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OPEN PEER REVIEW

An Investigation of Ultrasonography as a Method for Determining Orogastric Tube Placement in Newborns

Jun Chen, Lijun Liu, Chaomei Huang, Yiheng Dai

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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 · 12 Dec 2023 – 30 Dec 2023

Referee 1 Reviewer

MAJOR REVISION 12 Dec 2023

-Please provide references in the sections " OG tube insertion, and Ultrasound Examination".
-The radiographic study should be conducted for other clinical indications, not to determine the OG insertion site. Please put this in bold in the methods section.
-Please define the excluded neonates who did not undergo radiologic examination in this study.
-The study needs an ethics code.
-Please discuss the complications of incorrect placement of the gastric tube in the introduction and discussion sections.
-Some parts of the introduction belong in the discussion section; please correct this.

Referee 2 Reviewer

MAJOR REVISION 30 Dec 2023

Dear Authors
I reviewed your manuscript titled “An Investigation of Ultrasonography as a Method for Determining Orogastric Tube Placement in newborns”. I have some questions and comments.
1- For radiologic evaluation of tubes, how many radiologists were involved in analyzing the images? If more than one, you must perform a test of interobserver variability.
2- Was the neonatologist blinded to the radiology results? Explain the blinding method.

3- I encountered some problems in the results, as follows:

1) You mentioned that radiological assessment revealed that 96.2% (50 cases) of the tubes were placed in the stomach and only 3.8% (2 infants) were positioned in the GE junction. Ultrasound analysis confirmed that 98.1% (51 infants) had their tubes positioned in the stomach, while 1.9% (1 infant) were at the GE junction or above. We consider that there is just one false-positive case on ultrasound, but you mentioned that you had 5 false-negative and 7 false-positive cases. I feel there is a mismatch between these data; please clarify this issue.

2) You must be able to see the tip of the catheter by ultrasound to consider it present within the stomach. You had 7 false-positive cases, so if there was no tube within the stomach according to the X-ray, how do you explain this? What was mistakenly taken to be the tip of the tube?

4- As you know, due to the presence of gas within the stomach, sometimes we can see only part of the catheter, not the tip of the catheter. How did you manage these cases?

5- In the limitations section, you mentioned that “Secondly, although the ultrasound examinations were performed by a neonatologist with some experience in sonography, not all assessments were subjected to double-check procedures because of limited availability of trained personnel in our NICU”. Please explain this further. Did you check some cases by ultrasound twice?

Associate Editor

MAJOR REVISION 30 Dec 2023

Dear Authors
Due to our reviewers' comments, your manuscript requires major revision.

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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.

Dear Editors and Reviewers,

I sincerely appreciate the chance to submit the revised manuscript. Your valuable feedback and the dedication of both editors and reviewers are truly acknowledged. We have diligently addressed and incorporated the majority of the suggestions, including the improvement the manuscript's language flow using track changes. The modifications made in response to reviewers' comments have been clearly highlighted.

Below is a detailed response addressing each point from the reviewers.

Warm regards

Comments from Reviewer 1

Comment 1: For radiologic evaluation of tubes, how many radiologists were involved analyzing the images? If more than one, you must evaluate interobserver variability test.

Response: Thank you for your insightful comment regarding the radiologic evaluation of tubes. We recognize the importance of assessing interobserver variability, and we want to clarify that, due to limited resources, only one doctor specialized in neonatal radiology was available to review each image in this study. We have emphasized the efforts to maintain accuracy despite these limitations in the revised manuscript.

Comment 2: Was the neonatologist blind to the radiology results? Explain about blinding method.

Response: Thank you for your constructive feedback. We appreciate your suggestion, and we have incorporated a section on blinding (Section 2.6) in the methods part of our paper. This new section provides a detailed explanation of the blinding method employed in the study, specifically outlining how the neonatologist was kept blind to the radiology results to ensure impartiality in the assessment of orogastric tube placement.

Comment 3: You mentioned that Radiological assessment revealed that 96.2% (50 cases) of the tubes were placed in the stomach and only 3.8% (2 infants) were positioned in the GE junction. Ultrasound analysis confirmed that 98.1% (51 infants) had their tubes positioned in the stomach, while 1.9% (1 infant) were at the GE junction or above. We consider that just one case of false positive of ultrasound exist, but you mentioned that you had 5 false negative and 7 false positive cases, I feel mismatch between these data, please clarify this issue

Response: Thank you for bringing attention to the potential mismatch between tables 1 and 2. Your observation is important, and we appreciate the opportunity to clarify this issue. The criteria for assessing the position in the two tables were different. In table 1, we compared the anatomical position verified by radiology and ultrasound, a common approach in existing research. However, we acknowledge that the tube's function could be affected by variations in insertion length, which led us to introduce more accurate

positioning criteria verified by radiology and ultrasound separately, as detailed in the methods (Sections 2.5 and 2.6). We have now explicitly discussed the specific reasons for false positive and false negative cases in the revised manuscript.

Comment 4: You must be able to see tip of catheter by ultrasound to consider it presence within stomach. You had 7 false positive cases, so if there was no tube within stomach according to x-ray, how do you explain about it? What was taken mistakenly as tip of tube?

Response: Thank you for your insightful comment and the opportunity to provide further clarification. We have taken your feedback into consideration and made specific amendments to enhance the manuscript's clarity.

In the sensitivity and specificity analysis, we have introduced the concept of an "accurate" position for both radiology and ultrasound verification. The radiological criterion for accuracy was defined as the tip being placed within more than 2 cm but less than 5, corresponding to the tenth thoracic vertebra (T10). This definition accounts for situations where the tube's tip may have just passed the gastroesophageal junction, resulting in insufficient aspiration for the newborns.

Below Table 3, we have explicitly listed the definitions of accurate position for both radiology and ultrasound to improve the table's readability. In the Results section, specifically in "3.3 Agreement analyses," we explain the reason for the false positive cases. Among these patients, the radiological images showed tubes inserted within

the stomach but too short (the distance from the tip to T10 was less than 2 cm), which were not detected in ultrasound.

Comment 5: As you know due to presence of gas within stomach, sometimes we could just see a part of catheter, not the tip of catheter, how did you manage these cases?

Response: Thank you for highlighting a crucial aspect of our study, and we appreciate your input on how to address potential challenges in ultrasound examinations due to the presence of gas within the stomach.

Indeed, the presence of gas in the stomach can obstruct ultrasound visibility, especially in newborns supported with ventilation. To manage this issue, we carefully considered the timing of the ultrasound examination. We specifically enrolled newborns who had started feeding, and the examination was performed just before feeding. When excessive gas was detected in the stomach, the standard procedure involved the nurse aspirating the gastric tube before initiating feeding. This step is routinely performed before feeding according to our clinical process. During this step, we observed the flow of milk into the stomach to confirm the position of the tube. This technical detail has been included in the Methods section under "2.5 Ultrasound Examination." Additionally, Figure b in the manuscript provides a visual representation of a sonogram showing milk flowing from the tip of the tube. This approach was designed to enhance the accuracy of our ultrasound assessments.

Comment 6: In limitation, you mentioned that “Secondly, although

the ultrasound examinations were performed by a neonatologist with some experience in sonography, not all assessments were subjected to double-check procedures because of limited availability of trained personnel in our NICU” please explain about it more. Did you check some cases by ultrasound twice?

Response: Thank you for your insightful comment, and we appreciate your careful review of our manuscript. In response to your suggestion, we have revised the relevant section to provide more detailed information about the double-check procedures, addressing the limitation due to the limited availability of trained personnel in our NICU. We believe these enhancements contribute to the overall quality of the manuscript. Your feedback has been invaluable in refining our work, and we sincerely appreciate your thoughtful input.

Comments from Reviewer 2

It's wonderful to hear that Reviewer 2 provided valuable suggestion for the quality of your study.

Comment 1: Write the references in the parts " OG tube insertion, and Ultrasound Examination", please.

Response: Thank you for your suggestion. We appreciate the importance of providing references in relevant sections, and we had included appropriate citations for "OG tube insertion" and "Ultrasound Examination" in the manuscript.

Comment 2: The radiographic study should be conducted for other clinical indications not for insertion site of OG. Please, Bold this in the methods part.

Response: Thank you for your valuable comment. We acknowledge the importance of clarifying the purpose of the radiographic study in our methods section. To address this concern, we will explicitly state that the radiographic study was conducted for other clinical indications unrelated to the insertion site of the orogastric tube. We will emphasize this point by bolding the relevant information in the methods section-2.4 Radiological Assessment

Comment 3: Please, define excluded neonates that haven't had radiologic in this study.

Response: Thank you for your comment. We appreciate the opportunity to provide clarification regarding the excluded neonates who did not undergo radiologic assessment in our study. In the revised

manuscript, we had explicitly defined the criteria for neonates who were excluded from the radiologic assessment.

Comment 4: The study needs Ethic code.

Response: We appreciate the reviewer's attention to ethical considerations. The study was conducted following ethical principles and guidelines. The ethical code was added in the revised manuscript. We have included this information to provide transparency regarding the ethical oversight of our study.

Comment 5: Please, discuss about the complications of incorrect placement of the gastric tube insertion in introduction and discussion parts.

Response: We appreciate the valuable suggestion from the reviewer. In the revised manuscript, we have incorporated a discussion about the potential complications associated with incorrect placement of the gastric tube in both the introduction and discussion sections. Specifically, we highlight the importance of accurate tube placement to prevent complications such as aspiration, respiratory distress, and other adverse events.

Comment 6: Some parts of introduction are discussion part please correct that.

Response: Thank you for your valuable feedback. We acknowledge the inadvertent inclusion of discussion elements in the introduction section. We have carefully reviewed and revised the manuscript to rectify this issue, ensuring a clear and accurate separation between

the introduction and discussion sections.

2 Revision 1

3 comments · 20 Jan 2024 – 21 Jan 2024

Referee 3 Reviewer

MINOR REVISION 20 Jan 2024

Abstract: It is mentioned in the last lines of the abstract—this technique cannot replace the current radiological assessment. Authors must be clear that radiological assessment is not recommended as a routine confirmation; it is required only in difficult and doubtful cases.
Material and methods:
1. The mode of selection of cases should be mentioned.
2. The objectives of the study should be clearly defined.
3. Pilot study—some details can be mentioned.
4. In the consent, write parents in place of patients.
5. Radiological assessment mentions expert radiologists, but the clarification mentions only one expert.
6. Ultrasound examination: Was the specialized training evaluated and certified?
Results:
3.1: There is a mismatch between the text and table 1 regarding the number of males, i.e., 34 (65.4%) in the text and 33 (63.5%) in table 1. There is duplication of data in the text and table. Table 1 may be deleted.
Also, the text mentions 39 cases as preterm infants at less than 34 weeks, but the table shows 40 cases (16 at 28–32 weeks and 24 at 32–34 weeks).
3.2: Table 2 may be deleted.
Discussion:
1. There is mention of 55 newborns; how can this be explained?
2. The studies mentioned, 17, 8, 18: Was a radiological comparison of assessment done in these studies?

Referee 1 Reviewer

MAJOR REVISION 20 Jan 2024

Thank you for your correction, but please:
Correct "radiologists" in lines 78 and 79 if just one radiologist worked with you.
In line 70, write "Then the location of the OGs were marked."
I was a little confused. You checked an OG whose position was checked with PH and confirmed with radiography, rechecked the accuracy of radiology, which had a higher error rate than ultrasound, and then checked the accuracy of ultrasound with radiography as a standard. Please have a specialist review this manuscript.

Associate Editor

MAJOR REVISION 21 Jan 2024

Dear Authors
In light of the reviewers' comments, you need to revise your manuscript.

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.

Dear Editors and Reviewers,

I extend my sincere gratitude for providing the opportunity to submit the revised manuscript. Your invaluable feedback and the commitment of both editors and reviewers are deeply appreciated. The modifications made in response to reviewers' comments have been distinctly highlighted.

Below is a comprehensive response addressing each point raised by the reviewers.

Warm regards,

Y. D. & J. Ch.

Comments from Reviewer 1

Comment 1: Correct" radiologists" in lines 78, and 79, if just one radiologist worked with you. In line 70 write "Then the location of the OGs were marked”.

Response: Thank you for your feedback. We have carefully reviewed your comments and have incorporated the necessary corrections into the revised manuscript.

Comment 2: I was a little confused. You checked an OG whose position was checked with PH and confirmed with radiography, re-checked the accuracy of radiology, which had a higher error rate than ultrasound, and then checked the accuracy of ultrasound with radiography as a standard. please a specialist reviews this manuscript.

Response:

Thank you for your constructive feedback. We highly value your suggestion, and after thorough consideration with the entire team and consultation with a statistics professor, we addressed the identified issue in the revised manuscript. In our comprehensive review of the cases in the final analysis, we attributed the higher error rate in radiology to the limitations posed by the sample size. As part of our ongoing commitment to quality improvement in gastric tube assessments, we have continued data collection. Additional data has been incorporated to strengthen the findings in the final analysis. The revised results now indicate rates of 67.3% in radiological evaluation and 60.3% in ultrasonography assessment, as detailed in the manuscript. We appreciate your continued engagement and input.

Comments from Reviewer 2

Comment 1: Abstract: It is mentioned in the last lines of abstract—this technique cannot replace the current radiological assessment. Authors must be clear that radiological assessment is not recommended as a routine confirmation, it is required only in difficult and doubtful cases.

Response: Thank you for your suggestion. We acknowledge the significance of clearly conveying that routine confirmation should be avoided due to radiation hazards. Recognizing the constraints of the limited word count in the abstract, we have placed particular emphasis on this aspect within the methodology section, and we have highlighted the relevant term in bold for emphasis.

Comment 2: Material and methods:1. Mode of selection of cases should be mentioned.

Response: Thank you for your valuable comment. We recognize the importance of elucidating the case selection process in our methods section. In section "2.1 Study Design," we have delineated the inclusion and exclusion criteria employed in this study.

Comment 3: 2.Objectives of the study should be clearly defined.

Response: Thank you for your comment. We appreciate the opportunity to offer clarification on the study objectives. The objectives of this study are clearly outlined in the last paragraph of the introduction, with additional emphasis placed on these objectives in the opening sentence of the abstract.

Comment 4: 3.Pilot study -some details can be mentioned.

Response: We appreciate the reviewer's attention to the

considerations regarding the pilot study. In response, we have incorporated a dedicated section addressing the pilot study, now included as Section 2.6 in the manuscript.

Comment 5: 4.In the consent write –parents in place of patients.
Response:
We appreciate the valuable suggestion regarding this issue. In the revised manuscript, we have rectified this mistake.

Comment 6: 5. Radiological assessment shows –expert radiologists , in the clarification it is mentioned only one expert.
Response: Thank you for your valuable feedback. We have rectified this mistake in the revised version.

Comment 7: 6. Ultrasound examination: Was the specialized training evaluated and certified.
Response: We appreciate the valuable suggestion about this issue. The training process involved comprehensive instruction on the specific techniques relevant to our study, focusing on neonatal ultrasound applications such as lung ultrasound and catheter placement. While certification was not pursued, the training aimed to equip the operators with the necessary skills and knowledge for accurate and consistent ultrasound assessments in the context of orogastric tube placement verification.

Comment 8: 3.1: There is mismatch in the text and table 1 about number of males i.e 34 (65.4%) in the text and 33(63.5%) in the table1. There id duplication of data in the text and table. Table 1 may be deleted. Also text mentions 39 cases as pre terms less than 34 weeks but table shows 40 cases (16 as 28-32 weeks and 24 as 32-34

weeks).

Response: We appreciate the reviewer's keen observation. Upon careful review, a typographical error in the text regarding the numbers has been identified. We have corrected all instances of these errors, and in the revised manuscript, Table 1 has been deleted.

Comment 9: 3.2: Table 2 may be deleted.

Response: We appreciate the reviewer's observation. As Table 2 provides additional information about the tube's position, we have decided to retain it in the manuscript.

Comment 10: Discussion: 1.There is mention of 55 newborns , hoe to explain?. 2. The studies mentioned 17 , 8 ,18 : was there a radiological comparison of assessment done in these studies?.

Response: We appreciate the reviewer's diligence in pointing out this discrepancy. The number “55” had been revised in the manuscript. Regarding the studies mentioned (17, 8, 18), we acknowledge the importance of clarifying whether radiological comparisons were conducted in these studies. We will revisit the literature and explicitly state whether radiological assessments were part of the comparison in the mentioned studies. Your insights are valuable, and we thank the reviewer for bringing these points to our attention.

3 Revision 2

2 comments · 3 Feb 2024 – 3 Feb 2024

Referee 1 Reviewer

MINOR REVISION 3 Feb 2024

Please delete this sentence from line 70: "the tube was not used until its placement was confirmed
71 through radiological examination"

Associate Editor

MINOR REVISION 3 Feb 2024

Dear Authors
The reviewers decided on minor revision.

4

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.

Dear Editors and Reviewers,

I am sincerely thankful for the chance to submit the revised manuscript. Your invaluable feedback and the dedication of both editors and reviewers are deeply appreciated. The modifications made in response to reviewers' comments have been distinctly highlighted in yellow.

Below is a comprehensive response addressing each point raised by the reviewers.

Warm regards,

Y.H.D. & J.C.

Comments from Reviewer 1

Comment 1: Please submit the revised manuscript.

Response: Thank you for your valuable feedback. We have thoroughly reviewed your comments and have successfully submitted the revised manuscript. All modifications have been highlighted in yellow within the manuscript for your convenience.

Comments from Reviewer 2

Comment 1: Please delete this sentence from line 70"the tube was not used until its placement was confirmed 71 through radiological examination"

Response: Thank you for your constructive feedback. We greatly value your suggestion, and after careful consideration with the entire team, we have decided to delete this sentence.

4 Revision 3

2 comments · 2 Mar 2024 – 15 Mar 2024

Referee 1 Reviewer

ACCEPT 2 Mar 2024

Thank you for your revisions.

Associate Editor

ACCEPT 15 Mar 2024

Dear Authors
We are pleased to inform you that your article is accepted.