Critical appraisal of evidence

Could performance bias have influenced the prevention of pressure ulcers obtained with neuromuscular electrical stimulation in critically ill patients?

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ABSTRACT: This article aims to describe and reflect on a possible performance bias found in the randomized clinical trial by Baron et al, on the effectiveness of neuromuscular electrical stimulation for the prevention of pressure ulcers in critically ill patients.

KEYWORDS: Pressure Ulcer. ICU. Bias.

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First, I congratulate Baron et al.[1] for the important and relevant randomized clinical trial (RCT) developed with the aim of elucidating the effects and safety of neuromuscular electrical stimulation (NMES) for the prevention of pressure ulcers in critically ill patients. It is noteworthy that this RCT, taking into account the methodological quality, reduces the risk of some biases when performing the randomization of its sample and its allocation in a hidden way. However, it is important here to point out the existence of a methodological aspect related to the blinding process in the study that may have greatly influenced the results found and therefore, deserves to be described as a limitation of this study. In this context, although the study was conducted with the blinding of the evaluators, it is important to point out that it was not possible to blind the performers of the intervention, as well as the multidisciplinary team, which provided assistance to the patients. The presence of this performance bias may have influenced a possible better care by the team in the intervention group, compared to the control group. It would be worth analyzing this possible bias[2], which is an important methodological bias, as described in the Cochrane instrument ROB 2.[3]

In this sense, in order to understand the possible influence of performance bias on the results observed, it would be valid to have a description of the number of changes in positioning (supine to lateral decubitus) in patients who were allocated to the control group and the intervention group.[4] The authors describe in the protocol that a position change was programmed every two hours to prevent pressure ulcers in the control group. However, in practice, often these changes are not always carried out as scheduled. In the intervention group, the authors describe in a clear and objective way the number of times neuromuscular electrical stimulation was performed in the intervention group, which was 295 sessions, and to perform the intervention in the gluteal muscles, these patients had to be positioned in lateral decubitus. Differently, since for the patients in the control group there was no schedule for the application of electrostimulation, it is not clear whether these patients were, at least, kept in lateral decubitus during the same period and time window as the intervention group, even without the NMES application, which may lead to a deviation from treatment in this group.

Despite the possibility of the risk of performance bias, the effects found in Baron's study[1] were very significant, such as the reduction in relative risk (RR = 0.15; 0.05 – 0.40) and the number needed to treat (NNT: 3.3; 2.3-5.9). These data reinforce NMES as a promising intervention not only to reduce loss of strength and muscle mass in critically ill patients[5], but also as a strategy for preventing pressure ulcers. A possible mechanism that could justify these results was recently published by Yoshikawa et al.[6], which demonstrated that the use of NMES in the gluteal region helped to disperse sacral pressure in the supine position, which suggests a mechanism of biological plausibility for the use of NMES to prevent ulcers.

For future studies, it would be valid to control how many changes from dorsal to lateral decubitus were performed in the groups evaluated, as well as the time spent in each position, as this is a factor, already known, that directly impacts the occurrence of pressure ulcers.[4] Thus, the lack of similarity for this variable (number of positions in lateral decubitus) in the two groups may have overestimated the treatment effect. It is also suggested that, in the impossibility of carrying out this control of positioning at an experimental level for the different groups, that the authors include this variable as a covariate in the statistical analysis so that we can understand how much it truly impacts the evaluated outcomes. Another possibility to minimize this performance bias in future studies, could be the placement of electrical stimulation electrodes in the control group, but without the existence of electrical stimulation, that is, a sham group. This strategy could reduce the effect of the covariable amounts of lateral decubitus changes performed by the multidisciplinary team between the two groups, even with the impossibility of blinding those who perform the intervention. Such adjustments, in the methodological and/or protocol, are essential in order to resolve doubts about the real effectiveness of NMES in reducing the incidence of pressure ulcers.

Additionally, it is possible to observe that the control group had a longer stay in intensive care unit, which suggests that this group may have been exposed to a greater risk of the deleterious effects of inactivity, as described in table 2 of the study. This finding raises a relevant question: is immobility also another confounding variable for the results observed in the study? Baron et al.[1] did not discuss these aspects, but reported that the shorter stay in

the intervention group was due to the reduction in the secondary risk of pressure ulcers. However, this makes the intervention and control groups unequal for analytical purposes.

Finally, regarding the incidence of pressure ulcers observed in the study by Baron et al.[1], it is noted that the incidence of this was 35.6% in the control group, which can be considered much higher in relation to the data available in the literature, the which described a prevalence of 1 to 2%, when there was an implementation of a quality program by the multiprofessional team in the hospital environment.[7] Cullum et al.[8] cite values of a maximum of 23% of occurrence of pressure ulcers in a general population in the United Kingdom, USA, Ireland and Sweden. Gray et al.[9] reported a 1.8% occurrence of pressure ulcers in a UK population receiving health care. When analyzing Brazilian data, Teixeira et al.[10] identified an incidence of 11.4% in a retrospective cohort. These references indicate the presence of a considerable difference in the incidence values of pressure ulcers observed in the literature, when compared to the values found in the aforementioned RCT.[1]

Authors contributions

The authors declared that they have made substantial contributions to the work in terms of the conception or design of the research; the acquisition, analysis or interpretation of data for the work; and the writing or critical review for relevant intellectual content. All authors approved the final version to be published and agreed to take public responsibility for all aspects of the study.

Competing interests

No financial, legal, or political conflicts involving third parties (government, private companies, and foundations, etc.) were declared for any aspect of the submitted work (including but not limited to grants and funding, advisory board participation, study design, manuscript preparation, statistical analysis, etc.).

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