Author's response to reviews

Title: Administration of fibrinogen concentrate for refractory bleeding in massively transfused, non-trauma patients with coagulopathy A retrospective study with comparator group

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Author's response to reviews: see over
Prof. Jean-Louis Vincent, Editor –in –Chief, Critical Care

Seville, April 3rd 2013

Dear Prof. Vincent,

Please, fin enclosed the manuscript of our study “Efficacy of the prothrombin complex concentrate Prothromplex ® in patients requiring urgent reversal of vitamin K antagonists or presenting with uncontrolled bleeding” that we would like to be considered for publication in Critical Care.

Nowadays, the administration of prothrombin complex concentrate (PCC), rather than plasma frozen fresh, is recommended for reversing the anticoagulant effects of vitamin K antagonists (VKA+). Three 4-factors PCCs are used widely in Europe for this purpose: Prothromplex, Beriplex and Octaplex. However, the effectiveness of PCCs has been only assessed for the latter two compounds, and no data have been yet published on the effectiveness of Prothromplex ®, despite its wide use.

In addition, very few articles have been published on the use of PCC in situations of uncontrolled bleeding, when conventional therapy with blood products fails to control/arrest haemorrhage. Most of these patients are not receiving VKA (VKA-), and the indication PCC administration in this clinical context is controversial, as there are neither data documenting its efficacy nor recommendations on its use.

We report here our experience with Prothromplex ®. We believe that our study may be of interest because, as far as we now, this is the largest series (n=142) reported to date on the use of Prothromplex ®, in both VKA+ and VKA- patients.

We appreciate the opportunity of our manuscript being peer-reviewed and look forward to your decision on our contribution to Critical Care, in due time.

Competing interests

Santiago R Leal-Noval has received research funding from, CSL Behring and Baxter. He has also received honoraria for consultancy and/or travel support from CSL Behring, Baxter and Octapharma. Victoria Arellano has received research funding from CSL Behring and Baxter. Other authors declare no competing interest.

Authors’ contributions

Santiago R Leal-Noval conceived and conducted and directed the clinical work. Other authors collected clinical data and helped to draft the manuscript. All authors read and approved the final manuscript.

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Sincerely,

S. R. Leal-Noval, MD, PhD