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A box-shaped, shielding device for reducing the risk of COVID-19 droplet infection during gastrointestinal endoscopic procedures

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A box-shaped, shielding device for reducing the risk of COVID-19 droplet infection during gastrointestinal endoscopic procedures
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Dear Dr. Kawabata,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript.Also, please ensure that the track changes function is switched on when implementing the revisions. This enables the reviewers to rapidly verify all changes made.

Your revision is due by Aug 20, 2020.

To submit a revision, go to https://www.editorialmanager.com/jctres/ and log in as an Author.

You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1: In this small feasibility study, the authors describe the use of a so called "aerosol box" with a cuboid shape and two openings with the aim of protecting from infection with COVID-19 during gastrointestinal endoscopy.

According to the authors, the box could help in the situation of PPE shortage as an additional protection device. The study describes the implementation of this box and demonstrates its feasibility in two ERCP procedures, adressing especially the issues of patient safety as well as operability and visibility.

In my opinion however, this is only a proof-of-principle study, and the data presented are not sufficient to confirm the conclusion stated by the authors: "this box-shaped, shielding device can be used to reduce the risk of COVID-19 droplet infection during endoscopic procedures in the clinical setting".

Nevertheless, because of its innovative character, I still feel that the information is worth publishing. However, maybe the authors can expand on the following:

1. How can the box replace the use of PPE? In figure one, personnel seem still to be wearing full PPE including face shields. Isn't the box a mere additional protection or do the authors see the box as a substitute for some aspects of PPE? If yes, then how can the box be used to reduce the use of PPE? Perhaps the box could spare the use of face shields? How can the box help health care workers in the situation where PPE is scarce? Do the authors envisage the use of the box in other settings outside of GI endoscopy? Please expand on these points.
2. Do the authors have any information, even hypothetical, on the spread of aerosols within the endoscopy room after the box has been opened up at the end of the examination? Could this be a problem, since the issue of aerosol-spread is almost as important as droplet-spread?
3. I may be a bit worried about the reuse of the box within a short space of time even after alcohol disinfection. What do the authors think about cross contamination when the box is used for multiple patients? Did the authors review this point in any way? If the vinyl sheet around the framework is discarded completely then maybe this should be stated more clearly. In any case, I feel the authors should discuss more the issue of cross contamination between patients.
4. I agree that droplet protection is provided by the box, however, I am having some difficulty understanding how the box will protect from aerosol, after all the inside of the box is not under negative pressure. Please expand and explain better.
5. Finally, two minor points: please explain how the box affected position of endoscopy personnel and positioning of the C-Arm or the fluoroscopy during ERCP.

Thank you.

4.

Reviewer #2: In this work, the authors describe the utility of a boxshaped, shielding device for reducing the risk of COVID-19 droplet infection during endoscopic procedures. For this purpose, the authors retrospectively reviewed two ERCPs in which the shielding device was used and the authors observed no complications associated with the use of this device along with a good to excellent rating of operability, visibility and sense of security by the endoscopist and nurse. The manuscript would benefit from a video with a procedure performed with the shielding device as this would better allow to visualize endoscope maneuverability etc.

Reviewer #3: This is an interesting report on the innovative ways that are performed to limit contamination from COVID 19 during endoscopic procedures. The authors report two successful ERCP cases performed in patients under sedation with the described shield, which was positively accepted by the operators and assistants. The patients had a good clinical outcome regarding vital signs, during the procedure. Although the report is mostly descriptive, it has the merit of assessing the use of the device with some, albeit limited objective measures.
Some comments:
1. How to deal with patients requiring endotracheal intubation with the above devise?
2. The authors discuss measurement of aerosol transmission. Can the clarify in details how can the device be better assessed in regards to its protective attributes?
3. The device has to be tested for other endoscopic emergencies, such as GI bleeding, and can it be used for lower GI, where the contamination risk is equally, if not more increased?
4. Is there a control group, with non-COVID patients undergoing ERCP?
5. Where these mild COVID-19 patients? Could the device be used in patients with mores every diseases forms regarding higher concentrations of O2 and eventually intubation?

Authors' response

RESPONSE TO REVIEWER 1:
We wish to express our appreciation to the Reviewer 1 for his or her insightful comments, which have helped us significantly improve the paper.

Comment 1: *1. How can the box replace the use of PPE? In figure one, personnel seem still to be wearing full PPE including face shields. Isn't the box a mere additional protection or do the authors see the box as a substitute for some aspects of PPE? If yes, then how can the box be used to reduce the use of PPE? Perhaps the box could spare the use of face shields? How can the box help health care workers in the situation where PPE is scarce? Do the authors envisage the use of the box in other settings outside of GI endoscopy? Please expand on these points.*

Response:
I don't think that this device can replace the use of PPE because a protection before and after the procedures is also required and it may fail to protect aerosol transmission as the reviewer worried. Therefore, the box is expected to be used as an additional protection device and is expected to be particularly useful in case of otherwise insufficient infection protection, such as under condition of PPE shortage and emergent situation.

This device can also be used during other endoscopic procedures, including colonoscopy, bronchoscopy and laryngoscopy, provided the position of the box windows is modified to allow such endoscopes to be easily maneuvered. I added these descriptions in the Discussion section.

Comment *2*: *Do the authors have any information, even hypothetical, on the spread of aerosols within the endoscopy room after the box has been opened up at the end of the examination? Could this be a problem, since the issue of aerosol-spread is almost as important as droplet-spread?*

Response:
I completely agree with the reviewer's comment. Actually, this device may fail to protect aerosols that can remain airborne although it is able to suppress droplet-spread. I added a description regarding the risk of aerosol-spread even under using this device as below.

However, it seems to be difficult to replace the use of PPE with this device, as protection is still required before and after the procedure and the device may fail to protect from aerosols (the small respirable particles <5–10 μm in diameter) that can remain airborne and are capable of short- and long-range transport.

Comment 3: *I may be a bit worried about the reuse of the box within a short space of time even after alcohol disinfection. What do the authors think about cross contamination when the box is used for multiple patients? Did the authors review this point in any way? If the vinyl sheet around the framework is discarded completely then maybe this should be stated more clearly. In any case, I feel the authors should discuss more the issue of cross contamination between patients.*

Response:
I heartily agree with the reviewer's comment. The vinyl sheet around the framework should be discarded completely after each usage, as the reuse of the box within a short span of time even after alcohol disinfection may induce cross contamination between patients.
I added this description in the Discussion.

Comment 4: *I agree that droplet protection is provided by the box, however, I am having some difficulty understanding how the box will protect from aerosol, after all the inside of the box is not under negative pressure. Please expand and explain better.*

Response:
I agree with the reviewer's comment. This device may fail to protect aerosols that can remain airborne. I added a description regarding the risk of aerosol-spread even under using this device.

Comment 5: *Finally, two minor points: please explain how the box affected position of endoscopy personnel and positioning of the C-Arm or the fluoroscopy during ERCP.*

Response:

The box affected neither the position of endoscopy personnel nor the positioning of the C-Arm or the fluoroscopy during ERCP. The size of the box can be adjusted to the size of the fluoroscopic table and C-Arm.
I added this in the Discussion section.

RESPONSE TO REVIEWER 2:
We wish to express our appreciation to the Reviewer 2 for his or her insightful comment, which have helped us significantly improve the paper.

Comment: *The manuscript would benefit from a video with a procedure performed with the shielding device as this would better allow to visualize endoscope maneuverability etc.*

Response:
We heartily agree with the Reviewer's comment. We should have prepared for a video for better understanding of this device. Thus, we would like to introduce this device with a video another time.

RESPONSE TO REVIEWER 3:
We wish to express our appreciation to the Reviewer 3 for his or her insightful comment, which have helped us significantly improve the paper.

Comment 1:
How to deal with patients requiring endotracheal intubation with the above devise?

Response:
This device can also be used during other endoscopic procedures, including bronchoscopy, provided the position of the box windows is modified to allow such endoscopes to be easily maneuvered.
I added this description in the Discussion section.

Comment 2:
The authors discuss measurement of aerosol transmission. Can clarify in details how can the device be better assessed in regards to its protective attributes?

Response:
Experimental studies concerning the reduction in aerosol spray when using the box should be conducted. For example, a study measuring the concentration of aerosols in the box and at several points in the endoscopy room before, during and after the procedure, with the results compared to those obtained without the box should be conducted.
I added these descriptions in the Discussion section.

Comment 3:
The device has to be tested for other endoscopic emergencies, such as GI bleeding, and can it be used for lower GI, where the contamination risk is equally, if not more increased?

Response:
I heartily agree with your comment.
Larger, prospective, multicenter studies including GI endoscopic procedures, such as hemostasis, are needed to clarify the utility and safety of this device. Feasibility of practical application to other endoscopic procedures including colonoscopy, bronchoscopy and laryngoscopy should be also assessed while the position of the box windows adjusted.
I added these sentences in the Discussion.

Comment 4:
Is there a control group, with non-COVID patients undergoing ERCP?

Response:
I'm sorry but there was no control group with non-COVID patients undergoing ERCP this time because it was a small feasibility study. Accumulation of the cases using this box are needed to compare to the control group. I described the necessity of larger studies in the Discussion.

Comment 5:

Where these mild COVID-19 patients? Could the device be used in patients with mores every diseases forms regarding higher concentrations of O2 and eventually intubation?

Response:
I have no experiences using this device in such severe respiratory conditions. However, by adjusting the position of the box windows, this device can be used even for patients with severe respiratory conditions such as those under intubation, provided their general condition is deemed sufficient to tolerate endoscopic procedures.
I added this description in the Discussion.

2nd Editorial decision
29-Jul-2020

Ref.: Ms. No. JCTRes-D-20-00059R1
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Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: