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Effect of Mobile Shield Barrier to Protect Medical Personnel during Endoscopic Retrograde Cholangiopancreatography.

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Title Page

Title: Effect of Mobile Shield Barrier to Protect Medical Personnel during Endoscopic Retrograde Cholangiopancreatography.

Running title: Mobile Shield Barrier for Medical Personnel during ERCP

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Abstract

Objective: To investigate the effectiveness of radiation protection offered by a newly designed mobile shield barrier for medical personnel during endoscopic retrograde cholangiopancreatography (ERCP).

Design: Quasi-experimental prospective study

Setting: ERCP procedures conducted between October 2016 to June 2017 at a single secondary referral hospital that performs about 250 therapeutic ERCP procedures annually.

Interventions: A mobile shield barrier was a custom-made 2 mmPb shielding plate (width: 120 cm, height: 190 cm) with a 0.5 mmPb window (width: 115 cm, height: 60 cm) on its upper part was used. Four wheels were attached to the bottom to allow easy moving.

Primary and secondary outcome measures: The radiation doses were measured during ERCP using personal thermoluminescence dosimetry badges (TLD) on both sides of the mobile shield barrier (patient's side: TLD1 and medical staff's side: TLD2). The radiation doses were also measured on the outer surface of the thyroid shield of the endoscopist (TLD3), and on the chest area inside the protective apron of the endoscopist (TLD4) and the main assistant (TLD5). The TLD was changed and reported once every 3 months. The radiation dose measured by TLD badges were compared.

Results: During the study period, a total of 128 ERCP procedures were performed. The mean fluoroscopy time per procedure was 244.9 ± 257.0 seconds and the mean number of digital radiographs per procedure was 3.7 ± 1.0. TLD1 (outside the barrier) had a mean radiation dose of 26.85 ± 3.47 mSv and all the other TLDs (inside the barrier) had less than 1 mSv ($P < 0.001$). In the post hoc analysis, the difference between TLD1 and others showed a statistical significance; however, there were no significant differences between the TLDs inside the barrier.

Conclusion: Our mobile shield barrier was useful to reduce the radiation exposure of medical personnel during ERCP.

Article Summary

Strengths and limitations of this study:

- Our newly designed mobile shield barrier is large enough to shield the entire body of the medical personnel.
- Wheels on the bottom of the shield barrier allows easy movement of the shield.
- The study period was relatively short (9 months) and the number of ERCP procedures was not very large.
- Comparisons of the radiation dose were performed only between the inside and outside of the mobile shield barrier and an independent control group was not established.
- The cumulative radiation dose was measured once every 3 months, without measuring the radiation dose for each ERCP procedure.

Keywords: Radiation Protection; Cholangiopancreatography, Endoscopic Retrograde; Protective Devices; thermoluminescence dosimetry; Fluoroscopy

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) and its related procedures inevitably use ionizing radiation for imaging of the bile duct and pancreatic duct during the procedure, which poses a potential risk of radiation exposure of medical staff and patients[1]. The patient gains direct benefit from the procedure and is exposed to radiation only few times, whereas the medical staff are repeatedly exposed to radiation; therefore, more attention must be given to radiation protection for medical staff. To minimize the radiation exposure to patients and medical staff, the ALARA principle (as low as reasonably achievable) should be strictly followed and continuous monitoring of radiation exposure is required[2]. The International Commission on Radiological Protection recommends a maximum safe limit for the effective dose of 20 mSv/year (averaged over a defined 5-year period with no single year exceeding 50 mSv) for the whole body as well as for the eye,[3] and the Institute of Nuclear Safety of the Republic of Korea also applies this recommendation for the radiation dose limit for occupational exposure in planned exposure situations.

There are several factors that affect the radiation exposure of medical staffs during ERCP, one of which is the use of personal protective equipment and radiation protection shields[4]. However, use of these protection devices are often overlooked due to lack of awareness of radiation hazards and the discomfort of using protective devices. According to a survey conducted in the Republic of Korea in 2011, only 52.5% of endoscopists responded that they always wear thyroid shield, and 26.9% of them rarely or never wear it. Moreover, only 14% were lead glasses during the procedure and 69% never were it and the preparation rates of mobile shields or lead curtains were only 14% and 24%, respectively[5]. This propensity had not improved remarkably when a similar survey was conducted again in 2013[6]. It would be possible to reduce this tendency by creating shielding barriers that are easy to use and have excellent protection capabilities. Therefore, we designed a mobile shield barrier that could be placed between the patient and the medical staff while the fluoroscopy is being employed. The mobile barrier had the ability to shield the entire body of the medical staff during ERCP. The aim of this study was to

verify the effectiveness of our mobile shield barrier.

MATERIALS AND METHODS

Study design

This prospective quasi-experimental study was conducted in a secondary referral hospital which performs about 250 therapeutic ERCPs annually. The study period was between October 2016 and June 2017 and all the patients were over 18 years of age. Information including patient demographics, indication of ERCP, fluoroscopy time, and number of digital radiographs was recorded at the time of the procedure. During the study period, radiation exposure doses were measured at every therapeutic ERCP procedures. The study was approved by the Institutional Review Board (protocol number: EMCIRB 2017-07-013) of Eulji Hospital. The study was investigator-initiated and received no external funding.

Endoscopic retrograde cholangiopancreatography

All procedures were performed by using a Sonialvision Safire 17 fluoroscopy system (Shimadzu, Japan) which is an overcouch X-ray system comprising a digital table (ZS-100i, Shimadzu, Japan, width: 76.5 cm, height: 235 cm) and a high voltage X-ray generator (UD150BC-40, Shimadzu, Japan, 80kW) installed in 2011. The fluoroscopy mode was set as pulsed fluoroscopy with a rate of 30 frames per second. Fluoroscopy time was displayed on the monitor of the fluoroscopy controller. The entire ERCP procedure was performed under fluoroscopic guidance using a standard side-view duodenoscope (TJF-240, Olympus, Tokyo, Japan).

Mobile shield barrier

The mobile shield barrier was a custom-made 2 mmPb shield plate (width: 120 cm, height: 190 cm) with a 0.5 mmPb window (width: 115 cm, height: 60 cm) on the upper part. Four wheels were attached to the bottom to allow for easy moving. In order to facilitate the duodenoscope manipulation, a notch through which the shaft of the endoscope can be inserted was made on the side of the barrier. This mobile shield barrier was placed between patient and the medical staff, including the endoscopist and the assisting nurse while the fluoroscopy was employed (**Figure 1**). Each medical staff member wore a lead wrap-around protective apron (0.35-mm Pb), a thyroid shield (lead collar, 0.35-mm Pb), and lead goggles (0.75-mm Pb).

Outcome measurement

The radiation exposure doses were measured by personal thermoluminescence dosimetry (TLD) badges (InLight® Quixel, Hanil Nuclear Co., Ltd., Republic of Korea) and were changed and reported every 3 months according to the Regulations for Safety Management of Diagnostic Radiation of the National Dose Registry (NDR), a part of the Korea Centers for Disease Control and Prevention (KCDC).

TLD badges were attached to the surface of the patient's side (TLD1) and the medical staff's side (TLD2) of the mobile shield barrier at the level of the medical staff's neck. TLD3 was attached on the outer surface of thyroid shield of endoscopist, and TLD4 and TLD5 were placed inside the protective apron at the level of the chest of endoscopist and that of the main assistant. The primary outcome of the study was the radiation dose measured by the TLD badge. TLD1 and TLD2 are almost in the same position, but TLD1 is closer to the x-ray generator by about 1 cm due to the thickness of the mobile shield barrier.

Statistical analysis

Data are shown as the number (%) for categorical variables and the mean (± SD) for continuous variables. To compare the characteristics of the study groups, the chi-squared test or Fisher's exact test was used for categorical variables and the Student's t test was used for the continuous variables to compare two groups. We used one-way analysis of variance, followed by a post-hoc analysis using pairwise comparisons with Bonferroni adjustment to compare three or more groups, where appropriate. Double-sided *P*-values of < 0.05 were considered statistically significant. All statistical analyses were conducted using the R software (R for Windows 3.5.1; The R Foundation for Statistical Computing, Vienna, Austria).

Patient and public involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

RESULTS

Patients and procedure details

Patient characteristics and procedure details are described in **Table 1**.

Table 1. Patient and Procedural Characteristics

	Total	**1–3 Months**	**4–6 Months**	**7–9 Months**	**P-value**
N	128	43	47	38	

Age (years)(mean ± SD)	69.6 ± 14.5	69.6 ± 11.9	68.7 ± 16.1	70.7 ± 15.2	0.818
Sex					0.248
Male	49 (39.1%)	17 (39.5%)	14 (29.8%)	18 (47.4%)	
Female	79 (61.7%)	26 (60.5%)	33 (70.2%)	20 (52.6%)	
Indication of ERCP (no, %)					0.541
Bile duct stone	78 (60.9%)	27 (62.8%)	30 (63.8%)	21 (55.3%)	
Bile duct cancer	17 (13.3%)	6 (14.0%)	3 (6.4%)	8 (21.1%)	
Pancreatic cancer	4 (3.1%)	0 (0.0%)	2 (4.3%)	2 (5.3%)	
Pancreatitis	4 (3.1%)	2 (4.7%)	1 (2.1%)	1 (2.6%)	
Others	25 (19.5%)	8 (18.6%)	11 (23.4%)	6 (15.8%)	
Fluoroscopy time (second)(mean ± SD)	244.9 ± 257.0	254.6 ± 354.5	194.9 ± 156.9	295.7 ± 217.7	0.191
No. of digital radiographs (mean ± SD)	3.7 ± 1.0	3.8 ± 1.2	3.3 ± 0.8	4.2 ± 0.9	< 0.001

During the study period, a total of 128 ERCP procedures were performed. The mean age of patients were 69.6 ± 14.5 years. The indication for ERCP was mostly choledocholithiasis (60.9%). The mean fluoroscopy time per procedure was 244.9 ± 257.0 seconds and the mean number of digital radiographs per procedure was 3.7 ± 1.0. The patient age, sex, and indications for ERCP were not significantly different in each 3-month period.

Cumulative radiation exposure

The cumulative radiation exposure of each 3-month period is presented in **Table 2**.

Table 2. Radiation Exposure

	1–3 Months	4–6 Months	7–9 Months
Number of ERCP procedure	43	47	38
Cumulative fluoroscopy time	10949	9160	5966
Cumulative number of digital radiographs	165	153	158
Radiation dose (TLD1) (mSv) – barrier surface, patient's side	30.69	25.89	23.96
Radiation dose (TLD2) (mSv) – barrier surface, medical staff's side	1.50	0.25	0.22
Radiation dose (TLD3) (mSv) - on the thyriod shield	0.34	0.16	0.15
Radiation dose (TLD4) (mSv) - inside the lead apron, endoscopist	0.33	0.12	0.09
Radiation dose (TLD5) (mSv) - inside the lead apron, nurse	0.14	0.10	0.08

The cumulative fluoroscopy time and digital radiograph number as well as the TLD doses were highest in the first 3-month period. The mean TLD result of each location is presented in **Figure 2**. TLD1 (outside the barrier) had a mean radiation dose of 26.85 ± 3.47 mSv and all the rest of TLDs (inside the barrier) were less than 1 mSv ($P < 0.001$). In the post hoc analysis, the difference between TLD1 and the others showed statistical significance ($P < 0.001$); however, there were no significant differences between the TLDs inside the barrier ($P = 1.000$).

DISCUSSION

Several methods are used for protecting medical personnel from radiation during ERCP, and personal protective equipment is one of the methods[4]. Personal protective equipment, however, does not cover the entire body; moreover, its heavy weight can cause musculoskeletal disorders and can sometimes be disregarded due to discomfort[4,5]. In this study, we showed that the amount of radiation reaching the medical staff can be drastically reduced by using a mobile shield barrier. 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.

The idea of using a protective shield to protect medical staff from radiation during ERCP has been around for a long time. In 1996, Chen et al.[7] attempted to reduce the radiation exposure of medical personnel by using a 0.5 mm lead acrylic shield that hangs from the ceiling and could be placed between the patient and the endoscopist, which significantly reduced the radiation exposure of the endoscopist from 2.5 mR to 0.27 mR per procedure. In 2002, Johlin et al.[8] used a phantom model to demonstrate that a curtain of beads fashioned as a shield could reduce the radiation exposure of medical staff during ERCP. More recently, in 2011, Kim et al.[9] used a curtain-shaped protective shield composed of seven movable lead plates to reduce radiation. Several other studies have attempted to attach lead shields directly to X-ray tubes[10-12] or image intensifiers[13]. The above-mentioned studies commonly used a method of hanging a radiation protective shield from above, similar to a curtain. In contrast, 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. Another point to consider is that manipulation of the duodenoscope may be interrupted by the shielding barrier. We solved this problem by putting wheels on the bottom of the shield barrier to allow easy movement of the shield and a small notch was incorporated on the side to acquire space for movement of the duodenoscope shaft. We placed the shield barrier between the patient and medical staff only when using the fluoroscopy; during most of the time that the duodenoscope was manipulated, the shield barrier was moved slightly to one side so as not to interfere with the duodenoscope manipulation. In addition, ancillary effects are

expected to reduce unnecessary fluoroscopy time.

The amount of radiation the medical staff receives over a period is affected by various factors. 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, 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[4,14-16]. Moreover, the fluoroscopy time is determined by important factors such as the difficulty of the procedure,[17] the proficiency level of the endoscopist and the assistant,[18] education and awareness regarding radiation protection,[19,20] and the number of ERCP procedures during the period. Hence, the different scenarios at each institution and those of the ERCP units should be taken into account when comparing the degree of radiation exposure for each institution.

The fluoroscopy time per procedure in our study is approximately 4 minutes which is not significantly different from the fluoroscopy times of previous studies (5.32 to 14.5 minutes)[10,13,14]. The actual radiation dose received by medical personnel may differ from the radiation dose measured by the TLD; nonetheless, the radiation dose outside the mobile shield barrier exceeded 80 mSv only in 9 months. According to the results of our study alone, the amount of radiation exposure in areas without protective equipment is more than 150 mSv 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.

Our study had a few limitations. Our study was conducted for a relatively short period of 9 months and the number of ERCPs was not very large. In addition, only the radiation dose inside and outside the mobile shield barrier was compared without setting the independent control group without a mobile shield barrier. However, we showed reduction of the radiation dose by approximately 1/40 using the mobile shield barrier, which demonstrates remarkable efficacy and not only just a statistical difference.

Moreover, the radiation doses between the TLDs inside the mobile shield barrier were not significantly different, and this can help reduce the role of personal protective equipment.

In conclusion, radiation exposure in inevitable during ERCP and this can cause various health problems in medical personnel. It is essential to lower the radiation exposure by as much as possible and various protective equipment or devices should be used appropriately. Our mobile shield barrier was found to be extremely effective for reducing radiation exposure and could be one of the options for protecting medical personnel from radiation exposure during ERCP.

ACKNOWLEDGMENTS

None

STATEMENT OF COMPETING INTERESTS

None declared

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AUTHOR CONTRIBUTIONS

BKS contributed to the concept and design of the study. He also drafted the initial manuscript. KHC

critically reviewed the research protocol and contributed to analyzing of data and writing of the manuscript. YSP and SBA contributed to the data interpretation, and critically revised the manuscript. All authors were involved in editing the manuscript. All authors read and approved the final manuscript.

Patient consent

Not required.

ETHICAL APPROVAL

The study protocol was approved by the institutional review board of Eulji General Hospital (protocol number: EMCIRB 2017-07-013).

DATA SHARING STATEMENT

All available data can be obtained from the corresponding author.

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Figure legends

Figure 1. ERCP room and mobile shield barrier. (a) Size and shape of mobile shield barrier. (b) Arrangement of fluoroscopy tube, table, endoscopic instruments, and mobile shield barrier in the ERCP room. Locations of thermoluminescence dosimetry badges are indicated by circled numbers. E: endoscopist, A: assistant. (c) Photo of ERCP room and mobile shield barrier.

Figure 2. Box plot of thermoluminescence dosimetry value at different locations. Each number represents the mean value.

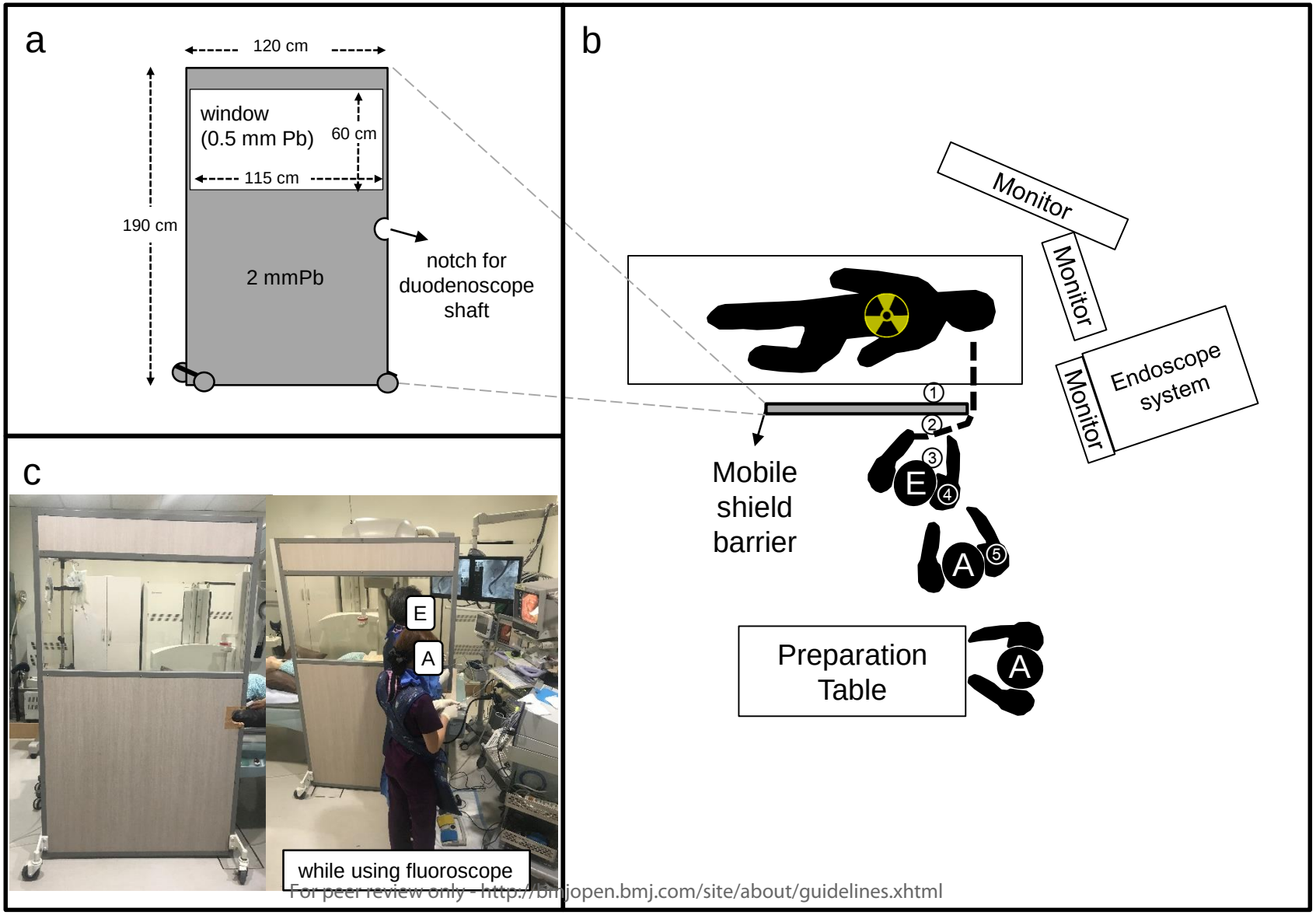
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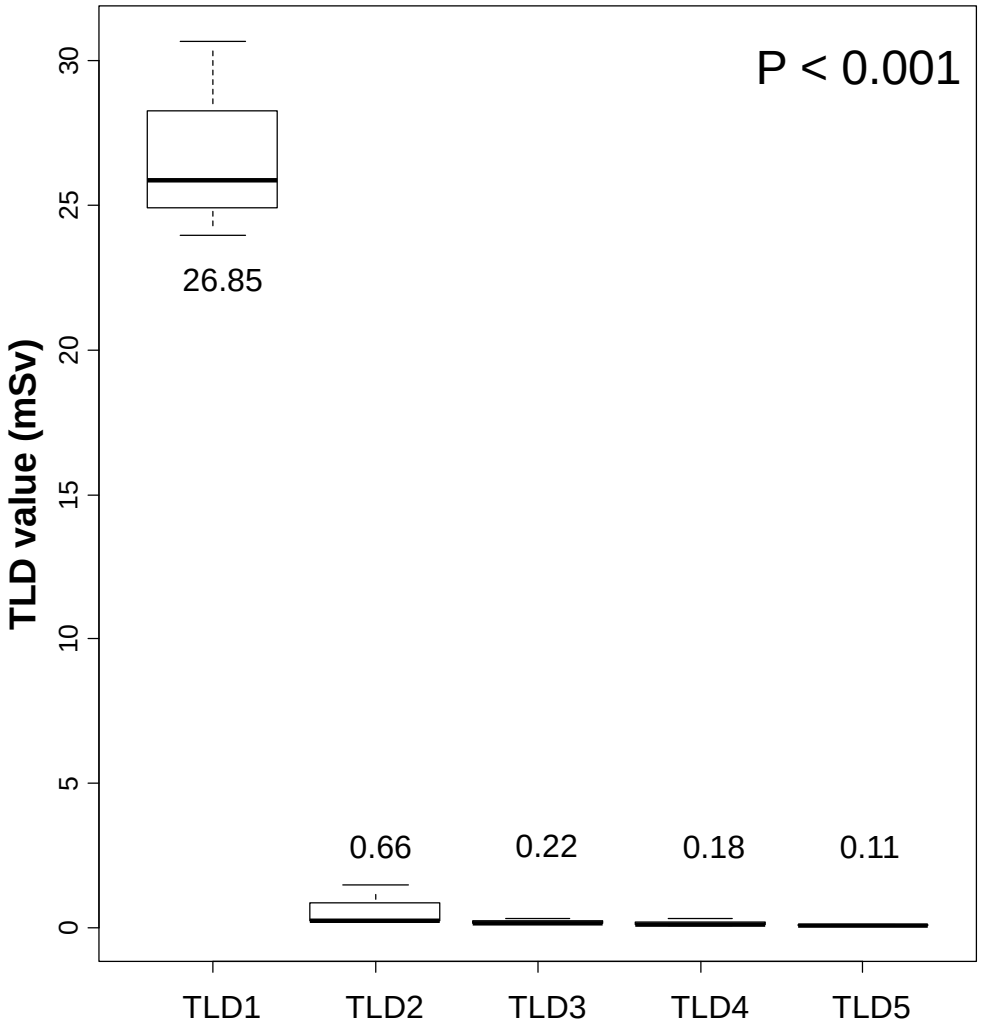
Figure 2



P-values of pairwise comparisons using Bonferroni adjustment

TLD 1 vs. TLD 2, TLD 1 vs. TLD 3, TLD 1 vs. TLD 4, TLD 1 vs. TLD 5; $P < 0.001$

TLD 2 vs. TLD 3, TLD 2 vs. TLD 4, TLD 2 vs. TLD 5; $P = 1.000$

TLD 3 vs. TLD 4, TLD 3 vs. TLD 5; $P = 1.000$

TLD 4 vs. TLD 5; $P = 1.000$

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#5
Objectives	3	State specific objectives, including any pre-specified hypotheses	#5-6
Methods			
Study design	4	Present key elements of study design early in the paper	#6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	#7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#7
Bias	9	Describe any efforts to address potential sources of bias	N/A
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#7-8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	#8-9
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	#8-10
		(b) Indicate number of participants with missing data for each variable of interest	#8
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	#9-10
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	#9-10
		(*b*) Report category boundaries when continuous variables were categorized	#9-10
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	#10-11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	#12
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#11-12
Generalisability	21	Discuss the generalisability (external validity) of the study results	#1-13
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#13

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Radiation Protection Effect of Mobile Shield Barrier for the Medical Personnel during Endoscopic Retrograde Cholangiopancreatography: a Quasi-experimental Prospective Study

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Title Page

Title: Radiation Protection Effect of Mobile Shield Barrier for the Medical Personnel during Endoscopic Retrograde Cholangiopancreatography: a Quasi-experimental Prospective Study.

Running title: Mobile Shield Barrier for Medical Personnel during ERCP

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Abstract

Objective: To investigate the effectiveness of radiation protection offered by a newly designed mobile shield barrier for medical personnel during endoscopic retrograde cholangiopancreatography (ERCP).

Design: Quasi-experimental prospective study

Setting: ERCP procedures conducted between October 2016 to June 2017 at a single secondary referral hospital that performs approximately 250 therapeutic ERCP procedures annually.

Interventions: The mobile shield barrier was a custom-made 2 mmPb shielding plate (width: 120 cm, height: 190 cm) with a 0.5 mmPb window (width: 115 cm, height: 60 cm) on its upper part was used. Four wheels were attached to the bottom to allow easy moving.

Primary and secondary outcome measures: The radiation doses were measured during ERCP using personal thermoluminescence dosimetry badges (TLD) on both sides of the mobile shield barrier (patient's side: TLD1 and medical staff's side: TLD2). The radiation doses were also measured on the outer surface of the thyroid shield of the endoscopist (TLD3), and on the chest area inside the protective apron of the endoscopist (TLD4) and the main assistant (TLD5). The TLD was changed and reported once every 3 months. The radiation dose measured by TLD badges were compared.

Results: During the study period, a total of 128 ERCP procedures were performed. The mean fluoroscopy time per procedure was 244.9 ± 257.0 seconds and the mean number of digital radiographs per procedure was 3.7 ± 1.0. TLD1 (outside the barrier) had a mean radiation dose of 26.85 ± 3.47 mSv and all the other TLDs (inside the barrier) had less than 1 mSv ($P < 0.001$). In the post hoc analysis, the difference between TLD1 and others showed a statistical significance; however, there were no significant differences between the TLDs inside the barrier.

Conclusion: Our mobile shield barrier was useful to reduce the radiation exposure of medical personnel

during ERCP.

Article Summary

Strengths and limitations of this study:

- The newly designed mobile shield was easy to apply, and dose not interfere with the ERCP procedure.
- The newly designed mobile shield was shown to significantly reduce the occupational dose to the endoscopist
- The study period was relatively short (9 months) and the number of ERCP procedures was not very large.
- Comparisons of the radiation dose were performed only between the inside and outside of the mobile shield barrier and an independent control group was not established.
- The cumulative radiation dose was measured once every 3 months, without measuring the radiation dose for each ERCP procedure.

Keywords: Radiation Protection; Cholangiopancreatography, Endoscopic Retrograde; Protective Devices; thermoluminescence dosimetry; occupational radiation dose

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) and its related procedures inevitably use ionising radiation for imaging of the bile duct and pancreatic duct during the procedure, which poses a potential risk of radiation exposure of medical staff and patients[1]. 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]. The patient gains direct benefit from the procedure and is exposed to radiation only few times, whereas the medical staff are repeatedly exposed to radiation; therefore, more attention must be given to radiation protection for medical staff. To minimize the radiation exposure to patients and medical staff, the ALARA principle (as low as reasonably achievable) should be strictly followed and continuous monitoring of radiation exposure is required[4]. The International Commission on Radiological Protection (ICRP) recommends a maximum safe limit for the effective dose of 20 mSv/year (averaged over a defined 5-year period with no single year exceeding 50 mSv) for the whole body as well as for the eye,[5] and the Institute of Nuclear Safety of the Republic of Korea also applies this recommendation for the radiation dose limit for occupational exposure in planned exposure situations.

There are several factors that affect the radiation exposure of medical staff during ERCP, one of which is the use of personal protective equipment and radiation protection shields[6]. However, use of these protection devices are often overlooked due to lack of awareness of radiation hazards and the discomfort of using protective devices. According to a survey conducted in the Republic of Korea in 2011, only 52.5% of endoscopists responded that they always wore thyroid shield, and 26.9% of them rarely or never wore it. Moreover, only 14% wore lead glasses during the procedure and 69% never wore it and the usage rates of mobile shields or lead curtains were only 14% and 24%, respectively[7]. This propensity had not improved remarkably when a similar survey was conducted again in 2013[8]. It would be possible to reduce this tendency by creating shielding barriers that are easy to use and have

excellent protection capabilities. Therefore, a mobile shield barrier was designed that could be placed between the patient and the medical staff while the fluoroscopy is being employed. The mobile barrier had the ability to shield the entire body of the medical staff during ERCP. The aim of this study was to verify the effectiveness of our mobile shield barrier.

MATERIALS AND METHODS

Study design

This prospective quasi-experimental study was conducted in a secondary referral hospital which performs about 250 therapeutic ERCPs annually. The study period was between October 2016 and June 2017 and all the patients were over 18 years of age. Information including patient demographics, indications for ERCP, fluoroscopy time and number of digital radiographs was recorded at the time of the procedure. 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. The study was approved by the Institutional Review Board (protocol number: EMCIRB 2017-07-013) of Eulji Hospital. The study was investigator-initiated and received no external funding.

Endoscopic retrograde cholangiopancreatography

All procedures were performed by using a Sonialvision Safire 17 fluoroscopy system (Shimadzu, Japan) which is an over-couch X-ray system comprising a digital table (ZS-100i, Shimadzu, Japan, width: 76.5 cm, height: 235 cm) and a high voltage X-ray generator (UD150BC-40, Shimadzu, Japan, 80kW) installed in 2011. The fluoroscopy mode was set as pulsed fluoroscopy with a rate of 30 frames per second. Fluoroscopy time was displayed on the monitor of the fluoroscopy controller. The entire ERCP procedure was performed under fluoroscopic guidance using a standard side-view duodenoscope (TJF-

240, Olympus, Tokyo, Japan). 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. There was no additional lead shielding in our ERCP room.

Mobile shield barrier

The mobile shield barrier was a custom-made 2 mmPb shield plate (width: 120 cm, height: 190 cm) with a 0.5 mmPb window (width: 115 cm, height: 60 cm) on the upper part. Four wheels were attached to the bottom to allow for easy moving. In order to facilitate the duodenoscope manipulation, a notch through which the shaft of the endoscope can be inserted was made on the side of the barrier. This mobile shield barrier was placed between patient and the medical staff, including the endoscopist and the assisting nurse while the fluoroscopy was employed (**Figure 1**). 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. Each medical staff member wore a lead wrap-around protective apron (0.35-mm Pb), a thyroid shield (lead collar, 0.35-mm Pb), and lead goggles (0.75-mm Pb).

Outcome measurement

The radiation exposure doses were measured by personal thermoluminescence dosimetry (TLD) badges (InLight® Quixel, Hanil Nuclear Co., Ltd., Republic of Korea) and were changed and reported every 3 months according to the Regulations for Safety Management of Diagnostic Radiation of the National Dose Registry (NDR), a part of the Korea Centers for Disease Control and Prevention (KCDC).

TLD badges were attached to the surface of the patient's side (TLD1) and the medical staff's side (TLD2) of the mobile shield barrier at the level of the medical staff's neck. TLD3 was attached on the outer

surface of thyroid shield of endoscopist, and TLD4 and TLD5 were placed inside the protective apron at the level of the chest of endoscopist and that of the main assistant. The primary outcome of the study was the radiation dose measured by the TLD badge. TLD1 and TLD2 are almost in the same position, but TLD1 is closer to the x-ray generator by about 1 cm due to the thickness of the mobile shield barrier.

Statistical analysis

Data are shown as the number (%) for categorical variables and the mean (± SD) for continuous variables. To compare the characteristics of the study groups, the chi-squared test or Fisher's exact test was used for categorical variables and the Student's t test was used for the continuous variables to compare two groups. We used one-way analysis of variance, followed by a post hoc analysis using pairwise comparisons with Bonferroni adjustment to compare three or more groups, where appropriate. Double-sided *P*-values of < 0.05 were considered statistically significant. All statistical analyses were conducted using the R software (R for Windows 3.5.1; The R Foundation for Statistical Computing, Vienna, Austria).

Patient and public involvement

This research was done without patient involvement. Patients were not invited to comment on the study design and were not consulted to develop patient relevant outcomes or interpret the results. Patients were not invited to contribute to the writing or editing of this document for readability or accuracy.

RESULTS

Patients and procedure details

Patient characteristics and procedure details are described in **Table 1**.

Table 1. Patient and Procedural Characteristics

	Total	**1–3 Months**	**4–6 Months**	**7–9 Months**	**P-value**
N	128	43	47	38	
Age (years) (mean ± SD)	69.6 ± 14.5	69.6 ± 11.9	68.7 ± 16.1	70.7 ± 15.2	0.818
Sex					0.248
Male	49 (39.1%)	17 (39.5%)	14 (29.8%)	18 (47.4%)	
Female	79 (61.7%)	26 (60.5%)	33 (70.2%)	20 (52.6%)	
Indications for ERCP (no, %)					0.541
Bile duct stone	78 (60.9%)	27 (62.8%)	30 (63.8%)	21 (55.3%)	
Bile duct cancer	17 (13.3%)	6 (14.0%)	3 (6.4%)	8 (21.1%)	
Pancreatic cancer	4 (3.1%)	0 (0.0%)	2 (4.3%)	2 (5.3%)	
Pancreatitis	4 (3.1%)	2 (4.7%)	1 (2.1%)	1 (2.6%)	
Others	25 (19.5%)	8 (18.6%)	11 (23.4%)	6 (15.8%)	
Fluoroscopy time (seconds) (mean ± SD)	244.9 ± 257.0	254.6 ± 354.5	194.9 ± 156.9	295.7 ± 217.7	0.191
No. of digital radiographs (mean ± SD)	3.7 ± 1.0	3.8 ± 1.2	3.3 ± 0.8	4.2 ± 0.9	< 0.001

During the study period, a total of 128 ERCP procedures were performed. The mean age of patients were 69.6 ± 14.5 years. The indication for ERCP was mostly choledocholithiasis (60.9%). The mean fluoroscopy time per procedure was 244.9 ± 257.0 seconds and the mean number of digital radiographs

per procedure was 3.7 ± 1.0. The patient age, sex, and indications for ERCP were not significantly different in each 3-month period.

Cumulative radiation exposure

The cumulative radiation exposure of each 3-month period is presented in **Table 2**.

Table 2. Radiation Exposure

	1–3 Months	**4–6 Months**	**7–9 Months**
Number of ERCP procedure	43	47	38
Cumulative fluoroscopy time	10949	9160	5966
Cumulative number of digital radiographs	165	153	158
Radiation dose (TLD1) (mSv) – barrier surface, patient's side	30.69	25.89	23.96
Radiation dose (TLD2) (mSv) – barrier surface, medical staff's side	1.50	0.25	0.22
Radiation dose (TLD3) (mSv) - on the thyroid shield	0.34	0.16	0.15
Radiation dose (TLD4) (mSv) - inside the lead apron, endoscopist	0.33	0.12	0.09
Radiation dose (TLD5) (mSv) - inside the lead apron, nurse	0.14	0.10	0.08

The cumulative fluoroscopy time and digital radiograph number as well as the TLD doses were highest in the first 3-month period. The mean TLD result of each location is presented in **Figure 2**. TLD1

(outside the barrier) had a mean radiation dose of 26.85 ± 3.47 mSv and all the rest of TLDs (inside the barrier) were less than 1 mSv ($P < 0.001$). In the post hoc analysis, the difference between TLD1 and the others showed statistical significance ($P < 0.001$); however, there were no significant differences between the TLDs inside the barrier ($P = 1.000$).

DISCUSSION

Several methods are used for protecting medical personnel from radiation during ERCP, and personal protective equipment is one of the methods[6]. Personal protective equipment, however, does not cover the entire body; moreover, its heavy weight can cause musculoskeletal disorders and can sometimes be disregarded due to discomfort[6,7]. In this study, we showed that the amount of radiation reaching the medical staff can be drastically reduced by using a mobile shield barrier. 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.

The idea of using a protective shield to protect medical staff from radiation during ERCP has been around for a long time. In 1996, Chen et al.[9] attempted to reduce the radiation exposure of medical personnel by using a 0.5 mm lead acrylic shield that hangs from the ceiling and could be placed between the patient and the endoscopist, which significantly reduced the radiation exposure of the endoscopist from 2.5 mR to 0.27 mR per procedure. In 2002, Johlin et al.[10] used a phantom model to demonstrate that a curtain of beads fashioned as a shield could reduce the radiation exposure of medical staff during ERCP. More recently, in 2011, Kim et al.[11] used a curtain-shaped protective shield composed of seven movable lead plates to reduce radiation. Several other studies have attempted to attach lead shields directly to X-ray tubes[12-14] or image intensifiers[15]. The above-mentioned studies commonly used a method of hanging a radiation protective shield from above, similar to a curtain. In contrast, our protective shield 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. 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. Another point to consider is that manipulation of the duodenoscope may be interrupted by the shielding barrier. This problem was solved by putting wheels on the bottom of the shield barrier to allow easy movement of the shield and a small notch was incorporated on the side to acquire space for movement of the duodenoscope shaft. The shield barrier was placed between the patient and medical staff only when using the fluoroscopy; during most of the time that the duodenoscope was manipulated, the shield barrier was moved slightly to one side so as not to interfere with the duodenoscope manipulation. In addition, ancillary effects are expected to reduce unnecessary fluoroscopy time.

The amount of radiation the medical staff receives over a period is affected by various factors. 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[6,16-19]. Moreover, the fluoroscopy time is determined by important factors such as the difficulty of the procedure,[20,21] the proficiency level of the endoscopist and the assistant,[22] education and awareness regarding radiation protection,[23,24] and the number of ERCP procedures during the period. Hence, the different scenarios at each institution and those of the ERCP units should be taken into account when comparing the degree of radiation exposure for each institution. 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[6]. Therefore, the radiation protection of medical staff should be more thorough.

The fluoroscopy time per procedure in our study is approximately 4 minutes which is not significantly different from the fluoroscopy times of previous studies (5.32 to 14.5 minutes)[12,15,16]. The actual radiation dose received by medical personnel may differ from the radiation dose measured by the TLD; nonetheless, the radiation dose outside the mobile shield barrier exceeded 80 mSv only in 9 months. 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[5] 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[5].

Our study had a few limitations. Our study was conducted for a relatively short period of 9 months and the number of ERCPs was not very large. In addition, only the radiation dose inside and outside the mobile shield barrier was compared without setting the independent control group without a mobile shield barrier or with different type of shield. The total procedure time and complication rate were not investigated and comparisons of those between with and without mobile shield barrier were not performed. However, we showed reduction of the radiation dose by approximately 1/40 using the mobile shield barrier, which demonstrates remarkable efficacy and not only just a statistical difference. Moreover, the radiation doses between the TLDs inside the mobile shield barrier were not significantly different, and this can help reduce the role of personal protective equipment. 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. 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[25]. Therefore, we think that the impact of mobile shield barrier to the post- ERCP pancreatitis would be minimal.

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. In conclusion, radiation exposure in inevitable during ERCP and this can cause various health problems in medical personnel. It is essential to lower the radiation exposure by as much as possible and various protective equipment or devices should be used appropriately. The newly designed mobile shield barrier was found to be extremely effective in reducing radiation exposure and could be one of the options for protecting medical personnel from radiation exposure during ERCP. It may be used for other fluoroscopic procedures, such as endoscopic pyloric stenting or colonic stenting and further research is needed.

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STATEMENT OF COMPETING INTERESTS

None declared

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AUTHOR CONTRIBUTIONS

BKS contributed to the concept and design of the study. He also drafted the initial manuscript. KHC critically reviewed the research protocol and contributed to analyzing of data and writing of the manuscript. YSP and SBA contributed to the data interpretation, and critically revised the manuscript. All authors were involved in editing the manuscript. All authors read and approved the final manuscript.

Patient consent

Not required.

ETHICAL APPROVAL

The study protocol was approved by the institutional review board of Eulji General Hospital (protocol number: EMCIRB 2017-07-013).

DATA SHARING STATEMENT

All available data can be obtained from the corresponding author.

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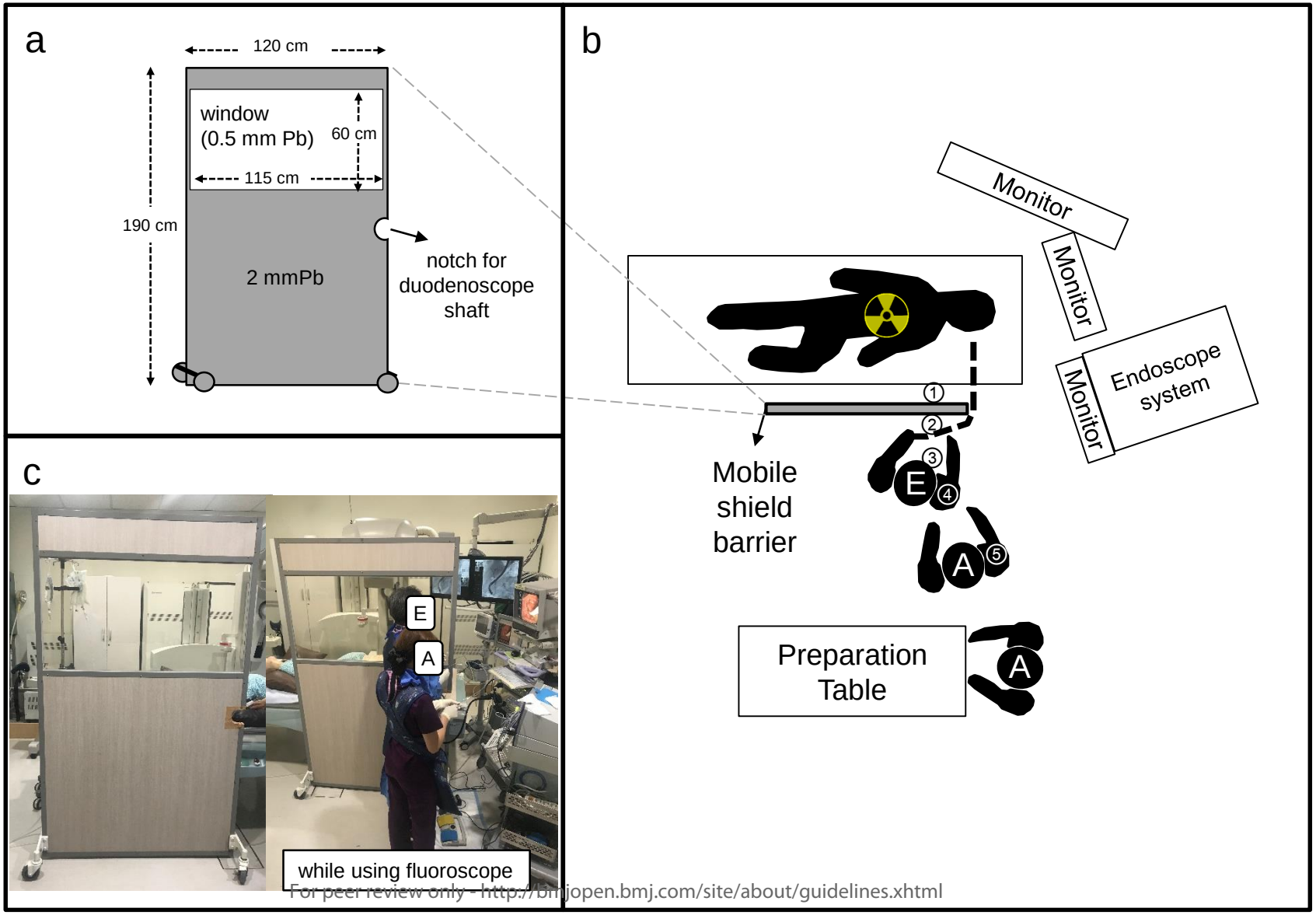
Figure legends

Figure 1. ERCP room and mobile shield barrier. (a) Size and shape of mobile shield barrier. (b) Arrangement of fluoroscopy tube, table, endoscopic instruments, and mobile shield barrier in the ERCP room. Locations of thermoluminescence dosimetry badges are indicated by circled numbers. E: endoscopist, A: assistant. (c) Photo of ERCP room and mobile shield barrier.

Figure 2. Box plot of thermoluminescence dosimetry value at different locations. Each number represents the mean value.

Figure 1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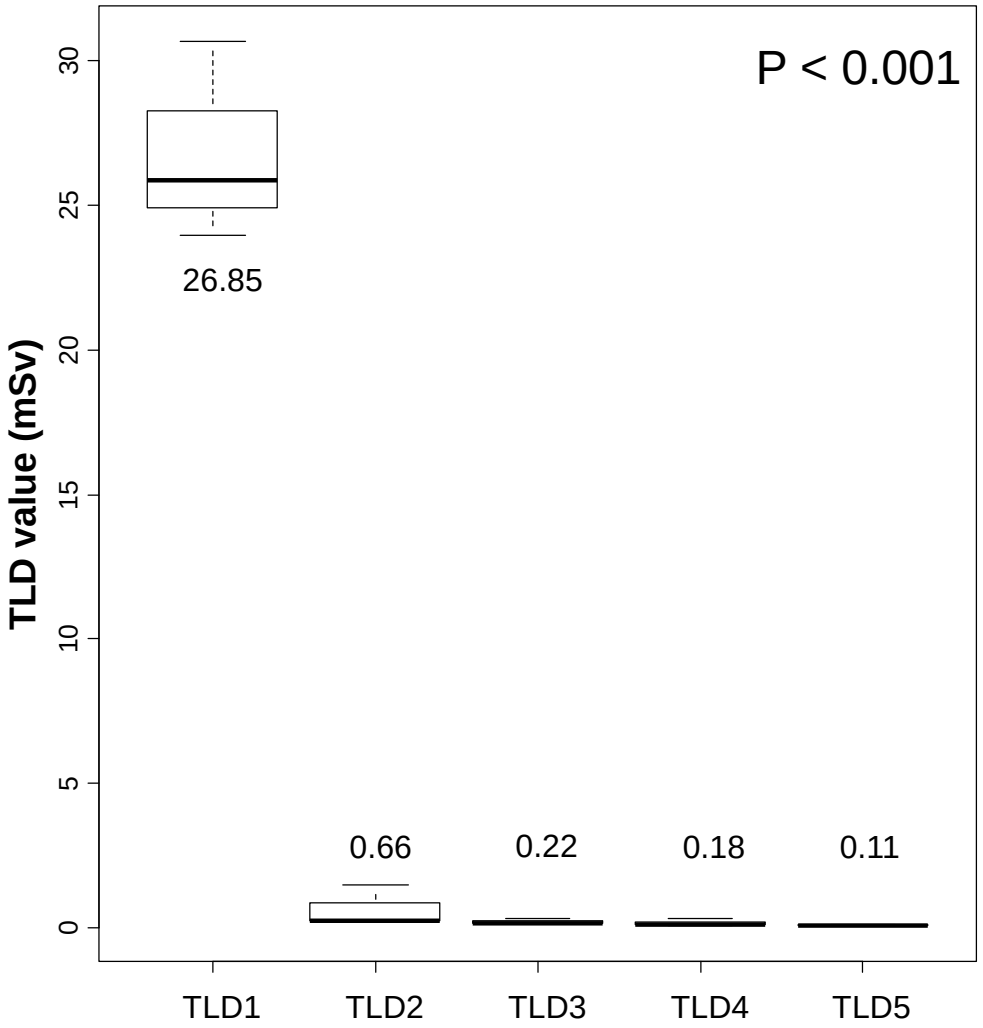

P-values of pairwise comparisons using Bonferroni adjustment

TLD 1 vs. TLD 2, TLD 1 vs. TLD 3, TLD 1 vs. TLD 4, TLD 1 vs. TLD 5; $P < 0.001$

TLD 2 vs. TLD 3, TLD 2 vs. TLD 4, TLD 2 vs. TLD 5; $P = 1.000$

TLD 3 vs. TLD 4, TLD 3 vs. TLD 5; $P = 1.000$

TLD 4 vs. TLD 5; $P = 1.000$

STROBE 2007 (v4) checklist of items to be included in reports of observational studies in epidemiology*

Checklist for cohort, case-control, and cross-sectional studies (combined)

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	#3
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	#3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	#5
Objectives	3	State specific objectives, including any pre-specified hypotheses	#5-6
Methods			
Study design	4	Present key elements of study design early in the paper	#6
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	#6
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	#7
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	#7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	#7
Bias	9	Describe any efforts to address potential sources of bias	N/A
Study size	10	Explain how the study size was arrived at	N/A
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	#7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	#7-8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed	N/A

		Cross-sectional study—If applicable, describe analytical methods taking account of sampling strategy	
		(*e*) Describe any sensitivity analyses	N/A
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	#8-9
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	#8-10
		(b) Indicate number of participants with missing data for each variable of interest	#8
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	#9-11
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	#9-11
		(*b*) Report category boundaries when continuous variables were categorized	#9-11
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A
Discussion			
Key results	18	Summarise key results with reference to study objectives	#11
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	#13-14
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	#11-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	#11-14
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	#15

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.