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2173-5727/

Improvement of the safety of a clinical process using failure mode and effects analysis: Prevention of venous thromboembolic disease in critically ill patients☆

Mejora en la seguridad de un proceso clínico utilizando el análisis modal de fallos y efectos: profilaxis de la enfermedad tromboembólica venosa en pacientes críticos

Dear Editor,

In the first place, we would like to thank you for your interest in our work. The goal of this work was to use the methodology from the Modal Analysis of Errors and Effects and implement a series of measures in order to improve this process and optimize the patient's safety (PS) on everything that has to do with the venous thromboembolic disease (VTED). One of these measures was the implementation of a 2014 protocol that was not fully developed in our paper because it was not the main goal of our work. However, while we were developing such protocol, seven special situations were established, among them, the management of renal failure (RF) that suggested the adjustment of enoxaparin based on the creatinine clearance (CrCl) rate, and according to the recommendations established by the Spanish Agency of Medicine and Medical Devices, and the Spanish Society of Hospital Pharmacy.[1] At the same time, if the patient remained under continuous renal replacement therapy, the same dose than without RF was used since no bioaccumulation has been confirmed so far.[2] Even so, we rather measure the concentrations of the anti-factor Xa as a safety measure because even though it has some limitations such as the absence of a clear correlation between the levels of anti-Xa and adverse events, or the poorly-established range of prophylactic levels, until these issues are resolved, it is still the best tool we have today to assess the effect of low-molecular-weight heparin (LMWH).

Enoxaparin was the only LMWH used in our study, which is the usual practice in 90 per cent of the intensive care units (ICU) in Madrid and nationwide, where enoxaparin and bemiparin are used in 95.2 per cent of ICUs.[3] Such a decision may be triggered by a lack of evidence favoring one particular molecule over another in terms of effectiveness. All the indications for enoxaparin have already been approved as its technical label confirms and, in these cases, we can reduce its dose as long as we follow the guidelines for VTED prevention and those from the very paper they mention. Also, while enoxaparin; dalteparin; tinzaparin; or nadroparin are comparable, they are not interchangeable, require different doses and use different units of measurement. This may be problematic when it comes to PS, which is precisely what the Medication Errors Reporting Program claimed after confirming deaths of patients, due to confusion when using different heparin molecules.[4] Finally, there is still controversy on issues such as bioaccumulation, and recent studies have concluded that the prophylactic use of enoxaparin in patients with CrCl rates $\leq$30 ml/min[5] is safe.

One of the characteristics of the ICU patient is his dynamicity. Just as we said in our work, another one of the measures for improvement suggested was the introduction of one daily PS checklist, and another bedside PS check-list, which is when we will proceed to adjust the VTED prevention measures.

For all the aforementioned, and with the only goal of optimizing the safety of our patients, we believe that the strategy adopted is the right one based not only on the evidence available, but also on our own experience after the implementation of the protocol.

Funding

Grants for the development of research projects awarded by The Healthcare Research Institute of Hospital 12 de Octubre, i+12, sponsored by AMGEN S.A.

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☆ Please cite this article as: Viejo Moreno R, Sánchez-Izquierdo Riera JA, Molano Álvarez E, Barea Mendoza JA, Temprano Vázquez S, Díaz Castellano L, et al. Mejora en la seguridad de un proceso clínico utilizando el análisis modal de fallos y efectos: profilaxis de la enfermedad tromboembólica venosa en pacientes críticos. Med Intensiva. 2018;42:135–136.

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