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CONTEMPORARY ISSUES IN RADIATION PROTECTION IN MEDICAL IMAGING SPECIAL FEATURE: REVIEW ARTICLE

The radiation doses and radiation protection on the endoscopic retrograde cholangiopancreatography procedures

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ABSTRACT

Although many interventions involving radiation exposure have been replaced to endoscopic procedure in the gastrointestinal and hepatobiliary fields, there remains no alternative for enteroscopy and endoscopic retrograde cholangiopancreatography (ERCP), which requires the use of radiation. In this review, we discuss the radiation doses and protective measures of endoscopic procedures, especially for ERCP. For the patient radiation dose, the average dose area product for diagnostic ERCP was 14–26 Gy.cm^2, while it increased to as high as 67–89 Gy.cm^2 for therapeutic ERCP. The corresponding entrance skin doses for diagnostic and therapeutic ERCP were 90 and 250 mGy, respectively. The mean effective doses were 3– 6 mSv for diagnostic ERCP and 12–20 mSv for therapeutic ERCP. For the occupational radiation dose, the typical doses were 94 µGy and 75 µGy for the eye and neck, respectively. However, with an overcouch-type X-ray unit, the eye and neck doses reached as high as 550 and 450 µGy, with maximal doses of up to 2.8 and 2.4 mGy/procedure, respectively.

A protective lead shield was effective for an over couch X-ray tube unit. It lowered scattered radiation by up to 89.1% in a phantom study. In actual measurements, the radiation exposure of the endoscopist closest to the unit was reduced to approximately 12%. In conclusion, there is a clear need for raising awareness among medical personnel involved endoscopic procedures to minimise radiation risks to both the patients and staff.

INTRODUCTION

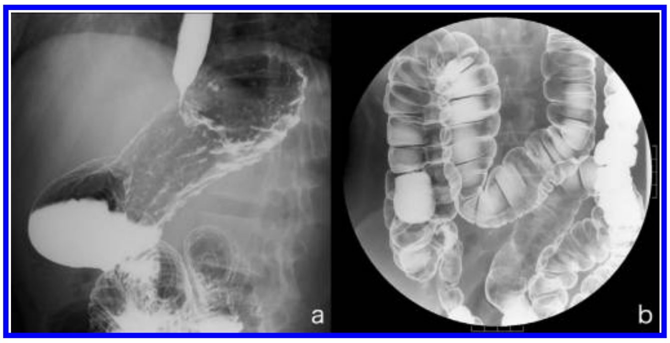
Radiation has become an essential approach in medicine and gives substantial benefits to patients in daily practice,[1] while it can cause stochastic effects in longer terms and tissue reactions in shorter terms.[2–7] Patients undergoing recurrent high-dose procedures using ionising radiation are exposed to a cumulative dose similar to that among atomic bomb explosion survivors.[8–11]

In the gastrointestinal and hepatobiliary fields, various interventions also involve radiation exposure. For example, barium meal examination, barium enema, and enteroscopy involve X-rays. Barium meal examination and barium enema, which are used to identify mucosal changes and evaluate lesions via oral or transanal administration of barium (Figure 1),[12–14] are standard examination procedures. However, they are also associated with radiation exposure problems, with the effective doses being 1–3 mSv (barium meal examination) and 7–8 mSv (barium enema).[15]

As such, these procedures have been replaced by upper gastrointestinal endoscopy and colonoscopy, with endoscopy not only allowing visualisation of the digestive tract and tissue collection for pathological diagnosis, but also eliminating the need for radiation.

Meanwhile, in the hepatobiliary diseases, the main endoscopic intervention is endoscopic retrograde cholangiopancreatography (ERCP), which requires radiation exposure. In principle, ERCP involves using contrast to view the bile and pancreatic ducts, via X-ray fluoroscopy. There are several ERCP-related procedures in both diagnosis (*e.g.* cytology and biopsy) and treatment (*e.g.* cholecystectomy

Figure 1. X-ray in barium meal examination and barium enema.



and drainage of bile duct obstruction), all of which require radiographic guidance. Unlike barium meal examination and barium enema, there is currently no alternative to ERCP. Recently, drainage therapy for biliopancreatic region diseases using ultrasound endoscopy has been reported, but it requires radiographic guidance as well as ERCP.[16]

However, the awareness of radiation exposure among endoscopists is still low. Although there are many reports on the evaluation of fluoroscopy endoscopic procedures, radiation dose is rarely used as an evaluation item.

International organisations, such as the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency, and the United Nations Scientific Committee on the Effects of Atomic Radiation and radiological societies have attempted to keep medical radiation exposure as low as reasonably achievable (ALARA) by establishing diagnostic reference levels (DRLs).[17] ICRP 135 recommends that all individuals who are involved in subjecting a patient to a medical exposure should be familiar with the DRL process as a tool for optimising protection.[18] However, there are still not enough data available on radiation exposure for gastrointestinal fluoroscopic procedures, including ERCP. There is no mention of ERCP in DRLs in the United States and the United Kingdom.[19,20] In DRL from Japan, there is a description of ERCP, but not in detail.[21] Therefore, endoscopists need to understand the current status of radiation exposure related to ERCP and raise their awareness of radiation protection.

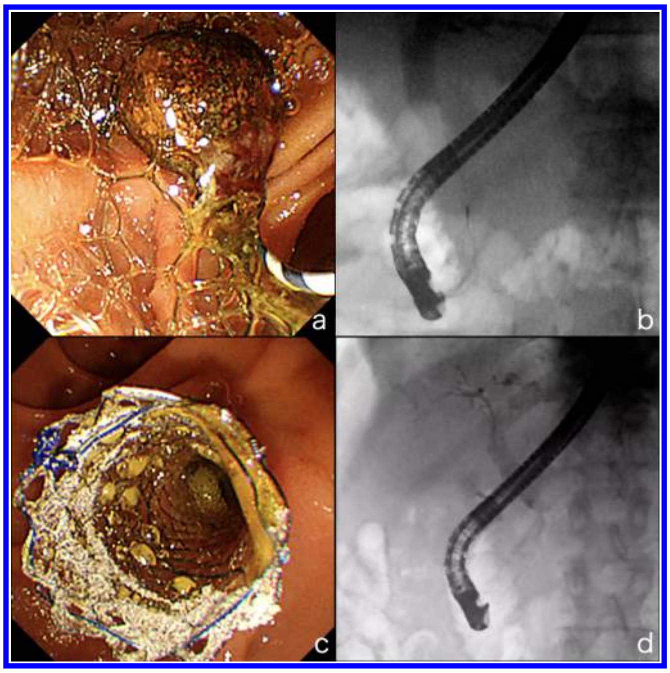
In this review, we discuss radiation doses and protective measures in ERCP.

ERCP

ERCP is a technique that combines the use of endoscopy and fluoroscopy to diagnose and treat biliary or pancreatic ductal systems. ERCP studies account for 8.5% of all fluoroscopically guided diagnostic and interventional procedures in the USA, with a mean effective dose of 4 mSv. They account for 4–5% of the total collective dose from fluoroscopically guided interventions.[22]

For ERCP, a duodenoscope is advanced into the duodenum, and transpapillary procedures, including cholangiopancreatography,

Figure 2. Therapeutic ERCP (a, b) Common bile duct stone removal (c, d) Biliary metallic stent placement. ERCP, endoscopic retrograde cholangiopancreatography



stone removal, and biliary drainage, are performed under the guidance of fluoroscopy.

Fluoroscopy is used to produce live and essential static images, while other procedures are performed with reference to endoscopic images. When the scope is inserted, fluoroscopy is used to verify the shape of the scope and position relationship within the duodenum. The insertion of cannulas and guidewires into the bile or pancreatic dust is also verified fluoroscopically. After successful cannulation, contrast injections are performed to evaluate the anatomy of the biliary and/or pancreatic ductal systems fluoroscopically.

There is a wide variety of ERCP-related procedures. Diagnostic ERCP techniques include bile duct and pancreatic duct angiography, biopsy, or cytology from stricture, while therapeutic ERCP includes stent placement for biliary or pancreatic duct stenosis and biliary or pancreatic stone. Fluoroscopy is essential for all these procedures (Figure 2).

Given that ERCP always involves radiation exposure, it can be challenging to perform in certain patients, such as in pregnant females in whom exposure to the foetus is a serious problem. The maximum permitted dose of ionising radiation to the foetus during the entire pregnancy is 0.005 Sv.[23–26] During ERCP, radiation exposure to the foetus may increase the risk of intrauterine foetal death, malformations, disturbance of growth and development, mutations, and cancer. Therefore, these risks should be discussed with pregnant patients and their families before ERCP. Lead shielding should be used to minimise the radiation exposure to the uterus.[26]

ERCP can apparently cause high patient and occupational doses, consequently requiring radiological protection. The European Society of Gastrointestinal Endoscopy guidelines on radiation protection in digestive endoscopy recommend the proper management of radiation exposure for ERCP. However, they reported a small sample size and concluded that little progress has been achieved to date.[27]

ICRP has published a number of reports that provide assistance in the protection and safety of radiation in medicine. In publication 85, ICRP covered the need of radiological protection issues in interventional procedures, however among the ERCP-related procedures, only endoscopic biliary drainage (EBD) was mentioned, and no other various ERCP-related procedures were described in detail.[28]

Patient radiation dose

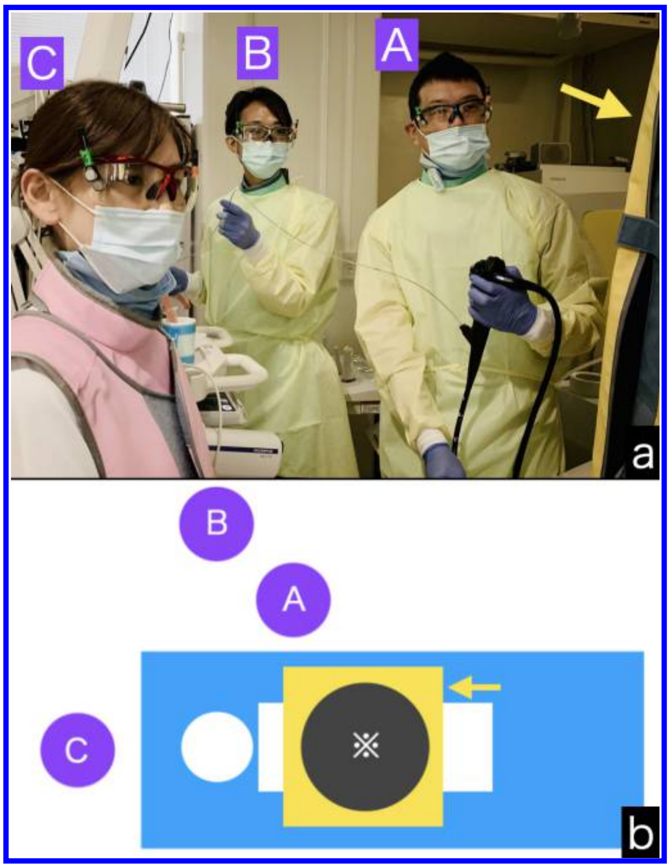
For the patient, the source of radiation exposure is the direct X-ray beam from the X-ray unit. The average dose–area product (DAP) for ERCP is approximately 13–66 Gy.cm², and effective doses range from 2 to 6 mSv/procedure.[29] In a report measuring 2778 radiation doses in ERCP, the median values of radiation dose and fluoroscopy time in ERCP were the air kerma (AK) 109 mGy, DAP 13.3 Gy.cm², and fluoroscopy time (FT) 10.0 min.[30] The radiation dose differs between each procedure in ERCP. In the examination of the difference in radiation dose depending on the target disease of ERCP from the same institution, proximal malignant biliary obstruction (MBO) was reported to require significantly longer procedure time and fluoroscopy time and resulted in greater RD than distal MBO (p = 0.0006,<0.0001,<0.0001) and common bile stones (p = 0.015, <0.0001, <0.0001).[31]

In the analysis of 372 cases of biliary drainage only, the mean values of radiation dose and fluoroscopy time during ERCP were AK 88.4 mGy, kerma–area product (KAP) 21.9 Gy.cm², and FT 16.0 min.[16]

The radiation dose differs between each procedure in ERCP. The ESGE guidelines report mean value of entrance skin dose (ESD) during ERCP ranges between 55 and 347 mGy in most studies, with values approximately three times higher for therapeutic compared with diagnostic ERCP. Mean values of KAP reported for diagnostic and therapeutic ERCP are in the range of 3–115 Gy.cm² and 8–333 Gycm2, respectively.[27] The amount of radiation exposure to ERCP further differs between diagnostic ERCP and therapeutic ERCP.[30,31] The average DAP for diagnostic ERCP is reported to 14–26 Gy.cm², while it reaches 67–89 Gy.cm² for therapeutic ERCP. The corresponding ESD for diagnostic and therapeutic ERCP are 90 mGy and 250 mGy, respectively. The mean effective doses are 3–6 mSv for diagnostic ERCP and 12–20 mSv for therapeutic ERCP.[32] Fluoroscopic exposure accounts for almost 70% of the dose for diagnostic ERCP and >90% of the dose for therapeutic ERCP, indicating that reduction of fluoroscopy time is an efficient approach for dose management.[32]

The devices used for therapeutic ERCP have evolved significantly,[33–37] and endoscopic treatment is now possible for cases of large stones and hilar bile duct stenosis, which were previously indicated for surgery. However, these procedures require a long examination time, which leads to an increase in the radiation dose. Therefore, the trend of higher radiation doses from therapeutic ERCP as compared to diagnostic ERCP will continue.

Figure 3. Positional relationship between medical staff and the X-ray unit in ERCP examination (a) Endoscopist (b) Assistant endoscopist (c) Nurse (※) X-ray unit. Arrow: protective lead shield for an over couch tube X-ray unit.



Occupational radiation dose

The major source of X-ray exposure for gastroenterologists and other staff is scattered radiation from the patient, rather than the primary X-ray beam.

In ERCP examinations, endoscopists, assistant endoscopists, and nurses usually enter the laboratory and stand beside the X-ray unit (Figure 3). Anaesthesiologists may also be present in some facilities.

Studies comparing the radiation exposure doses among medical staff reported differences in the staff who received the highest doses, ranging from nurses to endoscopists.[38,39] This difference might be because the location of X-ray units and positioning of medical staff vary among facilities. In general, health-care workers positioned closest to the X-ray unit receive the highest radiation exposure. If the endoscopist is closest to the X-ray unit, the occupational radiation dose of the endoscopist will be the highest among the medical staff.

Figure 4. Protective lead shield for an over couch tube X-ray unit.

Wearing a lead apron provides adequate protection from scattered radiation, and it has been reported to achieve an exposure of approximately 2–70 µSv/procedure.[29,40] In every ERCP procedure, the typical doses are 94–340 µGy to the head and neck region (eyes and thyroid) and 280–830 µGy to the fingers.[40,41]

Although it is well known that an over couch tube X-ray unit is not adequate for performing interventional procedures, ERCP commonly involves the use of this type of equipment (Figure 4). For gastroenterologists, typical doses are 94 µGy and 75 µGy for the eye and neck, respectively.[40] However, with use of an over couch type X-ray unit, the eye and neck doses increase to as high as 550 µGy and 450 µGy, with maximal doses up to 2.8 mGy and 2.4 mGy/procedure, respectively.[41]

Dose to the eye lens is crucial, and with moderate workloads, the annual equivalent dose limit for the eye lens (20 mSv) may be reached. Even with the use of a protective lead shield for over couch tube X-ray, the measured eye lens dose for the endoscopist standing closest to the X-ray unit was close to 20 mSv/year.[38] In a recent meta-analysis, the frequency of ERCPs exceeding the annual equivalent dose limit for the eye lens was also investigated and concluded that ocular radiation exposures in high-volume ERCP operators (>200 procedures/year) and operators performing complex ERCPs involving prolonged fluoroscopy, need to exercise caution in relation to ocular exposure.[42]

Difficulties with the ERCP technique may become apparent after the examination, so shielding using lead-lined glasses may be reasonable when performing ERCP.

Basic principles of radiation exposure protection in ERCP

One of the fundamentals of radiation protection in ERCP is the appropriate selection of indications for ERCP. If the purpose is to evaluate the bile duct and obtain pancreatic duct images, magnetic resonance cholangiopancreatography should be used instead as it requires less radiation exposure.[43]

It is important to develop a strategy before inserting the scope, as the extension of the procedure time leads to an extension of the fluoroscopy time and in turn, radiation exposure.

Training and experience can be useful for lowering radiation, as endoscopists' skills also have a significant impact on procedure time. It has been reported that fluoroscopy time is shortened when ERCP is performed by an endoscopist who has many years of experience with ERCP. Compared to endoscopists who performed more than 200 ERCPs in the previous year, endoscopists who performed less than 100 and 100–200 ERCPs in the previous year had 59 and 11% more fluoroscopy time, respectively. For every 10 year experience, the fluoroscopy time is decreased by 20%.[44] The patient's position also affects the eye lens radiation exposure in ERCP. The prone position is one-third of the lens exposure compared to the left lateral position.[45]

Patient and occupational exposure are also related. Unnecessarily prolonging fluoroscopy time, obtaining many unintended X-ray images, and approaching an X-ray unit or X-ray source without exposure protection will lead to an increase in radiation exposure and the potential risk of ionising radiation.

The three principles of radiation protection are "distance," "time," and "shielding."[46]

With respect to "distance," the longer the distance from the X-ray unit, the lower the radiation exposure. This is supported by the lower radiation dose of the assistant endoscopist than that of the endoscopist as the assistant endoscopist stands farther from the X-ray unit than does the endoscopist.[29] For "time," when fluoroscopy is used for guidance in endoscopy, the shortest possible fluoroscopy time is recommended for any procedure. Therefore, setting a limit on the examination time may reduce both the patient and occupational doses by significantly decreasing the fluoroscopy time and dose.[47] With respect to "shielding," shields and fully protective clothing (protective aprons, thyroid shields, lead glasses) can be used against radiation exposure. Acrylic shields, equivalent to 0.5 mm lead, are well known as radiation shields and have been reported to reduce occupational radiation exposure by a factor of 11.[48]

Recently, the usefulness of a protective lead shield for an over couch-tube X-ray unit has been reported (Figure 4).[49,50] In a phantom study, it was reported to reduce scattered radiation by up to 89.1%.[51]

In actual measurements, it was reported that using the protective shield, the radiation dose at the endoscopist's position was reduced up to 97%.[49] It was also reported that, when protective curtains were not used, the mean radiation doses to endoscopists, first assistants, second assistants, and nurses were 340.9, 27.5, 45.3, and 33.1 µSv, respectively; doses decreased to 42.6, 4.2, 13.1, and 10.6 µSv, respectively, when protective curtains were used ($p < 0.01$).[50]

The best approach for medical personnel is to wear protective clothing (protective aprons, thyroid shield, and lead glasses).

Figure 5. An endoscopist wearing glasses with both leaded glasses for radiation protection and a face shield for infection control.

Although it is not possible to document the health effects of radiation at the dose levels to which gastroenterologists performing ERCP or fluoroscopy are exposed, annual effective doses are typically 0–3 mSv when appropriate radiological protection tools and principles are applied.[29] However, many gastroenterologists do not routinely wear protective clothing during ERCP examinations, with only approximately 50% wearing a thyroid shield during ERCP.[52] This result means that gastroenterologists are not highly aware of radiation exposure and need to be educated. In addition, with the advent of coronavirus disease 2019 (COVID-19), which is currently throwing the world into confusion, endoscopists must also strengthen their infection protection measures. For example, those who normally wear glasses must wear a lead glass on top of their glasses, and a face shield on top of that to prevent infection (Figure 5). This heavy equipment clearly reduces visibility, and it is feared that the rate of wearing lead glasses will further decrease. This will require measures such as reducing the weight of radiation protection devices.

Development of equipment for radiation protection in ERCP

In addition to the three basic principles, the development of equipment has recently played an important role in reducing the radiation dose used in ERCP. Compared with a conventional continuous fluoroscopy unit, a grid-controlled pulsed fluoroscopy unit could achieve significantly lower patient doses without loss of diagnostic accuracy for various abdominal and pelvic fluoroscopic examinations.[53]

A C-arm X-ray unit with pulsed fluoroscopy placed under the table achieves markedly lower patient and worker doses than does an over couch tube X-ray unit.[41] However, in many facilities the over couch tube X-ray procedures are still being performed. One of the reasons for this situation is that the number of under couch systems is smaller than that of over couch systems, and the other is that many radiation fluoroscopy rooms are not large enough to use the C-arm X-ray unit, and at last but not least, lack of knowledge.

These advances in fluoroscopy equipment make it possible to lower the amount of radiation used without compromising the image quality required for the examination. A single-centre observational study of radiation dose used in ERCP over an 8-year period reported that the radiation dose was lower after fluoroscopy device updates.[54,55]

In ERCP, cholangiopancreatoscopy, which is a thin dedicated endoscope that can be inserted into the bile duct, may be used for detailed examination of the duct. The recently developed digital single-operator cholangiopancreatoscopy has significantly better resolution, resulting in lower radiation doses than those in conventional fibreoptic SCOP.[56]

Endoscopic ultrasound-guided drainage, a transgastrointestinal drainage procedure performed under fluoroscopy using EUS imaging and fluoroscopy for guidance, has recently gained popularity as a drainage treatment for pancreatobiliary diseases.[57–60] Although this procedure uses fluoroscopy, it also uses ultrasound images, and thus, the radiation dose is expected to be lower. However, the first study to assess radiation exposure in EUS-D compared with that in ERCP-D reported that the mean AK, KAP, and FT in the EUS-D group were higher by 53%, 28%, and 27%, respectively, than those in the ERCP-D group, PT was shorter by approximately 11% (AK; 135.0 *vs* 88.4, KAP; 28.1 *vs* 21.9, FT; 20.4 *vs* 16.0, PT; 38.7 *vs* 43.5).[16]

A prospective multicentre radiation dose measurement test is currently conducted in Japan, the results of a similar analysis are awaited.[61]

CONCLUSION

Several interventions for gastrointestinal and hepatobiliary diseases have been replaced to lower radiation exposure. However, ERCP that require the use of radiation remain as primary modalities, highlighting the need for radiation exposure protection measures. Some ERCP indications are expected to have high radiation exposure before the examination, such as post-operative gastrointestinal dissection cases and multiple common bile duct stones. However, many difficult ERCPs cannot be predicted pre-operatively, so it is recommended to be highly aware of radiation exposure protection in all ERCPs. Maintaining optimal X-ray equipment, using pulsed fluoroscopy, minimising fluoroscopy time, limiting the number of radiographic images, limiting the use of magnification, using shielding walls, and wearing full protective clothing every time (protective aprons, thyroid shield, lead glasses) can lower both patient and occupational radiation exposure.

As latest review described, the current situation requires imaging device manufacturers to urgently develop imaging technologies that are safer for patients.[62]

The low rate of usage of protective equipment among medical personnel highlights the need for education measures to raise awareness on the radiation risks to both patients and staff. To date, in a comparative study of ERCP-related procedures, the procedure success rate, clinical success rate, and complication rate, were comparative study items, but in 2020, the radiation dose was used as a comparative study item.[63]

From now on, it is expected that the radiation dose during ERCP will be evaluated on a national scale, and that it will lead to the situation where ERCP is performed by using radiation more appropriately.

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