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# Attitudes to radiation safety and cholangiogram interpretation in endoscopic retrograde cholangiopancreatography (ERCP): a UK survey

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## ABSTRACT

**Background** Fluoroscopy during endoscopic retrograde cholangiopancreatography (ERCP) exposes staff and patients to potentially harmful ionizing radiation. We performed a UK survey to explore trainee and trainer attitudes to radiation protection and cholangiogram interpretation in ERCP.

**Methods** An electronic 10-point survey was prospectively distributed to endoscopy unit leads, training programme directors between October and November 2019. Only UK-based ERCP trainees and trainers with hands-on procedural exposure were eligible for the survey.

**Results** The survey was completed by 107 respondents (58 trainees and 49 trainers), with an estimated overall response rate of 46%. Overall, 49% of respondents were up to date with their radiation protection course, 38% were aware of European Basic safety standards directive (BSSD), 38% wore radiation protection goggles, and 40% were aware of the average radiation screening dose per ERCP procedure. Compared with trainers, trainees were less likely to routinely wear thyroid protection shields (76% vs 92%; p=0.028), have awareness of the BSSD (20% vs 49%; p=0.037) or know their average procedural radiation dosages (21% vs 63%; p<0.001). With regard to cholangiogram interpretation, only 26% had received formal training, with 97% of trainees expressing a desire for further training.

**Conclusion** This survey highlights a relative complacency in safety attitudes to radiation protection during ERCP. These data provide impetus to improve training and quality assurance in radiation protection, which should be regarded as a mandatory safety aspect prior to commencing hands-on ERCP training.

## Significance of this study

### What is already known on this topic

- Endoscopic retrograde cholangiopancreatography (ERCP) involves the use of potentially harmful ionising radiation which can be mitigated through various endoscopist and procedural factors.
- National data on attitudes to radiation safety and cholangiogram interpretation are lacking.

### What this study adds

- The uptake of mandatory training in radiation safety is low.
- Usage of radioprotective personal protective equipment (PPE) and dosimeters is limited and varies between trainees and trainers.
- Only 26% received formal cholangiogram training, with 87% of respondents expressing the desire for additional training.

### How might it impact on clinical practice in the foreseeable future?

- Training in radiation safety and the use of PPE should be emphasised and audited in line with national legislation.
- Fluoroscopy time should be regularly measured and included as a safety metric for ERCP.
- Provisions for training in cholangiogram acquisition and interpretation should be addressed and covered in competency assessments during training.

## INTRODUCTION

Fluoroscopy is routinely used during endoscopic retrograde cholangiopancreatography (ERCP) to delineate biliary anatomy and guide therapeutic decision-making. This exposes patients, endoscopists and supporting staff to potentially harmful ionising radiation.[1] With the advent of non-invasive imaging modalities, ERCP is increasingly reserved for therapy, with resultant increases in average procedure times and radiation exposure.[2 3] Although it is unlikely that a single fluoroscopic procedure will have lasting sequelae, the cumulative effects over a prolonged period can be detrimental.[1 4] A therapeutic ERCP procedure may incur the radiation dose of as much as 1000 chest radiographs.[5] Efforts to minimise radiation exposure to personnel first began with the As Low As Reasonably Achievable (ALARA) principles and dose limits stipulated under the International Commission for Radiological Protection (ICRP), followed by ERCP-specific guidelines on radiation protection.[6] Despite this, the understanding of ALARA principles and the adoption of radioprotective personal protective equipment (PPE) remains variable.[7] Moreover, competency in the acquisition and interpretation of cholangiograms are important for successful ERCP and are determinants of radiation exposure.

We therefore conducted a nationwide UK survey to explore trainee and trainer attitudes to radiation protection in ERCP, to include aspects of cholangiogram interpretation, and to provide education on the rationale in support of practice considerations behind each survey question.

## METHODS

### Survey design

An electronic survey was designed and prospectively distributed to endoscopy unit leads and training programme directors between October–November 2019 for circulation to trainees and trainers with hands-on ERCP exposure. The survey had 10 points, covering radiation protection and cholangiogram interpretation (online supplemental figure 1).

### Radiation protection

To facilitate awareness of radiation protection practices, each radiation protection survey question was annotated with a rationale statement on their best practice based on available evidence and guidelines from national and international societies. This was performed on PubMed, Embase and Medline (English, full papers, dated until April 2020) using the combination keywords of ERCP, radiation and additional terms relevant to each survey question.

### Cholangiogram interpretation

As cholangiograms are the primary source of radiation exposure in ERCP, cholangiogram interpretation was included in the survey, comprising: cholangiogram reporting practices, formal training, subjective competence in interpretation and the desire for additional training.

### Statistical analysis

Survey responses were stratified according to trainee and trainer status to determine differences between groups. Comparisons of categorical and continuous data were made using Pearson $\chi^2$ and Mann-Whitney tests, respectively. Ad hoc univariable analyses were performed to explore strengths of associations between survey responses. Statistical analyses were performed in SPSS (V.25, IBM Corp), with $p<0.05$ indicative of significance.

## RESULTS

### Survey respondents

The survey was completed by 107 respondents, of whom 58 (54.2%) were ERCP trainees and 49 (47.8%) were trainers. Based on published UK-wide training data involving 109 trainees and 123 trainers,[8] the estimated overall response rate was 46% (trainees: 53%; trainers: 40%).

Survey responses, stratified by role, are summarised in tables 1 and 2.

### Radiation protection

Are you up to date with your radiation protection course?

*Finding*

Yes in 49% (43% of trainees vs 55% of trainers, p=0.216).

*Rationale*

Under the European Union Basic Safety and Standards Directive (BSSD) 2013 and the UK Health and Safety Executive,[9] all practitioners who apply ionising radiation

**Table 1** Survey responses relevant to radiation protection, stratified by endoscopic retrograde cholangiopancreatography (ERCP) trainee and trainer status

| | Overall (n=107) | Trainee (n=58) | Trainer (n=49) | P value |
|---|---|---|---|---|
| Up to date with radiation protection and hygiene course | 49% | 43% | 55% | 0.216 |
| Awareness of European Basic Safety Standards Directive for Radiation Safety | 38% | 29% | 49% | **0.037*** |
| Regularly wear radiation protection goggles | 38% | 38% | 39% | 0.929 |
| Regularly wear thyroid protection shield | 83% | 76% | 92% | **0.028*** |
| Awareness of average radiation screening dose per ERCP procedure | 40% | 21% | 63% | **<0.001*** |

*Denotes p <0.05 between trainee and trainer groups.

**Table 2** Survey responses relevant to cholangiogram interpretation, stratified by endoscopic retrograde cholangiopancreatography (ERCP) trainee and trainer status

| | Overall (n=107) | Trainee (n=58) | Trainer (n=49) | P value |
|---|---|---|---|---|
| Routine reporting of ERCP cholangiograms by radiologists | 22% | 29% | 14% | 0.063 |
| Received formal training in reporting ERCP cholangiograms | 26% | 21% | 33% | 0.161 |
| Confidence in reporting cholangiograms (visual analogue scale 0–100)† | 78 (58–90) | 61 (34–79) | 90 (78–99) | **<0.001*** |
| Would benefit from more training in reporting ERCP cholangiograms | 87% | 97% | 76% | **0.001** |

*Denotes p <0.05 between trainee and trainer groups.
†Presented in median and IQRs.

should undertake mandatory training in radiation protection.[4] The European Association of Nuclear Medicine recommends 30–50 hours of theory based learning which should be embedded at Trust/regional level to cover BSSD principles.[10] UK ERCPists are bound by the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R), which were updated in 2018 to incorporate BSSD (table 3).[11] Under IR(ME)R legistation 17(2), certification should be issued once a practitioner has been adequately trained.[11] An e-learning for healthcare (e-LfH) module is available to develop competence with IR(ME)R regulations,[12] covering fundamentals in physics, radiation protection, legal requirements, diagnostic and interventional radiology.

### Are you aware of European BSSD for radiation safety?

*Finding*

Yes in 38% (29% of trainees vs 49% of trainers, p=0.037). Fifty-eight per cent of those who had received up-to-date radiation protection training were aware of the BSSD, compared with 20% of those who had not (p<0.001).

*Rationale*

The European BSSD takes into account recommendations by the ICRP and aim to promote ALARA principles to monitor and minimise radiation emissions while maintaining adequate image quality.[4] In short, examiners can reduce the occupational exposure to radiation by using the principles based on distance from the X-ray tube,[9] fluoroscopy time[13] and shielding.[6]

### Do you regularly wear radiation protection goggles?

*Finding*

Yes in 38% (38% of trainees vs 39% trainers, p=0.929).

*Rationale*

Radiation exposure to the eye may lead to cataract formation. The ICRP recommends an annual dose limit to the eye of 20 mSv.[4 6] The mean dose of radiation exposure

**Table 3** Training requirements listed by regulations applicable to endoscopic retrograde cholangiopancreatography (ERCP) practitioners in the UK

| | |
|---|---|
| European Commission 2000[10] | Basic physics, mathematics and biology for radiation protection.<br>Radiation sources of exposure.<br>Interaction of radiation with matter.<br>Dosimetric quantities and units.<br>Theory of radiation detection and measurement.<br>Dosimetric calculations and measurements.<br>Biological effects of ionising radiation.<br>External dose assessment.<br>Internal dose assessment.<br>The role of international organisations in radiation protection (not essential).<br>Conceptual framework of radiation protection.<br>Occupational radiation protection.<br>Waste safety.<br>Physical protection and security of sources.<br>Intervention for protection of the public in chronic and acute exposure situations.<br>Medical exposures.<br>Regulatory control.<br>Emergency preparedness and response—accident analysis.<br>Safe use of radiation sources in relation to specific practices. |
| IR(ME)R 2017 (amended 2018)[11 12] | Interpretation of the regulations.<br>The basic physics associated with ionising radiations.<br>The risks associated with ionising radiations.<br>The radiobiological effects of exposure to ionising radiations.<br>The production of X-rays.<br>The applications of ionising radiations for diagnostic X-ray imaging.<br>The application of ionising radiations in nuclear medicine.<br>Practical examples of the roles of duty holders.<br>Practical examples of how to reduce patients' exposures to ionising radiations. |

to the eye of an ERCPist is approximately 0.01 mSv/procedure with an undercouch X-ray tube and 0.09 mSv/procedure with overcouch tubes.[14] Mobile C-arms in the UK are mainly undercouch. The use of radioprotective googles depends on procedural volume and X-ray delivery system. The ESGE guidance states that: "if an overcouch system is used with no radiation protection shield, all persons in the procedure room except the patient should wear radiation protection glasses with side panels or a radiation protection facemask".[6]

Do you regularly wear thyroid protection shield?

*Finding*

Yes in 83% (76% of trainees vs 92% trainers, p=0.028).

*Rationale*

The thyroid gland is a radiosensitive organ with a tendency for thyroid dysfunction and carcinoma. Radiation doses to the thyroid gland during ERCP is significant with unshielded overcouch systems (median of 0.3 mGy per ERCP).[15] Thyroid collars are recommended for staff members likely to receive monthly collar radiation monitor readings >4 mGy.[6]

Do you know the average radiation screening dose per ERCP procedure?

*Finding*

Yes in 40% (21% of trainees vs 63% trainers, p<0.001).

*Rationale*

Radiation doses are expressed in millisieverts (mSv). The radiation dose is dependent on a number of factors including body habitus, vulnerability of the body tissue screened, fluoroscopy time and the distance from the emission source. Larkin *et al* reported an average of 12.4 mSv for therapeutic level 1 ERCP.[13] Since radiation exposure during ERCP is directly proportional to the fluoroscopy time, the radiation threshold of 20 mSv/year set by the ICRP could be exceeded in a complex level 3 ERCP which sometimes requires >10 min of fluoroscopy time.[5] Moreover, fluoroscopy time is operator dependent,[16 17] varying between 49 s and 7 min for comparable level ERCPs.[18 19] Minimising the distance between fluoroscopy and endoscopy monitors can reduce fluoroscopy time by streamlining ergonomics (less rotational movements to view both screens).[20] The use of endoscopic ultrasound guidance and digital cholangioscopy (Spyglass) has also been shown to reduce fluoroscopy time.[21 22]

Unlike staff, radiation PPE is not routinely available to patients. It is the responsibility of the radiology department to monitor and reduce the radiation exposure to patients and the medical staff, although ERCP practitioners can take proactive measures to minimise exposure (table 4).

### ERCP cholangiograms

Responses relevant to cholangiogram interpretation are summarised in table 2. Twenty-two per cent of survey respondents indicated the routine reporting of ERCP cholangiograms by radiologists. Only 26% received formal training in reporting cholangiograms

**Table 4** Practical considerations for cholangiogram acquisition[31]

| | |
|---|---|
| *Positioning* | The prone position is favoured during ERCP as this is considered optimal for cannulating the papilla and for high-quality fluoroscopic images.<br>The supine position may improve visualisation of hilar anatomy, facilitate airway management or improve patient comfort.[32]<br>The left lateral position is as effective as the prone position but may incur higher rates of unintentional pancreatic duct cannulation.[33]<br>The positioning of the fluoroscopy and endoscopy monitors can affect ergonomics and fluoroscopy time.[20] |
| *Image capture* | Capture early and delayed images. Obtain scout film as a baseline and after a procedure.<br>Factors associated with reduced fluoroscopy dose include[16]:<br>**Endoscopist factors:**<br>1. High volume (>200 procedures per year).<br>2. Years of experience.<br>3. Understanding of the expected pathology and anticipated anatomy before ERCP.<br>**Procedural factors**[18]:<br>1. Actively limiting fluoroscopy time.<br>2. Collimating the X-ray beam to the smallest practical size.<br>3. Selecting the lowest reasonable image quality.<br>4. Avoiding unnecessary magnification.<br>5. Using pulsed instead of continuous fluoroscopy.<br>6. Selecting the lowest acceptable image quality.<br>7. Use of endoscopic ultrasound guided ERCP/cholangioscopy.[21 22] |
| *Contrast injection* | Contrast injection should precede negative suctioning/aspiration with the syringe in vertical position. Applying a 50:50 mix of contrast with normal saline facilitates flushing. Gentle contrast injection should be given by the endoscopist rather than assistant and should start with tip of the sphincterotome just below the hilum. This prevents small stones/debris disappearing in the intrahepatic ducts. Obtaining an occlusion cholangiogram using an appropriately sized balloon is essential for documenting stone clearance. |
| *Different scenarios* | **Pregnancy:** fluoroscopy may be safe if performed outside the first trimester with lead shielding of the uterus/fetus. Non-fluoroscopic ERCP could be considered if expertise is available.[22]<br>**Contrast allergy**: true contrast allergy is uncommon. The patient may be reassured as contrast is injected intraductally and not intravenously. Alternative agents, for example, non-iodine contrast / Primovist could be used. Resuscitation facilities containing epinephrine, hydrocortisone and antihistamines should be available.<br>**Hilar obstructions**: adequate assessment of pathology and anatomy is required before contrast injections after wire-guided cannulation. Contrast must be avoided in an obstructed system where deep wire guided cannulation has not been achieved. |

ERCP, endoscopic retrograde cholangiopancreatography.

(21% of trainees vs 33% of trainers, p=0.161). Confidence in cholangiogram reporting, as measuring on a 0–100 visual analogue scale, was higher in trainers (median 90, IQR 78–99) versus trainees (median 61, IQR 34–79; p<0.001). Eighty-seven per cent of survey respondents (97% of trainees vs 76% of trainers, p=0.001) expressed the desire for further training in cholangiogram interpretation.

## DISCUSSION

This UK survey provides insights on the attitudes and behaviours relevant to radiation protection and cholangiogram interpretation in ERCP which may be of interest to national bodies such as the Joint Advisory Group (JAG) and British Society of Gastroenterology (BSG).[23] Less than half of respondents were up to date with radiation protection training or were aware of their average radiation exposure. Compared with trainers, trainees were less likely to wear thyroid protection shields, have awareness of the BSSD or know their average procedural radiation dosages. These data provide impetus to improve training and induction practices in radiation protection, which could commence prior to hands-on ERCP training.

Data on the complications of radiation exposure in modern-day ERCPists are lacking but may be generalisable from other specialities. Using the maximal safe threshold of 20 mSv per year, the excess radiation exposure over a working lifetime is approximately 1Sv, resulting in a theoretical excess cancer risk of 1 in 1000.[4] From the National Registry for radiation workers, all-cause malignant neoplasms was significantly higher in this group, with excess relative risks of 0.28 per Sv for both mortality and incidence.[24] Lee *et al* estimated higher lifetime attributable risk of carcinoma in medical radiation workers, particularly in the colon and thyroid.[25] Regarding cataracts, a study subjecting interventional cardiologists to slit-lamp examinations found higher risks of posterior subcapsular opacities (38% vs 12% in unexposed controls, p=0.005).[26]

Surveys relevant to radiation protection in the ERCP workforce have been undertaken in UK,[27] USA[28] and South Korea,[29] with only one published as full text.[29] The 2008 UK survey (n=172; 5% trainees) reported that 42% never wore thyroid protection, 95% did not wear protective eyewear and 32% never used a dosimeter.[27] Only 29% had been on a radiation safety course within the previous 5 years. In the US survey (n=118; 11% trainees),[28] 51% did not wear a dosimeter and 25% did not routinely check their dosimeter for radiation exposure. Data from independent ERCPists in Korea also found that radiation protection glasses (38%) were infrequently used.[29]

Our survey provides novel data on cholangiogram training. Only 21% of trainees received formal training, with the majority of respondents expressing the desire for additional training. As cholangiograms require fluoroscopy time, this may be reduced through competent cholangiogram acquisition and interpretation. Practice considerations to improve image acquisition are summarised in table 3. Experienced trainers may be best placed to teach cholangiogram interpretation, ideally with radiologist input, by reviewing imaging within a pancreaticobiliary multidiscliplinary meeting and to develop familiarity with anatomical variations and pancreaticobiliary pathology. The ability to interpret pre-endoscopic imaging may aid to plan therapy and reduce fluoroscopy time. No studies have assessed the accuracy of cholangiogram interpretation during ERCP, or interventions to improve this, which should be prioritised for future study.

Several limitations should be acknowledged. First, this was an exploratory survey which prioritised compliance of responses over comprehensiveness. Data on annual procedural numbers, ERCPist experience, fluoroscopy time, specifications of X-ray systems were not elicited. This precluded the ability to estimate annual radiation dosages to correlate radiation protection practices or identify regional variations in practice. Second, we did not survey the availability of additional PPE (eg, radiation protection aprons and transparent protective shields) or dosimeter use. We also postulate that the requirements for BSSD training is likely to vary between hospitals, although this was not surveyed. Even though dosimeters are mandatory in most ERCP units, anecdotally, they are not always available in the UK.[27] Finally, the survey was conducted before COVID-19 which has overhauled endoscopy practices worldwide and introduced an additional layer of infection control PPE. It is unclear whether this has impacted on PPE practices for radiation safety.

Moving forward, the shortfalls in radiation protection during ERCP should be addressed through training and quality assurance (QA). This could involve mandating the IR(ME)R e-learning resource,[12] auditing departmental induction practices (in line with legislation),[11] and including this in JAG basic skills and Train-the-Trainers courses to target trainees and trainers.[23] Radiation protection and cholangiogram interpretation could be covered in formative assessments, which facilitate feedback provision in a breadth of ERCP competencies.[8] The TEESAT assessment tool (USA) assesses the cognitive aspects of cholangiogram practice, including appropriate use of fluoroscopy, proficient use of real time cholangiogram interpretation and subsequent management.[30] The UK ERCP DOPS assesses the interpretation of radiological images. As neither TEESAT nor DOPS covers radiation protection, these may be included in future iterations to cover relevant knowledge, skills and behaviours, and best practices including the documentation and minimisation of fluoroscopy time.

In terms of QA, there is evidence attesting to the operator-dependent nature of radiation exposure in ERCP.[18 19] Patient radiation exposure essentially


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doubled when procedures were performed by low-volume endoscopists.[17] Fluoroscopy time is an indirect measure of radiation exposure and could serves as a quality metric for safety in ERCP.[18] This is currently not included within the JAG, BSG or ESGE standards for ERCP but should be debated as a potential key performance indicator. The use of quality measures could be combined with clinical audit to emphasise and improve radiation protection practices in ERCP.

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