PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Radiation Protection Effect of Mobile Shield Barrier for the Medical
	Personnel during Endoscopic Retrograde
	Cholangiopancreatography: a Quasi-experimental Prospective
	Study
AUTHORS	Chung, Kwang Hyun; Park, Young Sook; Ahn, Sang Bong; Son,
	Byoung Kwan

VERSION 1 – REVIEW

REVIEWER	Tsutomu Nishida
	Toyonaka Municipal Hospital,Japan
REVIEW RETURNED	08-Dec-2018
GENERAL COMMENTS	Comments to the Author: Thank you for giving me the opportunity to review the manuscript: "Effect of Mobile Shield Barrier to Protect Medical Personnel during Endoscopic Retrograde Cholangiopancreatography". This paper is well written and this mobile shield barrier seems to be useful to reduce the radiation exposure of medical staff but I have some following comments.
	Major #1 I think there are some shields to reduce the radiation exposure for ERCP before now but this mobile shield barrier has improved points compared with previous one. The authors should explain and emphasize it.
	#2 Simply, I think this mobile shield barrier seems to be an obstacle and difficult to perform an ERCP procedure. Regarding objective assessment for ERCP performance, I would like to know the procedure time of ERCP compared with one without using the mobile shield barrier.
	#3 How about the rate of complications such as post ERCP pancreatitis, perforation, or bleeding during study period? I was wondering if there was a possibility of complication by using this devise because of difficulty of maneuvering a duodenoscope.
	#4 The authors should describe usage instructions of mobile shield barrier, for example, continuously or at the time of radiation exposure. If there was on or off, I feel it seems to cause a fall and dangerous for a patient.
	#5 The European Society of Gastrointestinal Endoscopy (ESGE) provided specific numerical levels of radiation exposure for ERCP in its guidelines for radiation protection in digestive endoscopy in 2012; the recommended entrance skin dose (ESD) was 55-347

mGy, and the recommended kerma-area product (KAP) was 3-333 Gy.cm2. As quality control of ERCP under the under fluoroscopic guidance, please provide such levels of radiation exposure.
Minor #1 I would recommend to refer to the recent paper evaluating radiation exposure dose during ERCP in large patients. PLoS One. 2018 Nov 19;13(11):e0207539. doi: 10.1371/journal.pone.0207539. eCollection 2018. Radiation exposure dose and influencing factors during endoscopic retrograde cholangiopancreatography.

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pa	nere is no mention of the number of endoscopists and assistant articipants that were involved in the study. This should be cluded.
A	better-quality photograph would be beneficial to the reader to sualise the position of the x-ray tube in relation to the operator
sc st ex th	nd nurse. In the image provided there seems to be a very big burce to image distance which is not ideal to minimise patient or aff dose. I would also note that a fluoroscopy rate of 30fps seems acceedingly high for ERCPs. Perhaps the authors could next study e effect of dose reduction to the patient if the frame rate is ropped to 12fps?
O cc as	ther discussion points that would make the paper more solid build be: does this concept potentially apply to other procedures s well? How does this solution affect/limit the endoscope beration? Why has p-value only been provided for age/sex?
S	pecific comments
Pa	age 3, Line 17: replace about with approximately. age 3, Line 20: A mobile shield barrier was a custom-made hould be 'The mobile shield barrier was a custom-made'.
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re	ne newly designed mobile shield was shown to significantly duce the occupational dose to the endoscopist"
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e.g. During the study period patient radiation doses were
measured for every therapeutic ERCP procedures.
Table 1, Page 9, line 13 and 28
Indication of ERCP should be changed to 'Indications for ERCP'
and (second) to (seconds)
Page 11, linés 13-17
This sentence needs reformatting: In addition, even inside the
shielding barrier, there is no significant difference between the
radiation doses reaching the inside and outside of the personal
protective equipment.
Page 11, line 41
Formal British English would use the term 'utilise'.
Page 13, line 9
There is mention of 'various health problems' that can arise in
medical personnel due to occupational radiation exposure, but this
is the first note of it in the manuscript. This concept should be
included in the introduction.
Also 'In conclusion, radiation exposure is inevitable
Line 15 should read 'extremely effective in reducing radiation
exposure'

VERSION 1 – AUTHOR RESPONSE

Reviewer(s)' Comments to Author:

Reviewer: 1 Reviewer Name: Tsutomu Nishida

Institution and Country: Toyonaka Municipal Hospital, Japan

Please state any competing interests or state 'None declared': None

Please leave your comments for the authors below

Comments to the Author:

Thank you for giving me the opportunity to review the manuscript:

"Effect of Mobile Shield Barrier to Protect Medical Personnel during Endoscopic Retrograde Cholangiopancreatography". This paper is well written and this mobile shield barrier seems to be useful to reduce the radiation exposure of medical staff but I have some following comments.

Major

#1 I think there are some shields to reduce the radiation exposure for ERCP before now but this mobile shield barrier has improved points compared with previous one. The authors should explain and emphasize it.

Response: Thank you for the important comment for our mobile shield barrier. We think the improved points of our mobile shield barrier compare to previous one are that ours is set on the floor which has less weight-related constraints; thus, we are able to utilise a shield that is bigger than that used in previous studies to cover a wider range which mentioned in second paragraph of "DISCUSSION" section. Also, it is not attached to wall, ceiling or fluoroscopy tube or table, it is easy to install and easy to remove. As your advice, we added following sentence in fifth paragraph on "DISCUSSION" section to emphasize it.

"Compared to the previous protective shields, the improvement of our mobile shield barrier is that it could have a bigger size because it is set on the floor. It covers wider range and does not interfere with the procedure. And because it is not attached to wall, ceiling, fluoroscopy tube or table, it is easy to install and easy to remove."

#2 Simply, I think this mobile shield barrier seems to be an obstacle and difficult to perform an ERCP procedure. Regarding objective assessment for ERCP performance, I would like to know the procedure time of ERCP compared with one without using the mobile shield barrier.

Response: We sincerely appreciate your comments and we understand your concerns. But, we used mobile shield barrier at all ERCP procedures during the study period therefore, unfortunately, it is not possible to compare the procedure time of ERCP with and without the use of the mobile shield barrier. However, we have used mobile shield barrier only when fluoroscopy was working, and since most of the time the duodenoscope was manipulated, the mobile shield barrier was moved slightly to one side which do not interfere the procedure. We think that the mobile shield barrier did not significantly increase the procedure time, but it takes time to move the mobile shield barrier, which takes less than 5 seconds. We added following sentence in "DISCUSSION" section as a limitation.

"The total procedure time and complication rate were not investigated and comparisons of those between with and without mobile shield barrier were not performed."

Also, we added following sentence on "DISCUSSION" section

"In the case of the total procedure time, considering that the mobile shield barrier was only used during the fluoroscopy was working, the impact on the total operation time was not considered to be significant, and fluoroscopy time did not differ much from other studies. Perhaps the time to move the mobile shield barrier to the left or right may be added, but it takes less than 5 seconds."

#3 How about the rate of complications such as post ERCP pancreatitis, perforation, or bleeding during study period? I was wondering if there was a possibility of complication by using this devise because of difficulty of maneuvering a duodenoscope.

Response: Thank you for the important point. As you mentioned, it is important that the protection device should not interfere with the procedure and should not cause complications. Because our study period was relatively short, and the number of procedures was not large, there were no major complications such as clinically significant bleeding or perforation. There were several mild post-ERCP pancreatitis occurred, but no severe pancreatitis was occurred. Considering that the main cause of pancreatitis is pancreatic duct injury and edema of papilla, most of them will occur while attempting ductal cannulation which is not the mobile shield barrier was using. Therefore, we think that the impact of mobile shield barrier to the post-ERCP pancreatitis would be minimal.

we added following sentence on "DISCUSSION" section

"During the study period, there were no major complications such as clinically significant bleeding or perforation. There were several mild post-ERCP pancreatitis occurred, but no severe pancreatitis was occurred. Considering that the main cause of pancreatitis is pancreatic duct injury and edema of papilla, most of them will occur while attempting ductal cannulation which is not the mobile shield barrier was using[21]. Therefore, we think that the impact of mobile shield barrier to the post-ERCP pancreatitis would be minimal."

#4 The authors should describe usage instructions of mobile shield barrier, for example, continuously or at the time of radiation exposure. If there was on or off, I feel it seems to cause a fall and dangerous for a patient.

Response: Thank you for the suggestion. As we mentioned in "Mobile shield barrier" paragraph on "MATERIALS AND METHODS" section, we only use mobile shield barrier during the fluoroscopy was working. When using a fluoroscope, the mobile shield barrier is placed in the torso-level of the patient, as shown in figure 1, to shield the operator's body. When fluoroscopy is not used, the mobile shield barrier is pushed to the left side and is positioned approximately at the waist-level of the patient. Because we used a device that fixes the patient's body when we perform ERCP, there is little risk that the patient will fall from the table, with or without mobile shield barrier, During the ERCP procedure in our institution, the patient had never been fall from the table.

To clarify this, we added following sentence in "Mobile shield barrier" paragraph on "MATERIALS AND METHODS" section

"While not using the fluoroscopy, the mobile shield barrier was moved slightly to the left as not to interfere with the duodenoscope manipulation and is located at the patient's waist level." #5 The European Society of Gastrointestinal Endoscopy (ESGE) provided specific numerical levels of radiation exposure for ERCP in its guidelines for radiation protection in digestive endoscopy in 2012; the recommended entrance skin dose (ESD) was 55-347 mGy, and the recommended kerma-area product (KAP) was 3-333 Gy.cm2. As quality control of ERCP under the under fluoroscopic guidance, please provide such levels of radiation exposure.

Response: Thank you for your thoughtful comment. However, we did not record the ESD and KAP because it was a study of the radiation exposure of medical personnel, not the degree of radiation exposure of patients. We thank again with your comment and will report the ESD and KAP in our future research as your advice.

Minor

#1 I would recommend to refer to the recent paper evaluating radiation exposure dose during ERCP in large patients. PLoS One. 2018 Nov 19;13(11):e0207539. doi: 10.1371/journal.pone.0207539. eCollection 2018. Radiation exposure dose and influencing factors during endoscopic retrograde cholangiopancreatography.

Response: Thank you for introducing a good paper. I added it to the reference to provide better information to readers as follows.

"Moreover, the fluoroscopy time is determined by important factors such as the difficulty of the procedure,[17,18]"

Reviewer: 2 Reviewer Name: Davide Fontanarosa, Senior Lecturer

Institution and Country: Queensland University of Technology, Australia

Please state any competing interests or state 'None declared': None declared

Please leave your comments for the authors below

General comments

The authors present a mobile shield barrier designed to minimize the risk of occupational exposure to gastroenterologists and assisting staff during ERCP procedures. Often, these staff members have no formal training in radiation protection and every effort should be made to minimise their occupational exposure. It is important to see improvements in work practices, and it is in particular reassuring that the staff involved in the procedures wear both thyroid collars and lead goggles.

In this specific study, though, a comparison with other methods should be provided, in my opinion.

Main regulatory organs already suggest using shieldings (for example, hanging from the ceiling, see "Radiation protection in digestive endoscopy: European Society of Digestive Endoscopy (ESGE) Guideline", cited also by the authors). What is the advantage of their system with respect to these other solutions is not really clear to me. And this of course also impacts on the novelty of the work, in particular considering products such as the Clear-Lead barrier by Biodex (<u>http://www.biodex.com/medical-imaging/products/radiation-protection/clear-lead-mobile-x-raybarriers</u>): how does the work presented by the authors compare to this solution?

Response: Thank you for your thoughtful comment. As you commented, several endoscopy societies recommend shielding of radiation during the ERCP procedure. However, as we have stated in the INTRODUCTION section of manuscript, the proportion of institutions that using protective shield are less than half. This is probably due to differences in interest in radiation protection, the characteristics of ERCP equipment, the condition of ERCP room and number of ERCP procedures. Therefore, it is necessary to be able to select and use various radiation shielding methods depending on the circumstances of each institution and the environment of the ERCP room. Since, several other fluoroscopic exams (e.g. upper gastrointestinal series, small bowel series and enteroclysis) are performed in ERCP room of our institution, our mobile shield barrier was designed to be easy to install and easy to remove, and we think that it will be useful for other institutions with similar to us. Although the product you have presented is similar to ours, it does not appear to be designed for being used in ERCP procedures, and no studies have been reported that confirm the feasibility and radiation protection effect using the equipment like ours when performing ERCP. Therefore, we think our study is meaningful because it shows the feasibility and effectiveness of the radiation protection shield which can be set on the floor and moved with wheel.

As far as I can understand, the whole rationale for this project is that: "our protective shield is set on the floor which has less weight-related constraints; thus, we are able to utilize a shield that is bigger than that used in previous studies to cover a wider range". The authors did not investigate (or show) what this quantitatively means. Is it necessary? Clinically relevant? Is there a clear advantage in larger thickness/wider area? A more clinical comparison with existing methods (in particular the Clear-Lead which is also on wheels) would have been useful instead of a simple comparison with a scenario where no shielding is provided. Or at least a well-developed discussion point showing the advantage over the other systems, for example: more freedom of operation for the staff? Etc...

<u>Response</u>: Thank you for your constructive feedback. In fact, our research design cannot prove that our mobile shield barrier is superior to other shields in terms of radiation protection effect because there were no comparisons with other shielding devices. We only have confirmed the effect by comparison with and without the use of a shield, and the theoretical advantage of a bigger shield is that it will prevent scattered waves reflected at various angles and ranges. Another advantage of our equipment is that it is relatively easy to install, move and remove, which is expected to be easy to apply in various institutions.

We added following sentence in second and fifth paragraph on "DISCUSSION" section to emphasize it.

"Although no direct comparison with other shielding devices has been performed, the theoretical advantage of a bigger size of our mobile shield barrier is that it will be able to shield scattered waves from more diverse angles and ranges."

"Compared to the previous protective shields, the improvement of our mobile shield barrier is that it could have a bigger size because it is set on the floor. It covers wider range and does not interfere with the procedure. And because it is not attached to wall, ceiling, fluoroscopy tube or table, it is easy to install and easy to remove."

Given that over table orientation of the x-ray tube presents a significantly higher exposure risk to staff, it would have been great to see a small section which discusses the problems associated with the over table tube orientation, and that additional protection is imperative.

Response: Thank you for the kind suggestion. We added following section on third paragraph in DISCUSSION section.

"Our institution is using an over-couch X-ray system, in which the amount of radiation received by medical staff is known to be higher than under-couch X-ray systems, especially on the thyroid gland and eyes, which is vulnerable to radiation, Therefore, the radiation protection of medical staff should be more thorough."

Page 12, line 40. A sentence should be added here quantitatively comparing the 'unshielded' and 'shielded' exposure to the ICRP limits. This would strengthen the statement that a more aggressive protection strategy is warranted, and that your shield could assist in achieving this goal.

Response: Thank you for the suggestion. We modified the sentence in fourth paragraph of the "DISCUSSION" section as follows.

"According to the results of our study alone, the amount of radiation exposure in areas without protective equipment is more than 150 mSv which exceeding the ICRP limits when we perform 250 ERCPs per year without shielding barriers. As this level is high, a more aggressive protection strategy is warranted, and our mobile shield barrier could be a possible solution by reducing the radiation exposure to less than 4 mSv/year which far below the ICRP limit."

There is no mention of the number of endoscopists and assistant participants that were involved in

the study. This should be included.

Response: Thank you for your thoughtful comment. All of the ERCP procedure was performed by one experienced endoscopist and two assistants participated in each ERCP procedure. A total of four assistants participated alternately during the study period. We added following sentence in "Endoscopic retrograde cholangiopancreatography" paragraph on "MATERIALS AND METHODS" section.

"One experienced endoscopist (BKS) performed all ERCP procedures and two assistants participated in each ERCP procedure. A total of four assistants participated alternately during the study period."

A better-quality photograph would be beneficial to the reader to visualise the position of the x-ray tube in relation to the operator and nurse. In the image provided there seems to be a very big source to image distance which is not ideal to minimise patient or staff dose.

Response: Thank you for your thoughtful comments. As you commented, the more distance between the X-ray source and the subject, the greater the risk of radiation exposure. However, during the ERCP, it is often necessary to see the patient's entire bile duct structure and the duodenum. In order to take a wide range of images, the distances between the source and the subject are often distant from each other.

I would also note that a fluoroscopy rate of 30fps seems exceedingly high for ERCPs. Perhaps the authors could next study the effect of dose reduction to the patient if the frame rate is dropped to 12fps?

Response: Thank you for your comment and suggestion. We totally agree with your comment and lowering the frame rate is a simple and effective way to reduce radiation exposure. In the next study, we will consider lowering the frame rate and we added this point on "DISCUSSION" section as follows.

"The physical environment of the ERCP unit, the distance between medical staff and the radiation source or the patient, the type of X-ray system (over-couch, under-couch, or mobile C-arm unit), the fluoroscopy parameters (use of pulsed rather than continuous fluoroscopy, **use of lower frame rates of fluoroscopy**, number of radiographs, use of collimation of X-ray beam, use of low magnification), and the use of protective equipment can affect the radiation dose[4,14-17]."

Other discussion points that would make the paper more solid could be: does this concept potentially apply to other procedures as well? How does this solution affect/limit the endoscope operation? Why

has p-value only been provided for age/sex?...

Response: Thank you for your suggestion. Perhaps we could use our mobile shield barrier for other procedures, for example pyloric stent insertion or colonic stent insertion, and further research is needed. We briefly mentioned this discussion point at the end of the "DISCUSSION" section as follows.

"It may be used for other fluoroscopic procedures, such as endoscopic pyloric stenting or colonic stenting and further research is needed."

In addition, we did not include other variables besides age, gender and indications for ERCP in the analysis because we thought that other patient factors were not variables that affect the radiation exposure of medical personnel.

Specific comments

Page 3, Line 17: replace about with approximately.

Page 3, Line 20: A mobile shield barrier was a custom-made.... Should be 'The mobile shield barrier was a custom-made'.

Page 4, Line 10-15 – the bullet points 'our newly designed movile shield barrier is large enough to shield the entire body of the medical personnel', and 'wheels on the bottom of the shield barrier allows easy movement of the shield' are not a strength of the conducted study. They are definitely of benefit in practical terms for the endoscopist, and should be included in the discussion and conclusion, but should not be noted as a study strength.

Possibly a more appropriate way to articulate the success of utilising the shield is "the newly designed mobile shield was shown to significantly reduce the occupational dose to the endoscopist"

<u>Response</u>: Thank you for the corrections and suggestions. We have made the appropriate changes. Also, we removed first two bullet points and added following bullet points instead

- The newly designed mobile shield was easy to apply, and dose not interfere with the E RCP procedure.
- The newly designed mobile shield was shown to significantly reduce the occupational dose to the endoscopist

Keywords:

I would also suggest adding occupational radiation dose, or occupational dose to your keywords.

<u>Response</u>: Thank you for the precious suggestion. We corrected the errors you pointed out and added "**occupational radiation dose**" in the keyword instead "fluoroscopy"

Page 5, line 9 Formal British English would use the term 'ionising' Page 5, Line 33 The word staff is a collective noun, so just 'staff' is correct Page 5, Lines 44-46 There are grammatical errors here. The term 'wear' should replace the term wore. Additionally, do the authors mean 'preparation' rates? Preparation would normally refer to procedures requiring a sterile drape applied to the lead shields, but traditionally ERCPs do not require this. Perhaps 'usage' may be a more appropriate term. Page 5, Line 52 The third person is preferred in scientific writing, I suggest perhaps something like 'therefore, a mobile shield barrier was designed that could be.....Also on Page 11, line 45, and 51 as well as Page 13, in 14 'our'

Response: Thank you for the corrections. The sentences were corrected as you suggested. And we modified the first-person sentence to the third-person sentence as follows.

"We solved this problem" to "This problem was solved by" "We placed the shield barrier" to "The shield barrier was placed" "Our" to "The newly designed"

Additional notes

It would be helpful to highlight whether the x-ray room had permanent lead shielding. Were there any existing table mounted lead shields?

<u>Response</u>: Thank you for the comment. We have no table mounted leading shielding and We added a comment on this fact as follows.

"There was no additional lead shielding in our ERCP room."

Page 6, Lines 22 Should read 'indications for ERCP'. This should also be changed in Table 1. The comma can also be removed after fluoroscopy time. Page 6, Line 25 The radiation exposure to whom should be defined;

e.g. During the study period patient radiation doses were measured for every therapeutic ERCP procedures.

<u>Response</u>: Thank you for the correction. We have made the appropriate changes and added following sentence to clarify from where the radiation exposure was made.

"During the study period, radiation exposure doses to inner and outer surface of mobile shield barrier and medical staff in the ERCP room were measured at every therapeutic ERCP procedures."

Table 1, Page 9, line 13 and 28Indication of ERCP should be changed to 'Indications for ERCP' and (second) to (seconds)

Page 11, lines 13-17

This sentence needs reformatting: In addition, even inside the shielding barrier, there is no significant difference between the radiation doses reaching the inside and outside of the personal protective equipment.

Response: Thank you for the pointing our mistake. We corrected the sentence as follows. "Moreover, from the inside the mobile shield barrier, there was no significant difference between the radiation doses reaching the inside and outside of the personal protective equipment."

Page 11, line 41 Formal British English would use the term 'utilise'

Response: Thank you for the correction. We have made the appropriate changes

Page 13, line 9

There is mention of 'various health problems' that can arise in medical personnel due to occupational radiation exposure, but this is the first note of it in the manuscript. This concept should be included in the introduction. Also 'In conclusion, radiation exposure is inevitable

Response: Thank you for your constructive feedback. We have added following sentence on "INTRODUCTION" section.

"Exposure of the human body to ionising radiation can result in damage to tissues and organs, and even with low levels of exposure may cause health problems, depending on the characteristics of each tissue[2]. Also, ionising radiation can cause genetic instability of cells, leading to cancer[3]."

Line 15 should read 'extremely effective in reducing radiation exposure.....'

Response: Thank you for the correction. We have made the appropriate changes

VERSION 2 – REVIEW

REVIEWER REVIEW RETURNED	Tsutomu Nishida Toyonaka Municipal Hospital, Japan 15-Jan-2019
GENERAL COMMENTS	I have read through the revised manuscript as well as the author's response to the reviewer's inquiries, and I was satisfied for the revised manuscript and recommend the manuscript for publication in BMJ Open Thank you.