deficiency.
- Human fibrinogen concentrate can be used in many clinical scenarios, including surgical and nonsurgical hemorrhage.
- The practical nature of reconstitution and administration of human fibrinogen concentrate has the potential to provide successful patient outcomes with improved clinical workflows.

References

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3. Stéphan F, Gutermann L, Bourget S, et al. Real-world experience with a human fibrinogen concentrate: clinical data from adult and pediatric patients requiring fibrinogen for bleeding control and prevention. *J Clin Pharmacol.* 2023;63:1186-1196.
4. Octapharma. Fibryga Prescribing Information. Available at: https://fibrygausa.com/20240731_pil_347_17.16_US_en.pdf. Accessed November 1, 2024.