

Radiation protection in digestive endoscopy: European Society of Digestive Endoscopy (ESGE) Guideline



Authors

J.-M. Dumonceau¹, F. J. Garcia-Fernandez², F. R. Verdun³, E. Carinou⁴, L. Donadille⁵, J. Damilakis⁶, I. Mouzas⁷, K. Paraskeva⁸, N. Ruiz-Lopez³, L. Struelens⁹, V. Tsapaki¹⁰, F. Vanhavere⁹, V. Valatas⁷, M. Sans-Merce³

Institutions

Institutions are listed at the end of article.

Bibliography

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Corresponding author

J.-M. Dumonceau, MD PhD
 Division of Gastroenterology
 and Hepatology
 Geneva University Hospitals
 Rue Gabrielle Perret Gentil 4
 1211 Geneva
 Switzerland
 Fax: + 41+22+3729366
 jmdumonceau@hotmail.com

This article expresses the current view of the European Society of Gastrointestinal Endoscopy (ESGE) about radiation protection for endoscopic procedures, in particular endoscopic retrograde cholangiopancreatography (ERCP). Particular cases, including pregnant women and pediatric patients, are also discussed. This Guideline was developed by a group of endoscopists and medical

physicists to ensure that all aspects of radiation protection are adequately dealt with. A two-page executive summary of evidence statements and recommendations is provided. The target readership for this Guideline mostly includes endoscopists, anesthesiologists, and endoscopy assistants who may be exposed to X-rays during endoscopic procedures.

1. Introduction

Ionizing radiation is used during diagnostic and therapeutic endoscopic procedures, most frequently during endoscopic retrograde cholangiopancreatography (ERCP). The current Guideline describes the types of X-ray systems that may be used for ERCP, radiation doses commonly reported for diagnostic and therapeutic ERCP, interventions that are effective in reducing radiation doses for the patient and staff members, and legal aspects of radiation protection (RP).

2. Methods

The European Society of Gastrointestinal Endoscopy (ESGE) commissioned and funded this Guideline. The methodology was similar to that used for other ESGE Guidelines [1, 2]. Briefly, subgroups were formed, each charged with a series of clearly defined key questions (see [Appendix e1](#), available online). The committee chair worked with subgroup speakers to identify pertinent search terms that always included, as a minimum, “radiation” and words pertinent to specific key questions. Evidence tables were generated for each key question based on evidence-based reviews or randomized controlled trials (RCTs) if these were available; otherwise, case-control studies, retrospective analyses, and case series were included. The number of articles retrieved and selected for each task force is indicated in

the Evidence table (see [Appendix e2](#), available online). Evidence levels and recommendation grades used in this Guideline were those recommended by the amended Scottish Intercollegiate Guidelines Network ([Table 1](#)), except for well-established laws of radiation physics that were considered to be Evidence level 1++[3]. Subgroups agreed by online communication on draft proposals that were presented to the entire group for general discussion during a meeting held in September 2010. The results of that discussion were incorporated into the subsequent Guideline version and again discussed by email until unanimous agreement was reached. Searches were re-run in February 2011 (this date should be taken into account for future updates) and a final draft was written during a second meeting in August 2011. All members of the Guideline development group approved the final draft; it was sent to all individual ESGE members in September 2011 and, after incorporation of their comments, it was endorsed by the ESGE Governing Board prior to submission to *Endoscopy* for international peer review. All members of the Guideline development group approved the final revised version before publication.

Technical terms related to radiation that are used in this Guideline are defined in [Table 2](#). Evidence statements and recommendations are stated in italics; key evidence statements and recommendations are in bold. This Guideline will be considered for revision in 2016, or sooner if important new evidence becomes available. Any up-

Table 1 Definitions of categories for evidence levels and recommendation grades used in this Guideline [3].

Evidence level	
1++	High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies; high quality case-control studies or cohort studies with a very low risk of confounding, bias, or chance and a high probability that the relationship is causal
2+	Well conducted case-control or cohort studies with a low risk of confounding, bias, or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias, or chance and a significant risk that the relationship is not causal
3	Nonanalytic studies, e. g. case reports, case series
4	Expert opinion
Recommendation grade	
A	At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population or a systematic review of RCTs or a body of evidence consisting principally of studies rated as 1+ directly applicable to the target population and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++ directly applicable to the target population and demonstrating overall consistency of results or extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 1- or 2+ directly applicable to the target population and demonstrating overall consistency of results or extrapolated evidence from studies rated as 2++
D	Evidence level 2-, 3 or 4 or extrapolated evidence from studies rated as 2+

RCT, randomized controlled trial

dates to the Guideline in the interim period will be noted on the ESGE website: <http://www.esge.com/esge-guidelines.html>.

3. Summary of recommendations

Education and training

Education programs in RP are mandatory under European Directive and Member States' laws for physicians who use diagnostic X-ray, including nonradiologists, to reduce radiation doses to patients while maintaining adequate image quality (Recommendation grade D).

State of knowledge

Types of X-ray systems

Systems that have the X-ray tube located above or under the patient table are described as "over-couch" or "under-couch" systems, respectively. Mobile X-ray units, also called "mobile C-arm units," are usually used under-couch. For ERCP, both over-couch and under-couch systems are used. The difference between over-couch and under-couch systems is more relevant to healthcare staff than to patients, as which area of a staff member's body receives most radiation exposure depends on which type of system is used. Staff radiation exposure may be significantly higher with mobile C-arm units and over-couch X-ray systems compared with stationary under-couch X-ray systems (Evidence level 2+).

Radiation doses during ERCP

The mean 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 kerma-area product (KAP) reported for diagnostic and therapeutic ERCP are in the range of 3–115 Gy·cm² and 8–333 Gy·cm², respectively (Evidence level 2+). Limited information regarding dose reference levels (DRLs) is available for ERCP. The United Kingdom (UK) and the Nordic RP authorities have proposed KAP values of 20 Gy·cm² and 50 Gy·cm², respectively. For examinations different from ERCP, recording patient radiation doses at a national level was followed by a decrease in patient radiation exposure (Evidence level 2-). We recommend reporting patient radiation doses in a national database (Recommendation grade D).

Dosimetric aspects

Staff monitoring

The effective dose (E) is best estimated by wearing two dosimeters: one at the neck, outside of the protective apron, and the other one under the protective apron, at waist level (Evidence level 1-). Radiation doses to the extremities (hands, fingers, legs) are low during ERCP with appropriate RP shielding, compared with recommended radiation dose limits (Evidence level 2+). For staff monitoring, the use of two dosimeters is recommended but a single dosimeter worn under the RP apron can provide a reasonable estimate of E in most cases and may be more practical. If this single dosimeter is worn over the apron it can also provide a good estimation of eye lens doses. With appropriate shielding, monitoring of extremity radiation doses is not needed. When no shielding is available, a sample of test measurements should be obtained to decide whether or not monitoring of extremity radiation doses is needed. (Recommendation grade C). An appropriate algorithm must be used to avoid overestimation or underestimation of E when only one dosimeter is used. With the forthcoming lowering of the recommended radiation dose limit for the eye lens to 20 mSv/year, monitoring of radiation doses at the level of the eye lens will be needed with over-couch systems that do not have adequate RP shielding. (Recommendation grade D).

Patient dose monitoring

Among the easily available metrics for radiation exposure, KAP is the best for monitoring patient radiation dose (Evidence level 2++). KAP should be monitored, and its cumulative value should be recorded in the patient file for every ERCP, by either the radiology technician or the attending endoscopist (Recommendation grade B).

Medical physicist availability

Endoscopists should have access to the support of a medical physicist to assess radiation doses and to optimize procedures (Recommendation grade D).

RP measures for staff

Personal RP measures

Radiation dose is inversely proportional to the square of the distance from the X-ray source (Evidence level 1++). Radiation exposure of staff members is significant; highest radiation doses are usually measured at the locations of the endoscopist and of the person monitoring patient sedation (Evidence level 2-). Staff should be positioned as far as possible from the X-ray source and from the patient, the source of scattered radiation (Recommendation grade A). We recommend positioning RP shields to protect all staff members, including the endoscopist and the person monitoring patient sedation (Recommendation grade D).

RP aprons with lead-equivalent thickness ≥ 0.25 mm effectively reduce radiation exposure. Musculoskeletal complaints are frequent amongst endoscopists performing ERCP and may be increased by RP aprons. Radiation exposure of the thyroid gland during ERCP may be significant, in particular when working with unshielded over-couch systems (Evidence level 2+). All persons in the procedure room (except the patient and people in the area behind a stationary shield if available) should wear a wrap-around (not front-only) RP apron and an RP collar with lead-equivalent thickness ≥ 0.25 mm when X-rays are used (Recommendation grade C). An RP apron with a collar attached to it may encourage the use of thyroid shields. RP aprons should be hung vertically, to prevent cracks, in a place that can be reached under the protection of an RP shield (e.g., behind a stationary shield close to the entrance door, or outside the endoscopy room). Moreover, they should be tested annually for defects (Recommendation grade D).

RP gloves are uncomfortable for ERCP and provide limited X-ray attenuation (Evidence level 2++); they are not recommended during ERCP (Recommendation grade B). Optimal RP of the eyes during fluoroscopy depends heavily upon location of the X-ray source and on RP shielding (Evidence level 2++). If an over-couch system is used with no RP shield, all persons in the procedure room except the patient should wear RP glasses with side panels or an RP facemask (Recommendation B).

Staff radiation exposure may be decreased by $\geq 90\%$ by using RP shields located between the X-ray tube/patient and the staff. Mobile C-arm units cause more radiation exposure to staff than stationary X-ray units, in part because of the frequent absence of RP shielding attached to these systems (Evidence level 2+). Shields of ≥ 0.5 mm lead-equivalent thickness should be positioned between the X-ray tube/patient and the staff, including when mobile C-arm units are used (Recommendation grade C).

Signs and warnings

Visible alarms (typically, light flashing when fluoroscopy is in progress, and posters that ask patients to inform about possible pregnancy) should be present, close to each door of an endoscopy room where there is a stationary X-ray unit (Recommendation D).

RP shielding of examination rooms

Appropriate structural shielding is required for stationary X-ray units, and should be considered with some mobile C-arm units. Room shielding requirements should be calculated by a medical physicist.

RP measures for the patient

Patient position

Radiation dose is inversely proportional to the square of the distance from the X-ray source (Evidence level 1++). Therefore, the patient should be positioned as far as possible from the X-ray tube (i.e., close to the X-ray detector) (Recommendation grade A).

Fluoroscopy parameters

Measures that decrease patient radiation exposure include: the use of pulsed rather than continuous fluoroscopy (Evidence level 2-), and of time-limited fluoroscopy (Evidence level 1-); avoidance of taking radiographs; increasing the tube voltage (this may decrease image quality) (Evidence level 2+); and collimating X-rays to a small field of view (this increases image quality) (Evidence level 1++). It is recommended to use pulsed fluoroscopy with the lowest possible pulse rate, rather than continuous fluoroscopy; to store when possible the "last image hold" as an alternative to taking a radiograph; to

collimate the X-ray beam to the smallest practical size; to increase tube voltage as far as possible without compromising image quality; and to use magnification modes only if necessary. The use of time-limited fluoroscopy may also be considered if this is not too impractical (Recommendation grade C).

Copper filtration

A reduction in patient radiation dose of approximately 50%, with reduction in image quality, can be achieved by inserting a copper filter in the X-ray beam (Evidence level 1-). We recommend testing the usefulness of copper filtration for ERCP procedures (Recommendation grade C).

RP shields

The most radiosensitive organs (thyroid gland, breasts, gonads, and eyes) should be kept out of the main X-ray beam whenever possible, especially in oblique radiographic projections. The use of RP shields to decrease patient radiation exposure is not recommended in the general patient population (Recommendation grade D).

Patient information about radiation risks

It is recommended to provide information to the patient about radiation risks only in the case of ERCP repetition within 1 month or in cases of high doses as defined by a $KAP > 300 \text{ Gy} \cdot \text{cm}^2$ (Recommendation grade D).

RP in special cases

Compared with adults, children are more sensitive to radiation exposure, especially at younger ages (Evidence level 1+). In children, there must be a strong clinical indication to for carrying out ERCP; this should be performed by experienced endoscopists only and RP measures similar to those used in adults should be strictly followed, including adjustment of collimation to the smaller size of children (Recommendation grade B). The most radiosensitive organs (thyroid gland, breasts, gonads, and eyes) should be protected with RP shields and should be kept out from the main X-ray beam, especially in oblique radiographic projections (Recommendation grade D). Magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS) are accurate in the detection of common bile duct (CBD) stones (Evidence 1+). Therapeutic ERCP is relatively safe and effective during pregnancy when performed by experienced endoscopists with adapted techniques. Fluoroscopy requirements may be reduced by using specific ERCP techniques (Evidence level 3). A pregnancy test should be obtained before ERCP in women for whom there is doubt about pregnancy (Recommendation grade D). ERCP in pregnant women should be performed only with a therapeutic purpose (Recommendation grade A); it is probably best performed by experienced ERCP endoscopists during the second trimester of pregnancy, strictly following recommendations to decrease patient radiation dose and with an RP apron wrapped around the patient's abdomen (Recommendation grade D).

Quality assurance

Legal requirements concerning the quality assurance of the equipment

Quality control of X-ray systems is mandatory and acceptance testing needs to be carried out before the first use of the equipment and thereafter on a regular basis (Recommendation grade D).

Table 2 Standard definitions of technical terms.

Term [Reference for official definition]	Symbol used in this Guideline	Unit	Definition
Absorbed dose [4]	D	Gy	Amount of energy imparted by ionizing radiation to unit mass of absorbing material.
Cumulative dose [5]	CD	Gy	Sum of air kerma from fluoroscopy and radiography from the beginning of the procedure measured at a specified point on the X-ray beam axis (e. g., at the interventional reference point). This point is representative of the position of the patient's skin.
Tissue reactions	–	–	Effects of radiation that are believed to have a threshold level below which no tissue reactions are seen; the threshold is variable, depending on the nature and condition of the exposed tissue. For doses in excess of the threshold, the severity of tissue reactions increases with radiation dose.
Dose reference level [6]	DRL	–	Radiation dose levels determined for typical examinations for groups of "standard" patients (70–75 kg) that are expected not to be exceeded for standard procedures when good and normal practices are applied.
Effective dose [7]	E	Sv	Average of radiation doses received by the different organs or tissues, weighted for the relative biological effectiveness of the types of ionizing radiation as well as for the sensitivity of the organs or tissues.
Entrance skin dose [8]	ESD	mGy	Absorbed dose to skin or muscle measured at the point where it enters the patient; it includes backscattered radiation (i. e. the radiation reflected back in the direction it came from).
Equivalent dose [9]	–	Sv	Value obtained by multiplying the absorbed dose by a radiation weighting factor, to take into account the degree of biological damage produced by a particular type of ionizing radiation.
Fluoroscopy time	FT	s	Total time of fluoroscopy use during an imaging or interventional procedure.
Gray [7]	Gy	Gy	Energy absorption of 1 joule per kg.
Kerma [4]	K	Gy	Ratio of the kinetic energies of all charged particles which are generated in a volume element by indirectly ionizing radiation (γ rays or neutrons) to the mass of the volume element
Air kerma [4]	K_{air}	Gy	Kerma in air.
Kerma – area product [8]	KAP	Gy·cm ²	Air kerma multiplied by the X-ray beam cross-sectional area at the point of measurement (this can be displayed on the equipment as dose-area product or DAP).
Scattered radiation	–	–	Radiation arising from interactions of the primary beam with patient tissues or other scattering medium (patient table or other).
Stochastic effects	–	–	Effects of radiation that are believed to happen without identifiable threshold. The probability that they occur increases with the radiation dose and their severity has no relationship to the radiation dose. Risk is cumulative with time.

Analysis of patient radiation dose values

Recorded KAP values should be used for the study of interendoscopist, intrahospital, and interhospital variations in patient radiation exposure and for comparison with the available regional and national DRLs (Recommendation Grade D).

Radiological unit selection for ERCP

The endoscopist and the medical physicist should be involved in the selection of the radiological system used for endoscopic examinations. They should determine in advance the desired radiological performance and RP specifications (Recommendation Grade D).

4. Education and training

Education programs in RP are mandatory under European Directive and Member States' laws for physicians who use diagnostic X-ray, including nonradiologists, to reduce radiation doses to patients while maintaining adequate image quality (Recommendation grade D).

Various international bodies, including the World Health Organization, the European Commission (EC) and the European Union (EU) Council (Council Directive 97/43/Euratom) stress the importance of educating and training physicians, medical physicists, maintenance engineers, and other auxiliary personnel involved in medical radiation exposure, to reduce patient radiation doses while maintaining the desired level of image quality [6, 10,

11]. EC guidelines recommend 30–50 hours of theoretical training (20 hours have been proposed by Vano et al. [12]) plus practical exercises and they detail a list of topics [10,12]; they also make recommendations for continuing education and training after qualification. These EC guidelines represent recommendations to the Member States. No evidence was found in the literature on how these educational programs should be carried out and on the number of cases required for an endoscopist to be proficient in RP during ERCP.

We therefore recommend in addition that credentialing of RP training programs be established by regulatory authorities at a national or a regional level, with the help of academic institutions, and scientific and/or professional societies.

5. State of knowledge

5.1. Tissue reactions and stochastic effects of radiation

Radiation effects on tissues can be classified as tissue reactions and stochastic effects, as defined in **Table 2**. Examples of tissue reactions include cataract formation, infertility, skin injury, and hair loss. These have been documented in interventional radiologists and cardiologists [13] and in patients who have undergone interventional cardiology and radiology procedures. Stochastic effects are more delayed compared with tissue reactions (years to decades vs. hours to months); examples of stochastic effects include radiation-induced cancers and genetic defects [14].

Table 3 Radiation exposure of the patient and of staff members during ERCP.

First author, year	Procedures, n	Equipment	Type of procedure	FT, minutes	KAP, Gy·cm ²	ESD, mGy	Staff radiation exposure, mGy
Chen, 1996 [16]	20	Siemens Siregraph D	Diagnostic, 40% Therapeutic, 60%	Mean, 8.5	n.a.	Diagnostic: – Mean, 76.9 Therapeutic: – Mean, 109	Endoscopist – Without shield, mean 21.8 ± 31.8 – With shield, mean 2.3 ± 3.8 Assistant – Without shield, mean 4.9 ± 8.7 – With shield, n.a. Anesthesiologist – n.a.
Heyd, 1996 [19]	72	Toshiba Fluorex DUA-450A under-couch system.	Diagnostic, 15% Therapeutic, 85%	Mean ± SD, 13.7 ± 10.5 Min, 2.3 Max, 63.2	n.a.	Mean ± SD, 73 ± 100 Min, 1.4 Max, 639	n.a.
Larkin, 2001 [22]	20	Siemens Optilux 25/17 HN	Diagnostic, 40% Therapeutic, 60%	Diagnostic: – Mean, 2.3 – Min, 1.1 – Max, 5.3 Therapeutic: – Mean, 10.5 – Min, 5.9 – Max, 16.6	Diagnostic: – Mean, 13.5 – Min, 6.8 – Max, 23.9 Therapeutic: – Mean, 66.8 – Min, 28.7 – Max, 108.5	n.a.	n.a.
Buls, 2002* [15]	54	General Electric Prestilix 1600 DRS over-couch system	Therapeutic	Mean, 6.0 Median, 5.2 3 rd quartile, 8.3	Mean, 49.9; Median, 39.0; 3 rd quartile, 60.3	Mean, 347; Median, 271; 3 rd quartile, 420 Max, 1180	Endoscopist – Eye: Mean, 0.55; 3 rd quartile, 0.66 – Neck: Mean, 0.45; 3 rd quartile, 0.60 – Hand: Mean 0.64; 3 rd quartile, 0.68 Assistant – Eye: Mean, 0.26; 3 rd quartile, 0.34 – Neck: Mean 0.20; 3 rd quartile, 0.25 – Hand: Mean, 0.27; 3 rd quartile, 0.30 Anesthesiologist – Eye: Mean, 0.35; 3 rd quartile, 0.49 – Neck: Mean, 0.26; 3 rd quartile, 0.34 – Hand: Mean, 0.42; 3 rd quartile, 0.45
Tsalafoutas, 2003 [26]	28	Prestilix 1600 s	Diagnostic, 25% Therapeutic, 75%	Diagnostic: – Mean, 3.1 – Min, 1.0 – Max, 6.9 – 3 rd quartile, 4.3 Therapeutic: – Mean, 6.0 – Min, 1.3 – Max, 23.5 – 3 rd quartile, 7.1	Diagnostic: – Mean, 13.7 – Min, 5.4 – Max, 28.4 – 3 rd quartile, 19.9 Therapeutic: – Mean, 41.8 – Min, 8.3 – Max, 204.1 – 3 rd quartile, 48.9	Diagnostic: – Mean, 55.0 – Min, 16.7 – Max, 121.0 – 3 rd quartile, 80.1 Therapeutic: – Mean, 178.9 – Min, 30.6 – Max, 819.3 – 3 rd quartile, 227.5	n.a.

Table 3 (Continuation)

First author, year	Procedures, n	Equipment	Type of procedure	FT, minutes	KAP, Gy·cm ²	ESD, mGy	Staff radiation exposure, mGy
Brambilla, 2004 [31]	383	Philips Integris V-5000 and Philips BV-300 plus	n.a.	Mean ± SD, 6.4 ± 5.1	Mean, 28 Min, 0.3 Max, 704 3 rd quartile, 33	n.a.	n.a.
Olgar, 2009 [30]	31	IDR-700 under-couch	Diagnostic (74%) Therapeutic (26%)	Diagnostic: – Mean, 1.9 – Min, 0.2 – Max, 7 – 3 rd quartile, n.a. Therapeutic: – Mean, 5.1 – Min, 0.4 – Max, 14.1 – 3 rd quartile, n.a.	Diagnostic: – Mean, 26.2 – Min, 3.4 – Max, 114.6 – 3 rd quartile, n.a. Therapeutic: – Mean, 69.8 – Min, 9.9 – Max, 332.5 – 3 rd quartile, n.a.	Diagnostic: – Mean, 76.7 – Min, 7.8 – Max, 261.1 – 3 rd quartile, n.a. Therapeutic: – Mean, 222.6 – Min, 28.2 – Max, 626.8 – 3 rd quartile, n.a.	Endoscopist – Thyroid 0.075 – Waist 0 – Right leg 0.076 – Left leg 1.194 – Right finger 0.289 – Left finger 0.835 – Eye 0.094

ERCP, endoscopic retrograde cholangiopancreatography; FT, fluoroscopy time; KAP, kerma-air product; ESD, entrance skin dose; SD, standard deviation; n.a., not available.
* Buls et al. excluded patients outside of the 60–80 kg range of body weight.

5.2. Types of X-ray systems

Systems that have the X-ray tube located above or under the patient table are described as “over-couch” or “under-couch” systems, respectively. Mobile X-ray units, also called “mobile C-arm units,” are usually used under-couch. For ERCP, both over-couch and under-couch systems are used. The difference between over-couch and under-couch systems is more relevant to healthcare staff than to patients, as which area of a staff member’s body receives most radiation exposure depends on which type of system is used. Staff radiation exposure may be significantly higher with mobile C-arm units and over-couch X-ray systems compared with stationary under-couch X-ray systems (Evidence level 2+).

Among 13 ERCP studies that were analyzed for the X-ray tube position, the distribution between the use of over-couch and under-couch systems was almost even [15–27]. Scattered radiation mostly affects the lower or the upper part of the bodies of staff with under-couch or over-couch systems, respectively. Radiation-induced cataract has been reported in interventional radiologists using over-couch X-ray systems without RP equipment [28]. Four studies were identified that reported radiation doses measured at the level of the endoscopist’s eye: the lowest mean radiation doses were observed with under-couch systems while radiation doses were particularly high with an over-couch system that had no protective shield [15, 16, 29, 30]. Regarding patient radiation doses with ERCP, no evidence was found about any possible impact of the position of the X-ray source or of patient position (prone vs. supine), although differences are likely to exist.

A single comparison of a stationary vs. a mobile X-ray unit (both under-couch) was found, that showed higher radiation doses with the mobile C-arm unit (with the stationary system, doses for the anesthesiologist and the endoscopist were 0.273 mGy/h and 0.013 mGy/h, respectively; corresponding values for the mobile C-arm unit were 0.9 mGy/h and 1.04 mGy/h, respectively) [21].

5.3. Radiation doses during ERCP

The mean 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 kerma–area product (KAP) reported for diagnostic and therapeutic ERCP are in the range of 3–115 Gy·cm² and 8–333 Gy·cm², respectively (Evidence level 2+). Limited information regarding dose reference levels (DRLs) is available for ERCP. The United Kingdom (UK) and the Nordic RP authorities have proposed KAP values of 20 Gy·cm² and 50 Gy·cm², respectively. For examinations different from ERCP, recording patient radiation doses at a national level was followed by a decrease in patient radiation exposure (Evidence level 2–). We recommend reporting patient radiation doses in a national database (Recommendation grade D).

► **Table 3** summarizes values of ESD and of KAP measured during ERCP with a variety of X-ray systems. The most important factors influencing patient radiation doses include the duration of fluoroscopic examination (fluoroscopy time, FT), the number of radiographs taken, patient body size, and exposure parameters (e.g., pulsed vs. continuous fluoroscopy) [16, 19, 22, 26]. KAP and ESD values are higher for therapeutic compared with diagnostic ERCPs, mostly because of longer FT during therapeutic procedures.

DRLs are defined as the 3 rd quartile of KAP values measured in a large series of procedures for a particular radiological examination. According to good clinical practice, they should not be ex-

ceeded for standard procedures (they represent a guide, not a limit). Member States of the EU were required to promote the establishment and the use of DRLs according to a Directive (97/43/Euratom) that had to be implemented into national laws by Member States not later than May 2000 [6]. Although the establishment of DRLs would be very useful in view of the large range of KAP values reported during ERCP (Table 3), little progress has been made so far. In Nordic European countries, the DRLs proposed for ERCP do not report separately on diagnostic and therapeutic procedures [32]; in the UK, DRLs have been established for “biliary drainage/intervention” based on data collected in approximately 40 examination rooms [33]; however “biliary drainage/intervention” was not clearly defined [34]. Every 5 years in the UK, a review of the National Patient Dose Database reports the doses of patient radiation exposure for several examinations. The latest review included data from approximately 25 % of UK hospitals; it showed that the mean patient radiation doses have progressively decreased over time, suggesting that some of the hospitals exceeding the DRLs have taken corrective actions [33].

Values proposed for DRLs in Nordic European countries and in the UK, together with those reported in Table 3, were used to propose DRLs for therapeutic ERCP during the development of the current Guideline. Few data were found; as an indication, the 3rd quartile of KAP values reported for therapeutic ERCP in various studies ranged between 33.0 and 60.3 Gy·cm² [15,26,31].

6. Dosimetric aspects

6.1. Staff monitoring

The effective dose (E) is best estimated by wearing two dosimeters: one at the neck, outside of the protective apron, and the other one under the protective apron, at waist level (Evidence level 1–). Radiation doses to the extremities (hands, fingers, legs) are low during ERCP with appropriate RP shielding, compared with recommended radiation dose limits (Evidence level 2+). For staff monitoring, the use of two dosimeters is recommended but a single dosimeter worn under the RP apron can provide a reasonable estimate of E in most cases and may be more practical. If this single dosimeter is worn over the apron it can also provide a good estimation of eye lens doses. With appropriate shielding, monitoring of extremity radiation doses is not needed. When no shielding is available, a sample of test measurements should be obtained to decide whether or not monitoring of extremity radiation doses is needed.

(Recommendation grade C). An appropriate algorithm must be used to avoid overestimation or underestimation of E when only one dosimeter is used. With the forthcoming lowering of the recommended radiation dose limit for the eye lens to 2 mSv/year, monitoring of radiation doses at the level of the eye lens will be needed with over-couch systems that do not have adequate RP shielding. (Recommendation grade D).

E provides a measure of the radiation damage caused by partial and whole body irradiation. Recommended radiation dose limits have been defined for persons with occupational exposure to X-rays (Table 4) [7]. Several review articles recommend the wearing of two dosimeters, one over and one under the RP apron, because this allows a better estimation of E compared with a single dosimeter [35–38]. There are different algorithms for estimating E, depending on the number and location of dosimeters that are worn and the use of RP aprons and thyroid collars [39]. Many national legal requirements clearly state how many, when, and where dosimeters should be worn, and how E should be estimated. No EU harmonization exists on this topic. E to endoscopists has been estimated to be 2–90 μSv per ERCP based on measurements using two dosimeters [23], and as 3–70 μSv when one dosimeter was used [16,23,30,40,41]. Doses to endoscopy assistants are reported to be lower [16,20,23]. The annual price of dosimetry ranges from 30 to 150 EUR per person, including the cost of dosimeter rental and of measurements.

Radiation doses at the level of extremities are approximately 30 μSv per ERCP (median values) [42]; these values are low enough to recommend no routine monitoring of extremity radiation doses. However, when no appropriate shielding is available and over-couch X-ray tubes are used, higher radiation doses have been reported (between 350 and 800 μSv per procedure) [15,30,43]. In such cases, monitoring of extremity radiation doses using ring or wrist dosimeters is indicated. When no RP shielding is available, it is recommended that test measurements be performed to determine the order of magnitude of extremity doses, for example by introducing a routine monitoring program for a few months using ring or wrist dosimeters. These measurements can be extrapolated to yearly doses and compared with the annual dose limits. Any need for continuous extremity dose monitoring can then be decided upon by the RP officer.

For the eye lens, the International Commission on Radiological Protection (ICRP) has proposed lowering the recommended radiation dose limits of E from 150 mSv to 20 mSv averaged over 5 years, with no single year exceeding 50 mSv [8,30]. This proposal

Type of limit	Annual limit, mSv	
	Occupational exposure	General public
Effective dose	20, averaged over defined periods of 5 years ¹	1
Annual equivalent dose in:		
Lens of the eye ²	20	15
Skin ^{3,4}	500	50
Extremities	500	
Pregnant woman	2 (measured at the abdomen surface for the whole pregnancy)	
Fetus ⁵	1	

Table 4 Recommended radiation dose limits for workers with occupational exposure [7].

¹ With the further provision that the effective dose should not exceed 50 mSv in any single year. Additional restrictions apply to the occupational exposure of pregnant women.

² This radiation dose limit has recently been recommended by an International Commission of Radiation Protection Task Group but it has not yet been implemented in European regulations.

³ The limitation on effective dose provides sufficient protection for the skin against stochastic effects.

⁴ Averaged over 1 cm² area of skin regardless of the area exposed.

⁵ Radiation dose limit in European regulations.

will be adopted by the Basic Safety Standards of the EC, so that monitoring of eye lens doses will be required when no shielding is present in over-couch systems.

6.2. Patient dose monitoring

Among the easily available metrics for radiation exposure, KAP is the best for monitoring patient radiation dose (Evidence level 2++). KAP should be monitored, and its cumulative value should be recorded in the patient file for every ERCP, by either the radiology technician or the attending endoscopist (Recommendation grade B).

According to the Council of Europe Directive 97/43/Euratom (Article 8) [6, 11], patient radiation doses must be estimated. The Directive has been implemented in national legislations, as shown in France for example [44]. According to the Directive, a record of dosimetry data should be maintained for each patient, including for procedures performed with a mobile C-arm unit. Other existing guidelines recommend dose recording only when ESD exceeds 1–2 Gy for a procedure, with ERCP not listed as a procedure with radiation-associated risk in Food and Drug Administration (FDA) recommendations [45–47].

Although the link between KAP and patient E is indirect, KAP is one of the best available parameters for estimating ESD and E to the patient (and to the fetus in the case of pregnancy) [24, 30, 48, 49]. KAP is generally measured using a KAP-meter, i.e., a large area ionization chamber located immediately at the exit of the X-ray tube and collimation device. The cost of a KAP meter may vary widely depending on specifications; a reference price is 3000 EUR. KAP values can also be calculated using an internal algorithm that takes into account the X-ray generator settings combined with collimator data. FT has been investigated as an alternative measure for estimating KAP and/or patient E; some studies reported a good correlation [22, 26, 30, 48], but other studies reported poor correlation [31, 32]. In compliance with FDA requirements [50], up-to-date fluoroscopy equipment can provide an estimate of the cumulative dose [51]. This measure correlates better with ESD compared with KAP values [52]; however it is not yet widely available.

6.3. Medical physicist availability

Endoscopists should have access to the support of a medical physicist to assess radiation doses and to optimize procedures (Recommendation grade D).

There is a consensus in the literature, reflected in the Council Directive 97/43/Euratom (which is binding on EU Member States), about the requirement for involving a medical physicist [11]. His/her responsibilities would include quality control of the radiological suites, patient radiation dose monitoring, optimization of the compromise between acceptable image quality and lowest possible radiation dose to patients, and specific procedures to apply when a pregnant patient is involved [37, 53, 54]. Collaborative training programs involving the endoscopists, the radiation safety officer, and the medical physicist may also be useful.

7. RP measures for staff



7.1. Personal RP measures

7.1.1. Staff positioning

Radiation dose is inversely proportional to the square of the distance from the X-ray source (Evidence level 1++). Radiation exposure of staff members is significant; highest radiation doses are usually measured at the locations of the endoscopist and of the person mon-

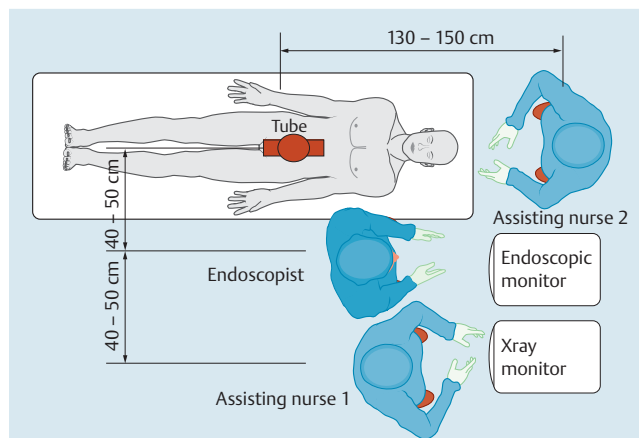


Fig. 1 Typical patient and staff positioning during endoscopic retrograde cholangiopancreatography (ERCP).

itoring patient sedation (Evidence level 2–). Staff should be positioned as far as possible from the X-ray tube and from the patient, the source of scattered radiation (Recommendation grade A). We recommend positioning RP shields to protect all staff members, including the endoscopist and the person monitoring patient sedation (Recommendation grade D).

Staff radiation exposure strongly depends on staff positioning during ERCP (● Fig. 1). Because radiation doses decrease with the distance from the X-ray source and the endoscopy assistant is partially shielded by the endoscopist, the highest radiation doses are measured at the locations of the endoscopist and of the person monitoring patient sedation (● Table 3) [15, 21].

7.1.2. Protective aprons and collars

RP aprons with lead-equivalent thickness ≥ 0.25 mm effectively reduce radiation exposure. Musculoskeletal complaints are frequent amongst endoscopists performing ERCP and may be increased by RP aprons. Radiation exposure of the thyroid gland during ERCP may be significant, in particular when working with unshielded over-couch systems (Evidence level 2+). All persons in the procedure room (except the patient and people in the area behind a stationary RP shield if available) should wear a wrap-around (not front-only) RP apron and an RP collar with lead-equivalent thickness ≥ 0.25 mm when X-rays are used (Recommendation grade C). An RP apron with a collar attached to it may encourage the use of thyroid shields. RP aprons should be hung vertically, to prevent cracks, in a place that can be reached under the protection of an RP shield (e.g., behind a stationary RP shield close to the entrance door or outside the endoscopy room). Moreover, they should be tested annually for defects (Recommendation grade D).

RP aprons of 0.25 mm lead-equivalent thickness attenuate $\geq 90\%$ of scattered X-rays that strike them [40, 55, 56]. In a small experimental study based on an FT of 20 min per ERCP and standard E limits, it was estimated that, with regard to RP, fewer than one ERCP per month was permissible if no protective apron was used [40]. Radiation doses to the thyroid gland during ERCP may be significant particularly with unshielded over-couch 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 [57].

A majority of endoscopists performing ERCP have musculoskeletal complaints, back and neck pain being the most frequent [58]. Furthermore, musculoskeletal injuries are more frequent

amongst physicians who wear RP aprons compared with those who do not, and in those who have been practicing ERCP longer [58–61]. RP aprons are available in various shapes (front-protecting only, double-sided, two-piece, one-piece) and materials. A lightweight model, well-fitting, and reaching down to the knees should be chosen. Two-piece RP aprons or one-piece RP aprons with a waist belt may distribute the load more evenly across the spine and pelvis [62]. Wrap-around RP aprons with 0.25 mm lead-equivalent thickness provide a 0.5 mm lead equivalence in the front part of the body. In most currently available RP aprons, lead has been replaced with lightweight lead composite or lead-free material (barium, tungsten, tin, and antimony) that provide the same protection as lead at approximately 30% of the weight [63].

7.1.3. RP gloves and glasses

RP gloves are uncomfortable for ERCP and provide limited X-ray attenuation (Evidence level 2++); they are not recommended during ERCP (Recommendation grade B). Optimal RP of the eyes during fluoroscopy depends heavily upon location of the X-ray source and on RP shielding (Evidence level 2++). If an over-couch system is used with no RP shield, all persons in the procedure room except the patient should wear RP glasses with side panels or an RP facemask (Recommendation B).

RP gloves are expensive, have a short lifespan, attenuate X-rays by only 15%–30%, and add scattered X-rays within the glove [64]. The best practice is to keep the hands out of the X-ray beam rather than wearing RP gloves.

The lens of the eye is one of the most radiosensitive human tissues and lens exposure to ionizing radiation can cause cataract [13]. In a controlled study that included 209 persons, the relative risk of posterior subcapsular lens opacities in interventional cardiologists compared with unexposed controls was 3.2 (38% vs. 12%; $P=0.005$) [29]. Most commercially available RP glasses have lenses of ≥ 0.5 mm lead-equivalent thickness that effectively attenuate radiation transmission to the eyes; they must have side panels to block scattered radiation while the wearer looks at the display monitor during fluoroscopy. Such RP glasses may be heavy and uncomfortable. Photochromic lenses are lighter but they transmit 50% of radiation if the angle of incidence is within 60° of the perpendicular to the lens [65]. RP of the eyes can also be achieved with an RP facemask or a mobile barrier that can prevent scattered radiation from reaching the head of the staff member and avoid the discomfort associated with RP glasses [66]. RP glasses are recommended only when over-couch systems are used.

7.1.4. RP shielding above and/or below the table

Staff radiation exposure may be decreased by $\geq 90\%$ by using RP shields located between the X-ray tube/patient and the staff. Mobile C-arm units cause more radiation exposure to staff than stationary X-ray units, in part because of the frequent absence of RP shielding attached to these systems (Evidence level 2+). Shields of ≥ 0.5 mm lead-equivalent thickness should be positioned between the X-ray tube/patient and the staff, including when mobile C-arm units are used (Recommendation grade C).

Although RP aprons are effective, X-ray doses to the unshielded parts of the body may be significant during ERCP. For example, radiation doses at the level of operators' legs were found to be as high as 2.6 mSv per procedure when no shield was used [67]. Mobile C-arm units provide more radiation exposure to staff members than stationary X-ray units mainly because these types of

systems do not usually have a shield attached [21]. Radiation exposure to the staff may be decreased by 90% using RP shields; depending on their location, RP shields protect the endoscopist and/or the person monitoring patient sedation [16, 19,21]. The size of the protected zone increases when the shielding is moved closer to the X-ray source [68]. Shields should be located above or below the patient table for over-couch or under-couch systems, respectively. A vertical shield suspended from the patient table is a standard accessory for under-couch stationary X-ray systems. If no RP shield is attached or with other types of X-ray systems (C-arm units/over-couch systems), a free-standing vertical shield should be added, either hanging from the ceiling or movable on the floor, between the patient and the endoscopist, and a second one should be placed to protect the person monitoring patient sedation (● Fig. 1). Approximate costs of articulated window lead glass RP shields, stand-alone whole-body mobile RP shields, and vertical RP shields attached to the patient table are 5000, 3000, and 1000 EUR, respectively (● Fig. 2 and ● Fig. 3). Shields may also decrease the risk of inadvertent radiation exposure to people entering the endoscopy room without adequate RP.

7.2. Signs and warnings

Visible alarms (typically, light flashing when fluoroscopy is in progress, and posters that ask patients to inform about possible pregnancy) should be present, close to each door of an endoscopy room where there is a stationary X-ray unit (Recommendation D).

There are no trials available regarding this issue but radiation-warning lights inside and outside the examination room are recommended; they must operate automatically [68]. Regulations



Fig. 2 Mobile radiation shields with drapes at the bottom, suspended from ceiling.



Fig. 3 Under-couch X-ray system with protective radiation shields placed under and over the table, to protect the endoscopist from radiation that originates from the X-ray tube and from the patient (scattered radiation), respectively.

about warnings that are activated when X-rays are being delivered vary considerably between EU countries (e.g., warning lights outside of the room are legally required in Greece). Doors leading into the X-ray room must have signs that indicate the presence of the X-ray unit. Notices that ask patients to inform about possible pregnancy should be posted at the reception area [69].

7.3 RP shielding of examination rooms

Appropriate structural shielding is required for stationary X-ray units and should be considered with some mobile C-arm units. Room shielding requirements should be calculated by a medical physicist.

In most countries, the law requires that appropriate structural RP shielding is in place in the walls, doors, ceiling, and floor of a room housing a stationary X-ray unit. It also recommends that structural RP shielding is considered for procedure rooms where mobile C-arm units are routinely used [70]. This is intended to reduce radiation exposure of workers and the general population to a level lower than the established limits. Recommendations are available for how room RP shielding should be put in place; most recent recommendations are more accurate and allow reduction of shielding costs [71–73]. Room RP shielding should be designed by a medical physicist to ensure that the required degree of RP is achieved [73]. Stationary X-ray systems must provide a control booth with a viewing window that must have RP properties such that no operator is occupationally exposed to radiation doses higher than recommended E limits.

7.4. Special case: pregnant staff

A female employee in a working environment with risk of radiation exposure has the right to know about potential radiation hazards to the unborn child before she becomes pregnant or decides to formally declare her pregnancy. Furthermore, in some countries legislation requires that women immediately declare their pregnancy. The employer of a declared pregnant worker must evaluate the work situation and ensure that the radiation dose to the conceptus is kept below the maximum permissible level during the remaining gestation period. A method has been developed to anticipate the radiation dose to the fetus and to determine the maximum workload allowed for a pregnant employee; this methodology may be used for implementing an RP program designed for pregnant staff working in ERCP rooms [74].

8. RP measures for the patient



8.1. Patient position

Radiation dose is inversely proportional to the square of the distance from the X-ray source (Evidence level 1++). Therefore, the patient should be positioned as far as possible from the X-ray tube (i. e., close to the X-ray detector) (Recommendation grade A).

8.2. Fluoroscopy parameters

Measures that decrease patient radiation exposure include: the use of pulsed rather than continuous fluoroscopy (Evidence level 2–), and of time-limited fluoroscopy (Evidence level 1–); avoidance of taking radiographs; increasing the tube voltage (this may decrease image quality) (Evidence level 2+); and collimating X-rays to a small field of view (this increases image quality) (Evidence level 1++).

It is recommended to use pulsed fluoroscopy with the lowest possible pulse rate, rather than continuous fluoroscopy; to store when possible the “last image hold” as an alternative to taking a radiograph; to collimate the X-ray beam to the smallest practical size; to increase tube voltage as far as possible without compromising image quality; and to use magnification modes only if necessary. The use of time-limited fluoroscopy may also be considered if this is not too impractical (Recommendation grade C).

The most important measures to reduce radiation doses and to comply with the ALARA principles (ALARA stands for “As Low As Reasonably Achievable”) are listed in **Table 5**. The simplest measures to decrease patient as well as staff radiation exposure consist of using fluoroscopy for less time and not taking any radiographs. FT is inversely correlated with endoscopist experience [27, 75], with a reported decrease in FT of 20% per 10 years of experience [75]. Pulsed fluoroscopy is effective for reducing radiation exposure in interventional procedures (a rate of 7.5 pulses per second may reduce radiation exposure by up to 70%–80%) [76, 77]. The use of pulsed fluoroscopy was shown not to significantly affect image quality for examinations different from ERCP [78]; during ERCP, we feel that it may be used most of the time, with higher pulse rates or continuous modes used for delicate phases of the procedure. Taking radiographs accounts for 10%–30% of the total radiation dose during ERCP [16, 19, 22, 26]. This extra radiation can be avoided by using when possible the “last image hold” feature of fluoroscopy systems in place of taking true radiographs. As an example, in one study that used a digital radiographic unit and an additional copper filter, KAP for one radiograph was equivalent to 2–4 s of fluoroscopy [15]. Selecting the lowest reasonable image quality also allows reduction of radiation doses (most of the modern mobile and stationary X-

Table 5 Recommendations for reducing patient radiation dose during ERCP.

– Position the patient as far as possible from the X-ray tube
– Limit fluoroscopy time
– Use pulsed fluoroscopy at a rate as low as possible
– Select the lowest reasonable image quality in fluoroscopy mode
– Collimate the X-ray beam to the smallest practical size
– Avoid unnecessary magnification
– Use “last image hold” rather than taking radiographs
– Increase tube voltage (kV) as much as allowed by image quality
– Experienced endoscopist for performing more complex cases

ERCP, endoscopic retrograde cholangiopancreatography

ray systems provide the possibility of selecting different image qualities in fluoroscopy mode).

Collimation of the X-ray beam also decreases patient and staff radiation exposure, in proportion to the image field area, and it improves image quality by reducing the scattered radiation that reaches the X-ray detector [79]. On the other hand, magnification of the X-ray image requires higher X-ray doses. As an example, in a ERCP study, air kerma (K_{air}) was increased by a factor of approximately 4 by switching the field of view from 38 cm to 15 cm (a magnification factor of 2.5) [15]. Nonetheless, as the X-ray beam reaches a smaller area, the total energy imparted to the patient is grossly similar to that observed at low magnification with a larger area. Increasing tube voltage is another means of decreasing patient radiation exposure (by approximately 20% for an increase in tube voltage of 20 kV) but this may decrease image quality and it increases scattered radiation to staff members, although the latter has little clinical relevance [15, 16, 19, 80]. A value of 80–90 kV is usually recommended. Recording of radiation doses seems to induce radiation awareness, which eventually leads to shorter FT and reduced radiation doses [81]. An RCT showed that limiting the use of fluoroscopy to 3-s periods allowed a significant decrease in FT [41]; however, the difference was significant in multivariate but not in univariate analysis and the consensus of the endoscopists participating in that RCT was that using fluoroscopy with a time limit of 3 s was cumbersome.

8.3. Copper filtration

A reduction in patient radiation dose of approximately 50%, with reduction in image quality, can be achieved by inserting a copper filter in the X-ray beam (Evidence level 1–). We recommend testing the usefulness of copper filtration for ERCP procedures (Recommendation grade C).

Copper filters (0.1–0.5 mm thick) are installed in most modern fluoroscopy units to reduce patient radiation exposure. As the copper filters are removable, endoscopists can assess whether image quality is adequate for ERCP. Such filters can also be taped onto older X-ray units. In a study that was performed in phantoms during various human cardiology interventions, the insertion of a 0.35 mm thick copper filter in the X-ray beam reduced the ESD by a mean of 58% with insignificant detriment to the image quality as evaluated by unblinded evaluators [82]. Data on radiation dose reduction and absence of significant alteration in image quality were confirmed in an RCT of barium enema examinations where evaluators were blinded to the patient allocation group [83]. A potential drawback of this method is an increased load on the X-ray tube, which can create overheating, but overheating due to copper filters is not problematic with modern X-ray units.

8.4. RP shields

The most radiosensitive organs (thyroid gland, breasts, gonads and eyes) should be kept out of the main X-ray beam whenever possible, particularly in oblique radiographic projections. The use of RP shields to decrease patient radiation exposure is not recommended in the general patient population (Recommendation grade D).

No original study that investigated this topic was found in the literature; special patient populations (i.e., children and pregnant women) are dealt with below.

8.5. Patient information about radiation risks

It is recommended to provide information to the patient about radiation risks only in the case of ERCP repetition within 1 month or in cases of high doses as defined by a KAP >300 Gy·cm² (Recommendation grade D).

No original study on this topic was found in the field of digestive endoscopy; general recommendations from various bodies (e.g., the ICRP) are available for interventional radiology [46]. In this field, patient counseling is recommended if ESD reaches or exceeds 2 to 3 Gy [46, 84]. ESD values reported during ERCP are below 2 Gy [84, 85], and there are no reports of radiation-induced tissue reactions following ERCP [86]. Therefore, conditions requiring patient counseling are likely exceptional, limited to procedures lasting for hours with frequent fluoroscopy use.

8.6. RP in special cases

8.6.1. Pediatric patients

Compared with adults, children are more sensitive to radiation exposure, especially at younger ages (Evidence level 1+). In children, there must be a strong clinical indication for carrying out ERCP; this should be performed by experienced endoscopists only and RP measures similar to those used in adults should be strictly followed, including adjustment of collimation to the smaller size of children (Recommendation grade B). The most radiosensitive organs (thyroid gland, breasts, gonads, and eyes) should be protected with RP shields and should be kept out from the main X-ray beam, especially in oblique radiographic projections (Recommendation grade D).

In children, the sensitivity to cancer induction by radiation is considered to be higher than in adults by a factor of three to five. Follow-up studies after diagnostic X-ray examinations in children showed that cancer risks were correlated with radiation doses and were greatest for children irradiated early in life; risks for solid tumors persisted at least until the age of 50 years [14]. Because of the smaller size of children compared with adults, radiosensitive organs are closer together, so it could be difficult to position them outside of the X-ray beam. For all these reasons, ALARA concepts should be even more strictly followed in children [87].

8.6.2. Women of childbearing age, and pregnant patients

Magnetic resonance cholangiopancreatography (MRCP) and endoscopic ultrasound (EUS) are accurate in the detection of common bile duct (CBD) stones (Evidence 1+). Therapeutic ERCP is relatively safe and effective during pregnancy when performed by experienced endoscopists with adapted techniques. Fluoroscopy requirements may be reduced by using specific ERCP techniques (Evidence level 3). A pregnancy test should be obtained before ERCP in women for whom there is doubt about pregnancy (Recommendation grade D). ERCP in pregnant women should be performed only with a therapeutic purpose (Recommendation grade A); it is probably best performed by experienced ERCP endoscopists during the second trimester of pregnancy, strictly following recommendations to de-

crease patient radiation dose and with an RP apron wrapped around the patient's abdomen (Recommendation grade D).

All women with childbearing potential should be thoroughly investigated about their reproductive status before ERCP. If any doubt exists, a pregnancy test should be obtained before performing ERCP. Cholelithiasis is the most frequent symptomatic biliary disease during pregnancy. If CBD stones are suspected, MRCP and EUS are accurate diagnostic tools that are devoid of radiation risks [88, 89]. ERCP is the standard of care for treating choledocholithiasis during pregnancy: several case series are summarized in **Appendix e3** (available online; [e90–e96,e97, e98–e100,e101]), with most of them reporting no increase in the incidence of abnormal babies, preterm deliveries (less than 5%) or abortion. On the other hand, surgical treatment of choledocholithiasis during the first trimester has historically been associated with a high abortion rate (12%–60%), but more recent case series suggest that laparoscopic cholecystectomy is safe during pregnancy [e102, e103,]. Although ERCP seems to be reasonably safe throughout the whole gestational period [e101], non-urgent ERCP is probably best performed during the second trimester because the fetus is more susceptible during organogenesis in the first trimester and the path of the X-ray beam is in the proximity of the unborn child during the third trimester.

The risk to the fetus for tissue reactions appears to have a threshold of 10 mGy [e104]. For stochastic effects no threshold radiation dose is assumed. Therefore, the probability of a radiation-induced cancer can be reduced by keeping radiation exposure as low as possible. Shielding the fetus by placing a RP apron between the X-ray tube and the abdomen of the pregnant woman is recommended during fluoroscopy [e105, e106,]. Therefore, it is particularly important to determine whether the X-ray source is located below or above the patient (placing a protective apron under the woman's abdomen would be detrimental with over-couch systems). Only experienced ERCP endoscopists should perform these procedures as FT decreases with endoscopist experience [75]. Specific cannulation techniques have been used to bring about little or no radiation exposure to pregnant patients, including wire-guided cannulation and biliary access confirmation by bile aspiration [e97, e107]. Without fluoroscopy, complete CBD stone removal cannot be thoroughly checked (except by intraductal ultrasonography, and use of the latter is usually impractical) [e108]. In our opinion, the risks of recurrent cholangitis and of requirement for a second procedure probably outweigh the risk of short periods of fluoroscopy.

9. Quality assurance

9.1. Legal requirements concerning the quality assurance of the equipment

Quality control of X-ray systems is mandatory and acceptance testing needs to be carried out before the first use of the equipment and thereafter on a regular basis (Recommendation grade D).

In a national survey, ratios between the maximum and the minimum ESD values for various fluoroscopy units were in the range of 3 to 4 [e109]. This suggests that commissioning of the fluoroscopy units should be performed in the framework of the acceptance testing of X-ray systems before their first use with a patient. Annual stability testing of the fluoroscopy units is generally adopted, and the following parameters are evaluated during these tests: beam quality, beam collimation, equivalence between indicated and measured KAP, maximum E rate, and image

quality parameters. The holder of the installation is responsible for the implementation of quality control [e110, e111].

9.2. Analysis of patient radiation dose values

Recorded KAP values should be used for the study of interendoscopist, intrahospital and interhospital variations in patient radiation exposure and for comparison with the available regional and national DRLs (Recommendation Grade D).

The mean KAP value from a representative sample of adult patients may be used as a measure of the typical dose from ERCPs performed by a particular endoscopist. We recommend comparing this value with corresponding mean KAP values of other endoscopists and with available regional or national DRLs, in order to ensure comparable dose levels between endoscopists and centers.

9.3. Radiological unit selection for ERCP

The endoscopist and the medical physicist should be involved in the selection of the radiological system used for endoscopic examinations. They should determine in advance the desired radiological performance and RP specifications (Recommendation Grade D).

In choosing an X-ray system, the availability of experienced technical personnel in a given center should also be taken into consideration, so that prompt technical service is assured in the event of technical problems. At the time of installation, equipment performance evaluations should be conducted in order to ensure that the purchase specifications meet regulatory requirements. The records of the acceptance testing should be retained throughout the lifetime of the equipment for comparison with monitoring results in order to assess continued acceptability of performance [e112].

Use of the guideline

The aim of this guideline is to provide caregivers with a comprehensive framework on how to use X-ray systems in a clinical setting. ESGE guidelines represent a consensus of best practice based on the available evidence at the time of preparation. They might not apply in all situations and should be interpreted in the light of specific clinical situations and resource availability. Further controlled clinical studies may be needed to clarify aspects of these statements, and revision may be necessary as new data appear. Clinical considerations may justify a course of action at variance to these recommendations. ESGE guidelines are intended to be an educational device to provide information that may assist endoscopists in providing care to patients. They are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment.

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Institutions

- ¹ Service of Gastroenterology and Hepatology, Geneva University Hospitals, Geneva, Switzerland
- ² Service of Gastroenterology and Hepatology, Hospital S. Juan Dios del Aljarafe, Seville, Spain
- ³ Institute of Radiation Physics, University Hospital Center of Lausanne, Switzerland
- ⁴ Greek Atomic Energy Commission (GAEC), Agia Paraskevi, Athens, Greece
- ⁵ Institut de Radioprotection et de Sûreté Nucléaire (IRSN), Fontenay-aux-Roses, France

- ⁶ Department of Medical Physics, Faculty of Medicine, University of Crete, Iraklion, Crete, Greece
- ⁷ Department of Gastroenterology, University of Crete, Iraklion, Crete, Greece
- ⁸ Departments of Gastroenterology, Konstantopoulou-Agia Olga Hospital, Athens, Greece
- ⁹ Belgian Nuclear Research Centre (SCK-CEN), Mol, Belgium
- ¹⁰ Medical Physics Department, Konstantopoulou-Agia Olga Hospital, Athens, Greece

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