The efficacy and safety of itopride in feeding intolerance of critically ill patients receiving enteral nutrition: a randomized, double-blind study

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Abstract

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Background
Enteral feeding intolerance (EFI) is a frequent problem in the Intensive care unit (ICU) and is associated with poor clinical outcomes leading to worse prognosis in terms of mortality and ICU stay. Nowadays, prokinetic drugs are the mainstay of therapy in EFI. However, available prokinetics have uncertain efficacy and safety profiles. Itopride, is a prokinetic agent which is different and unique from the available prokinetics because of its dual mode of action as well as its tolerability and safety. The current study compared the efficacy and safety of Itopride against metoclopramide for EFI in critically ill patients. Moreover, it tested the utility and applicability of ultrasonography to measure gastric residual volume (GRV) in this population.

Methods
This randomized, double-blind study included 76 EFI patients who were randomly assigned to either Itopride or metoclopramide group. The primary outcome was to measure GRV by ultrasonography. Secondary outcomes included the percentage ratio of enteral feed volume, energy and protein received by patients over 7 days of treatment, ICU length of stay, safety parameters and occurrence of infectious complications or vomiting.

Results
Thirty-five patients of each group completed the study. At day 7, itopride significantly decreased GRV compared with metoclopramide group ($p_j=_j0.001$). Moreover, there was a significant increase in the ratios of received enteral nutrition feed volume, calories, and protein after the one-week therapy in the itopride group more than the metoclopramide group ($p_j=_j0.001$), ($p_j=_j0.002$), ($p_j=_j0.01$), respectively and there were no differences in any secondary outcomes or adverse events between the two groups.

Conclusion
In critically ill patients with EFI, itopride was well tolerated with superior efficacy to metoclopramide. In addition, we demonstrated that ultrasonography is a simple, non-invasive, inexpensive, and undemanding method for GRV measurements and can offer reliable assessments in the gastric emptying modality.

Trial registration
The trial was registered in ClinicalTrials.gov (NCT03698292). Date: October 5, 2018

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