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OPEN PEER REVIEW

The Effect of the Use of Planned Entera Meal Solution on Duration of Patients Weaning from Mechanical Ventilator and Length of Stay in the ICU, a Clinical Trial

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About this report

This open peer review (OPR) report shows the public comments made on this article during peer review, by the reviewers, the associate editor and the editor-in-chief, for every revision round, together with the authors' replies. Comments appear only with the consent of the people who wrote them. Reviewers who chose to sign their report are named; the others are shown as "Referee". Comments are edited for language only, and confidential remarks to the editors are not included.

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1 Original submission

3 comments · 3 Aug 2023 – 4 Aug 2023

Referee 1 Reviewer

MAJOR REVISION 3 Aug 2023

Dear editor
Greeting,
I appreciated the opportunity to read a valuable research project. This manuscript addresses an important issue in critical care nursing. However, there are several points for which the authors are expected to provide the necessary explanations or make the necessary corrections.

- The entire manuscript needs to be revised in terms of English writing style. Input from an academic English language expert can help in this regard.
- The point that has caused great confusion in this article is whether the process of being separated from the ventilator (weaning) or the duration of mechanical ventilation was considered. Weaning is a process that usually takes a few hours, while mechanical ventilation can last for days.
- Another very important point is that, throughout the article, considerable emphasis has been placed on variables for which the comparison between the two groups was not statistically significant. In both the results and the discussion, these comparisons have been presented as if they were statistically significant. However, greater emphasis should be placed on why the differences in these variables between the two groups are not statistically significant.
- In the abstract section, the conclusion should include both the general results of the study and the researchers' suggestions.
- The gavage that patients receive as a routine feeding method is actually a planned feeding method, like the feeding method that you have used as an intervention in this study. Therefore, the title should be as follows: The effect of planned use of Standard Entera Meal solution on ....
- The introduction should start by discussing the importance of nutrition in patients admitted to the intensive care unit, because the independent variable in your study is the nutritional status of the patients. Then it should be stated that nutritional status can affect many factors, such as mechanical ventilation, length of hospitalization in the ICU, and patients' serum albumin levels. Then discuss the use of the Standard Entera Meal solution and how this method differs from other methods of feeding patients hospitalized in the intensive care unit. Finally, the necessity of conducting the study should be mentioned.
- This research is a single-blind study because the patients do not know their group allocations.
- On what basis was the sample size determined?
- It seems that there should have been many more inclusion criteria for this study, such as disease severity score (Apache score) and GCS level. Disease severity plays a fundamental role in determining the amount of energy required by patients; for example, a patient in a vegetative state will definitely have a longer duration of mechanical ventilation.
- Was the intervention performed with the permission of the intensivist? He should prescribe the feeding method.
- It should be stated which company produces the Standard Entera Meal solution and exactly what its ingredients are.
- How was the target energy calculated for each patient? You know that the energy needed by each patient may differ, and there are standard formulas to calculate it.
- Exactly how long did the administration of Entera Meal solution continue? Like the routine gavage method, did it continue as long as the patient had an NG tube?
- Considering that the intervention was repeated on different days, please mention exactly when the serum albumin level was measured.

• In the results, the results related to the duration of mechanical ventilation should be reported first, because it is the main variable of the research. In general, the style of reporting results should be revised.
• In the tables, it should be specified which statistical test each p-value corresponds to. Also, the unit of measurement for each variable should be mentioned (for example, hours or days). Report the values of t, f, and x2 in the tables.
• Instead of comparing patients under 50 and over 50 years old, age can be blocked using an ANCOVA test (completely randomized block design).
• Tables 3, 4 and 5 can be merged.
• The discussion should start with the main variables. The discussion is disorganized; the results for each variable should be discussed separately. At the end, if there is a relationship between the investigated variables, it should be stated.
• Regarding the variables that did not differ statistically between the two groups, it is emphasized again that the reason for this should be addressed in more detail.
• In the discussion, the relationship between the demographic variables and the variables under investigation has been discussed, while no such relationship has been mentioned in the results.
• Please mention the limitations of the research.
• It is possible to use more references for this study.

Kind Regards

Associate Editor MAJOR REVISION 4 Aug 2023

Dear Author,
Based on our reviewers' comments, your manuscript needs some revision in all sections. Please revise and resubmit.
Thank you very much indeed.

Editor-in-Chief MAJOR REVISION 4 Aug 2023

Dear Author,
Please revise your manuscript based on the reviewers' comments and resubmit.
Thank you

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Revision 1

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

Reviewers' Comments:

Reviewer 1:
Dear editor
Greeting,
I appreciated the opportunity to read a valuable research project. This manuscript is written about an important issue in the critical care nursing. However, there are several points, which the authors are expected to provide the necessary explanation about them or conduct the necessary corrections.

Dear reviewer

Greeting,

Thank you for your valuable comments.
• *The entire of the manuscript needs to be revised in terms of English writing style. Benefiting from the opinions of an academic English language expert can help in this regard.*

It was revised.
• *The point that has caused great confusion in this article is which one of the process of being separated from the ventilator (weaning) or the duration of using mechanical ventilation was considered? Weaning is a process that usually takes a few hours, while mechanical ventilation can last for days*

It means the process of isolating/ separating the patient from mechanical ventilation.

It was mentioned in the text.
• *Another point that is very important is that in the whole article, a lot of maneuvering has been done on variables whose comparison in two groups was not statistically significant. Both in the results and in the discussion, it has been presented as if the comparison of these variables between the two groups has become statistically significant. However, it should be more emphasized why the difference of these variables in two groups is not statistically significant.* They were revised.

• *In the abstract section, the conclusion should include both the general results of the study and the suggestions of the researchers.*
• *The gavage that patients receive as a routine feeding method is actually a planned feeding method like the feeding method that you have used as an intervention in this study. Therefore, the title should be like this; The effect of planned use of Standard Entera Meal solution on ....*

Thanks for your suggestion. It was applied.

• *The introduction should start by talking about the importance of nutrition in patients admitted to the intensive care unit, because the independent variable in your study is the nutritional status of the patients. Then it should be stated that nutritional status can affect many factors such as mechanical ventilation, length of hospitalization in ICU and serum*

albumin level of patients. Then talk about the use of the Standard Entera Meal solution and the difference that this method has with other methods of feeding patients hospitalized in the intensive care unit. Finally, the necessity of conducting the study should be mentioned. It was Modified according to your suggestion.

• *This research is a single blind study because the patients do not know about the allocation of groups.*

The guardians of the patients knew about the use of the interventional solution according to the informed consent.

• *On what basis is the sample size determined?* It was written in the text.

• *It seems that there should have been much more inclusion criteria for this study, criteria such as disease severity score (Apache score) and level of GCS. Because the severity of the disease plays a fundamental role in determining the amount of energy required by patients, or that, for example, a vegetative patient will definitely have a longer duration of mechanical ventilation.* Disease severity score (Apache score) and level of GCS were not among the inclusion criteria. It is suggested to be included in future studies. It was mentioned in the limitations.

• *Is the intervention done with the permission of the intensivist? Because he should prescribe the feeding method.* The order of gavage was with the attending physician, but its content and amount was determined by the nutritionist. It was mentioned in the method.

• *It should be stated in which company the Standard Entera Meal solution is produced and what exactly its ingredients include.*

It was mentioned in the method.

• *How was the target energy calculated for each patient? You know that the energy needed by each patient may be different and there are standard formulas to calculate it.*

It was mentioned in the method.

• *Exactly how long has the administration of Entera Meal solution continued? Like the routine gavage method, did it continue as long as the patient had an NG tube?* Yes, they were similar to the routine group in terms of timing and continuation.

It was mentioned in the method.

• *Considering that the intervention was repeated on different days, please mention when exactly the serum albumin level was measured.* The amount of albumin was recorded and analyzed before the intervention and the last test at the end of the study period. It was mentioned in the method.

• *In the results, the results related to the duration of using mechanical ventilation should be reported first, because it is the main variable of the research. In general, the style of reporting results should be revised.* It was revised.

• *In the tables, it should be specified which statistical test each p-value corresponds to. Also, the scale for measuring each variable should be mentioned (For example, hour or day). Mention the amount of the t, f, x2 in the tables.* They were mentioned.

• *Instead of comparing under 50 and over 50 years old, age can be blocked with an*

ANCOVA test (Completely randomized block design).
• *Tables 3, 4 and 5 can be merged.* Tables 3 and 4 were merged. Also, Tables 5 and 2 were merged.
• *The discussion should start with the main variables. There is dispersal in the discussion, in fact, the results of each variable should be discussed separately. In the end, if there is a relationship between the investigated variables, it should be stated.* It was modified.
• *Regarding the variables that did not statistically differ between th e two groups, it is emphasized again that the reason for this should be addressed more.* It was modified.
• *In the discussion, the relationship between the demographic variables and the variables under investigation has been talked about, while nothing like this has been mentioned in the results.* They were mentioned.
• *Please mention the limitations of the research.* They were mentioned.
• *It is possible to use more references for this study.* More references were used.

Kind Regards.

Reviewer 2:
dear author
interesting study. However, there are points in the method that may be biased.

Dear reviewer

Greeting,

Thank you for your valuable comments.
comments:
Answeres are blue colour .

- Abbreviations must be mentioned in full for the first time in the abstract. they were modified.

- please add a literature review in the intriduction. It was added.

- Is the type of underlying disease and the cause that caused the patient to undergo mechanical ventilation not clinically important? Definitely, the underlying disease is the most important factor that affects the length of hospitalization and... How did you balance this between the control and intervention groups? This case can cause selection bias, and for example, patients who were in the control group were hospitalized for a longer period of time due to underlying problems. How exactly do you know the findings are relevant or planned nutrition? In the study, there was no statistically significant difference between the two groups in terms of having one or more underlying diseases (diabetes, hypertension, or both). Not having kidney or liver diseases were also the entry criteria. It was mentioned in the text.

- Please add reference for Standard Entera Meal solution. It was added (7 references).

- why you did not use blinding? Because the content and appearance of nutrition were different in the two groups and it was not possible to blind the ward nurses and researchers. In terms of ethical considerations, the guardians of nutritional patients were also informed.

-You should discuss why you measured the albumin level? What is the importance of this variable in these patients? It was explained in the introduction section.

- In table number 1, list the main reasons that caused mechanical ventilation for the patient for both groups. It was mentioned at the beginning of the findings. It was not compared in two groups, which is one of the limitations of the research. mentioned in the limitations.

- please add study limitations. . It was added.

Chapter 1 > Associate Editor's Comments:

Associate Editor 1:
Dear Author,
Based on our reviewer comments, your manuscript need some revsion in all section. please revise and resubmit.
Thank you very much indeed.

Dear *Associate Editor,*

Greeting,

Thank you for the valuable comments.

They were revised.

Chapter 2 > EIC Decision:

Dear Author,
Please revise your manuscript based on reviewers comments and resubmit
Thank you

2 Revision 1

3 comments · 11 Sep 2023 – 18 Sep 2023

Referee 1 Reviewer

MINOR REVISION 11 Sep 2023

Greetings, and thank you to the authors for the positive revisions they have made. Most points have been addressed well. Only a few points require further review.
1) I still believe that the duration of weaning should be replaced with the duration of connection to the ventilator. This is also clearly evident from the results in the tables. The entire weaning process may take a few hours, but it is the duration of connection to the ventilator that may last for days.
2) Nevertheless, although the family is aware of the group assignment, the patients are in a coma and are unaware of their group assignment, so the study is single-blind.
3) The study limitations should be written separately.

Associate Editor

MINOR REVISION 18 Sep 2023

Dear author,
Thank you for submitting your manuscript to JJCDC. This study is interesting in the chronic illness field. Based on our reviewers' comments, your article needs some minor revisions in all parts. I recommend you revise the manuscript and resubmit it as soon as possible.
With best regards.

Editor-in-Chief

MINOR REVISION 18 Sep 2023

Dear author,
Based on our reviewers' comments, your article needs some minor revisions in all parts. I recommend you revise the manuscript and resubmit it as soon as possible.
With best regards.

3

Revision 2

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

With greetings and respect,

With thanks for the efforts and valuable comments of the respected reviewer, the responses to the comments:

1. I still believe that instead of the duration of weaning, the duration of connection to the ventilator should be written. This is also clearly evident from the results of the tables. The weaning process as a whole may take a few hours, but it is the duration of connection to the ventilator that may take days.

Thank you for your careful attention. In other studies, we have examined the duration of connection to the ventilator with other variables. However, in this study, as is evident in Table 3, the duration is reported in minutes, and the aim of the study was the duration of the process of separating the patient from the ventilator. 2. In any case, although the families know the allocated group, the patients are in a coma and do not know the allocated group; therefore, the study is single-blind. This was applied in the text. 3. The limitations of the study should be written separately. Corrected.

3 Revision 2

3 comments · 29 Sep 2023 – 1 Oct 2023

Referee 1 Reviewer

MINOR REVISION 29 Sep 2023

Greetings, and thank you to the respected authors for their responses. All revisions have been made. However, regarding the main variable (weaning duration), if the values obtained are in minutes, as the authors have stated, this is not scientifically justifiable. The weaning process does not take 4 minutes or 8 minutes. This process may take several hours or even a day; removing the endotracheal tube alone takes 10 minutes (a duration of 4 minutes or 8 minutes has no scientific value). In my opinion, it would be better to examine this issue further. The duration of connection to the ventilator (in days) is a variable that is consistent with this study and the data obtained from it.

Associate Editor

MINOR REVISION 1 Oct 2023

Dear Author,
You should respond to reviewer comments as soon as possible.
Thank you

Editor-in-Chief

MINOR REVISION 1 Oct 2023

Dear Author,
Based on the reviewers' comments, you should revise and resubmit.
Thank you

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Revision 3

AUTHORS' RESPONSE TO REVIEWERS

Authors' reply to reviewers

The next pages contain the authors' point-by-point reply to the comments of this revision round, as submitted with the revised manuscript. It is published as the authors wrote it.

With thanks for the efforts and very valuable comment of the respected reviewer, the response to the comment:

Comment: Regarding the main variable (weaning duration), if the numbers obtained are in minutes, as the authors state, this is not scientifically justifiable; the weaning process is not 4 minutes or 8 minutes. This process may take several hours or even a day; just removing the endotracheal tube takes 10 minutes (whether this is 4 minutes or 8 minutes has no scientific value). In my opinion, it would be better to examine this issue further. The duration of connection to the ventilator (in days) is a variable that is appropriate to this research and the data obtained from it.

Response: The matter was checked again with the research team. The comment was completely correct. The duration was indeed the duration of connection to the ventilator (in days), which was corrected and applied in the text (in red).

4 Revision 3

2 comments · 7 Oct 2023 – 7 Oct 2023

Associate Editor

ACCEPT 7 Oct 2023

Dear Author,
All comments have been made.
Thank you

Editor-in-Chief

ACCEPT 7 Oct 2023

Dear Author,
All comments have been made and this manuscript is acceptable.
Thank you