

Category : **Hematology: bleeding\transfusion**

A481 - First real-world experiences with a new human fibrinogen (fibryga®) in france based on temporary authorization

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Introduction:

The objective of the study was to describe the conditions of use of FIBRYGA® 1g, a new, highly purified, human fibrinogen (HF) recently granted a temporary import authorization for use in congenital and acquired fibrinogen deficiencies in France.

Methods:

Observational, non-interventional, non-comparative, retrospective study conducted in 5 French hospital centres using FIBRYGA®. Data from patients with fibrinogen deficiency having received FIBRYGA® from December 2017 to July 2019 were retrieved from their medical files. Indications, modalities, efficacy and safety outcomes were recorded. Indications encompassed non-surgical bleeding (NSB) either spontaneous or traumatic, including post-partum haemorrhage (PPH), bleeding during surgery (SB) or administration to prevent bleeding during planned surgery. Treatment success was defined as control of the bleeding or haemoglobin loss <20% for bleeding treatment and as absence of major perioperative haemorrhage for pre-surgical prevention.

Results:

This analysis included 110 patients aged $56,7 \pm 17,7$ years and 60% were male. All presented an acquired fibrinogen deficiency requiring administration of HF. Indications were NSB (n=45, 40.9%) including 15 (13.6%) PPH, SB (n=31, 28.2%), and prevention of SB (n=34; 30,9%). Cardiac surgeries were the main procedures associated with treatment and prevention of SB. Mean total doses of FC were $2.95 \pm 1.66g$, $2.00 \pm 1.37g$ and $2.21 \pm 1.23g$ for NSB, SB and prevention of SB. Success rates were 88.4% (95%CI 78.8-98.0%), 96.8% (95%CI 90.6-100%) and 91.2% (95%CI 81.6-100%) respectively. For PPH, mean dose of HF was $2.53 \pm 0.74g$ with a success rate of 86.7% (95%CI 69.5-100%). Overall, tolerance was good.

Conclusion:

Fibrinogen concentrate FIBRYGA® is mostly used for bleeding control. In one third of patients, HF was administered preventively to avoid bleeding during surgery. Use of FIBRYGA® was associated with favourable efficacy outcomes.