

Emotional or evidence based medicine – is there a moral tragedy in haemostatic therapy?

Sibylle Kozek-Langenecker^{1, #}, Benny Sørensen^{2,3}, John Hess⁴ and Donat R Spahn⁵.

¹Department of Anaesthesia and Intensive Care, Evangelical Hospital Vienna, Hans-Sachs-Gasse 10-12, 1180-Vienna, Austria

²Haemostasis Research Unit, Centre for Haemostasis and Thrombosis, Guy's and St Thomas' Hospital & King's College London School of Medicine, Westminster Bridge Road, London, UK SE1 7EH

³Centre for Haemophilia and Thrombosis, Aarhus University Hospital, Skejby - Brendstrupgårdsvej 100, Skejby, Denmark, 8200

⁴University of Maryland School of Medicine, Department of Pathology, 10 South Pine Street, MSTF, Baltimore, Maryland, USA, 21201-1192

⁵Institute of Anaesthesiology, University Hospital Zurich, Raemistrasse 100, 8091 Zurich, Switzerland

Corresponding author: S. Kozek-Langenecker: sibylle.kozek@aon.at

Sir,

We strongly recommend that critical evaluation of medical practice is based on evidence rather than emotional reaction. Surprisingly, Stanworth & Hunt [1] seem to resort to the latter in response to our review. [2] Their questioning of ethics and morals appears unjustified, since we fully acknowledged multiple, serious limitations of the current evidence and methodologies within our review. They claim “the danger of this review is that the message supports a move toward greater use of fibrinogen concentrate without proper evaluation”, ignoring our final statement that “more high-quality, prospective studies are required before any definitive conclusions can be drawn”.

Proposing cryoprecipitate as an alternative source of fibrinogen is irrelevant in most European countries, where cryoprecipitate is not used due to safety concerns. [3] Cryoprecipitate is no longer regarded as appropriate therapy for hereditary bleeding disorders in Europe, the US or the UK, hence its administration for acquired coagulopathies represents a double standard. [4]

Fibrinogen concentrate was first licensed in Brazil 1963. Over 3 million grams have been used since 1985, mainly in countries where fibrinogen concentrate has approval for acquired bleeding. In Germany, Austria and Switzerland, fibrinogen concentrate represents standard of care in most hospitals; it is typically used as first-line haemostatic intervention. Restricting use of fibrinogen concentrate to clinical trials as suggested by Stanworth & Hunt seems absurd – consistent application of this principle would abolish the use of all blood bank products.

If there is a “moral tragedy”, it is the acceptance of FFP and cryoprecipitate in practice, despite the absence of evidence to confirm efficacy. [3,5]

References

1. Stanworth SJ, Hunt BJ: **The desperate need for good-quality clinical trials to evaluate the optimal source and dose of fibrinogen in managing bleeding.** *Crit Care* 2011, **15**(6):1006.
2. Kozek-Langenecker S, Sorensen B, Hess J, Spahn DR: **Clinical effectiveness of fresh frozen plasma compared with fibrinogen concentrate: a systematic review.** *Crit Care* 2011, **15**(5):R239.
3. Sorensen B, Bevan D: **A critical evaluation of cryoprecipitate for replacement of fibrinogen.** *Br J Haematol* 2010, **149**(6):834-843.
4. Bevan DH: **Cardiac bypass haemostasis: putting blood through the mill.** *Br J Haematol* 1999, **104**(2):208-219.
5. Stanworth SJ, Brunskill SJ, Hyde CJ, McClelland DB, Murphy MF: **Is fresh frozen plasma clinically effective? A systematic review of randomized controlled trials.** *Br J Haematol* 2004, **126**(1):139-152.