Considerations regarding analysis of clinical trials of dressings to venous ulcers *

Considerações sobre a análise de ensaios clínicos de curativos para úlceras venosas

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We read with interest the article by Frade et al concerning a clinical trial on the treatment of venous ulcers (VU) with latex biomembrane dressings versus an antibiotic and fibrinolisin cream.[1] The relevance of VU to society either due to the incidence, the impact on quality of life, or the cost inflicted to the health system has motivated us to make some comments.

Occlusive dressings have advantages over traditional techniques with creams and gauze, mainly, due to their convenient posology and adherence to treatment.[2] The possibility of using the latex biomembrane is stimulating and well designed clinical trials should provide better evidence of its effectiveness.

The study by Frade et al uses a modest sample, does not refer to randomization of the treatments and had an unequal follow-up of the study arms: 30 days for the control group and 120 days for the biomembrane. These aspects interfere with the interpretation of the results.

External compression measures increase the effectiveness of the treatments and are indicated to all patients with VU with arterial competence.[3] In a systematic review on occlusive dressings in VU, the type of dressing did not affect healing when applied together with a compression system.[4] The absence of compression measures in this study reduces the comparability of the competence of the patients´ venous return, and the external generalization of the results.

Finally, healing of chronic wounds is a complex phenomenon that is influenced by several factors, such as circulatory and nutritional conditions, diabetes, age, lipodermatosclerosis, chronicity, and the size of the ulcer itself.[5] The behavior of these variables must be weighted in the analysis of the healing speed in explanatory multivariate models. The bivariate analysis of the ulcers´ healing fraction may not produce reliable results. In addition, the reduction fraction is higher for ulcers which are smaller at the beginning, and such speed differs in different points of observation of the phenomenon. The longitudinal analysis in clinical trials of healing benefits from mixed generalized linear models, with the absolute values of the area, in order to contemplate these aspects. ❑

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