LETTER TO THE EDITOR

Author Response: Emphasizing Patient-centered Outcomes and Improved Exclusion Criteria in Randomized Control Trials for Clinical Nutrition in ICU

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Dear Editor,

We are thankful for the authors for showing interest in our study and sharing their insightful comments.[1] We take this privilege to respond to the queries raised. Addressing the first point of discussion regarding the inclusion of patient-centered outcomes, the "Introduction" to our published study enlists the various studies done so far addressing indirect calorimetry (IC)-guided nutrition and its effect on patient-centered outcomes like mortality, morbidity, length of stay in the intensive care unit (ICU), quality of life, and functional outcomes at ICU discharge. In a gist, these studies are largely inconclusive in supporting the routine use of IC for medical nutrition therapy. In the introduction to our study, we have also mentioned the "problem statement" dealing with the issue of sarcopenia in critically ill ICU patients. Further, we have emphasized the primary motive or the research question that drove our study. Our research question was to determine whether IC can be used to mitigate sarcopenia in ICU, and we intended to address our study specifically pertinent to the problem statement, since sarcopenia is already known to be associated with worse clinical outcomes depending upon its severity.[2–5]

Regarding the second point of discussion, our study considered the patient's prior functional status, number of organ failures, and number of days of prior ICU admission. Being aware that these factors could confound the Quadriceps Muscle Thickness (QMT), we carefully designed the study to include NUTRIC, APACHE, and SOFA scores and compare them between the two groups to exclude the effect of these confounding factors. The NUTRIC score considers the number of prior days of admission, reflecting the baseline metabolic status of patients in both groups. Organ support and organ failures are reflected by the APACHE and SOFA scores that were compared between the two groups. Since these parameters were comparable between the groups, we have concluded that these factors have not confounded the effect on the QMT due to the IC intervention. We have mentioned this information in the "Discussion" of our study. We do agree that extracorporeal membrane oxygenation (ECMO) and continuous renal replacement therapy (CRRT) should have been mentioned in the exclusion criteria, however, incidentally, none of our patients were on these therapies in either of the study groups.

Thirdly, as has been rightly mentioned by the authors, "blinding" is necessary to minimize the influence of subjective bias.[1] We agree that, though our study was a randomized study, but it was limited by lack of blinding.

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Fourthly, regarding the adverse events, we had a provision to withdraw such patients if we faced feed intolerance or severe re-feeding to stop enteric nutrition. This is mentioned in the study methodology as "Withdrawal criteria". Since we did not face a situation which fulfilled the withdrawal criteria in the study population, we did not have to analyze, discuss or withdraw a patient from the study.

Lastly, regarding the overstatement of the conclusion, we have mentioned various studies performed till date by various researchers studying sarcopenia in the ICU assessed by bedside ultrasonography.[6] Although we agree that sarcopenia and muscle wasting are not exactly synonymous, loss of muscle mass is a must for the patient to have pre-sarcopenia or sarcopenia. Degree of loss of muscle strength or function, along with muscle mass loss, can be used to grade the severity of sarcopenia.[7] Since we found a significantly lower percentage reduction in QMT in the IC group, we came to the conclusion that the IC group had less sarcopenia compared to the WBE group.

We hope these clarifications address your queries/considerations.

We once again thank the authors for the interest shown in our study, and we immensely value your comments.

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