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Radiation exposure to patients during endoscopic retrograde cholangiopancreatography: A multicentre study in Finland

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ABSTRACT

Purpose: Endoscopic retrograde cholangiopancreatography (ERCP) has the potential for high patient dose, which is why attention is required regarding radiation protection. The available data about patient radiation doses in ERCP show a large variation that needs to be further investigated. The aim of this study was to determine the radiation doses to patients during ERCP, evaluate the risk of radiation-induced injury and to calculate the effective dose (ED) in patients who underwent an ERCP procedure.
Methods: A multicentre study which included ten hospitals was carried out in Finland. A total of 227 patient radiation doses in ERCP were recorded during a 4-month period in 2012. Entrance surface dose (ESD) was estimated by using thermoluminescent dosimeters (TLD) implemented in one of the hospitals. ED was calculated from dose area product (DAP) measurements. The data were analysed with the IBM SPSS Statistics version 21 (2012) software.
Results: The patient radiation doses in ERCP varied significantly in this study. The mean DAP was 5.15 (0.08–57.00) Gy cm^2, fluoroscopy time 2.4 (0.03–22.2) min and the number of X-ray images was 2.5 (0–14). A strong linear correlation was observed between the DAP and fluoroscopy time. The average ESD and ED in ERCP was 10 mGy and 1 mSv, respectively.
Conclusion: Patients received a greater radiation dose in therapeutic ERCP compared to diagnostic ERCP. The increase in frequency and complexity of ERCP procedures indicates the possibility of an increase in radiation exposure to patient. The results suggest that efforts at optimization and dose reduction in ERCP should be made.

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an essential tool in the treatment of the hepatobiliary system.[1,2] During the last few decades ERCP has evolved from a diagnostic to an almost exclusively therapeutic procedure. Magnetic resonance cholangiopancreatography (MRCP) has rapidly replaced ERCP as a diagnostic procedure in the evaluation of the biliary and pancreatic ducts. The sensitivity and specificity of MRCP for the diagnosis in various pancreaticobiliary disorders has been found to be relatively high.[3–6] Advances in knowledge, equipment, technique and the possibility of endobiliary therapy have contributed to an increasing number of therapeutic procedures that are performed in conjunction with ERCP.[3,7,8] Thus, ERCP is a highly technical and demanding invasive procedure carrying a high potential risk of severe complications. The most common complications are pancreatitis, haemorrhage, perforation, cholangitis and other infectious complications. ERCP-related mortality rate is approximately 1.0%.[9,10]

ERCP is performed under fluoroscopic guidance and digital radiographs are usually taken to demonstrate anatomy and pathology, as well as for the documentation of findings. During ERCP, both patients and healthcare staff are exposed to ionizing radiation and a potential risk of radiation-induced injury. This makes the ERCP undoubtedly an interventional radiological procedure. However, ERCP is not generally performed by a radiologist, but by a gastroenterologist or even by a general surgeon.[7,8,11,12] It has been found that endoscopists' experience is inversely associated with fluoroscopy time, and procedures performed with the involvement of a Gastroenterology (GI) fellow were associated with longer fluoroscopy times.[13,14] Some of the procedural factors, such as stent

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insertion, lithotripsy, needle-knife sphincterotomy, biopsies, use of a guidewire, additional guidewires and balloon catheter were also associated with longer fluoroscopy time.[14]

Previous studies have evaluated the radiation exposure to patients during ERCP, showing significant variation in radiation doses.[6–8,11,12,15,18–23,26,27] In its publication 117 released in 2010 the International Commission on Radiological Protection (ICRP) addressed the fact that ERCP has the potential to impart skin doses exceeding 1 Gy even though tissue reactions from fluoroscopically guided procedures have mostly been reported in interventional radiology and cardiology. The level of fluoroscopy use outside imaging departments consequently creates potential risk for such injuries.[16] The first step towards patient dose optimization is to establish the diagnostic reference levels (DRLs) for ERCP, despite the complexity of the fluoroscopic procedures and clinical conditions that are strongly dependent on the individual.[17–19] The establishment of DRLs might be quite useful in view of the large variation of DAP values reported during ERCP,[17] but only a few data were found. The United Kingdom (UK) and the Nordic Radiation Protection authorities have proposed DRLs of 20 Gy cm^2 and 50 Gy cm^2 for ERCP.[19,31] The 3-rd quartile of DAP values reported for therapeutic ERCP ranged between 33.0 and 60.3 Gy cm^2 in previous studies.[7,20,21] In addition, the ICRP recommends that DRLs should be based on relevant local, regional or national data[32] and for all those reasons there was an essential need to establish DRLs for ERCP in Finland.

The aim of this study was to determine the radiation doses to patients during ERCP. Furthermore, the purpose of this study was to evaluate the risk of radiation-induced injury in ERCP and to estimate the patient's effective dose as an indicator of the risk for stochastic effect. According to the ICRP 103 (2007) guidelines effective dose is suitable for the assessment of population dose, but not applicable to any single individual. However, it is useful for comparing and optimizing imaging procedures that use ionizing radiation, specifically when comparing examinations from different techniques or similar methods used in various hospitals.[25]

Materials and methods

The study was conducted in Finland during the years 2011–2012. Patient exposure data were collected from ten hospitals in which the ERCP examinations are performed, including five university hospitals and five central hospitals. A total of 227 patients' radiation doses in ERCP were recorded consecutively over a 4-month period without setting any restrictions on patient weight, sex or condition. For each examination dose area product (DAP), fluoroscopy time and number of digital radiographs were collected. Patient body characteristic, such as age, sex, height, weight and body mass index (BMI) were registered as well. In addition, it was appropriate to clarify if ERCP examinations were purely diagnostic in nature or had some type of therapeutic intervention.

The ERCP examinations were carried out in hospitals both in X-ray departments and endoscopy units. The X-ray equipment used in ERCP consists of a stationary fluoroscopic X-ray system, multipurpose fluoroscopy system (c-arm) or mobile c-arm unit, with X-ray tube located above ("over-couch" system) or under ("under-couch" system) the patient table. The field size of image intensifier or flat-panel detector, units of the DAP-meter and total filtration of the X-ray beam varied according to the fluoroscopy machine used. In some of the hospitals the X-ray equipment was controlled by a radiographer while in the others ERCP was performed without involvement of a radiographer.

Entrance surface dose (ESD) was estimated by using thermoluminescent dosimeters (TLD) implemented in one of the hospitals. TLD readings were taken only in one hospital due to lack of read-out equipment in other hospitals and time, and subsequently in order to negative probable sources of error. Measurements were carried out in 13 ERCP examinations over a 2-week period. DAP, fluoroscopy time and number of digital radiographs were recorded in the same examinations. For each measurement, TLD was positioned over the liver region of the patient's skin and on the central axis of the X-ray beam. All dosimeters were calibrated previously against energies used in the study. Prior to each irradiation TLD were annealed and the read-out of dosimeters was done manually by Alnor Dosacus TLD reader.

The patients' effective dose was calculated from DAP measurements by using a conversion coefficient of 0.19 mSv/Gy·cm^2.[7] Informed consent was obtained from all patients before the ERCP procedure in accordance with guidelines set forth by the institutional board of each hospital. Statistical analysis was performed using the IBM SPSS Statistics version 21 (2012) software. Frequencies, percentages, mean, median and standard deviations were calculated for the demographic data; in addition, a third quartile was measured for the dosimetry data. Possible statistical differences between variables were assessed using a non-parametric Mann–Whitney U test and a level of significance ($p < 0.05$) was used in the test.

Results

Most of the ERCP examinations in this study were therapeutic (91%) in nature, while a minority consisted of diagnostic ERCP (9%). Of a total of 227 patients who underwent ERCP examination approximately 52% ($n = 119$) were male and 48% ($n = 108$) female. The mean age of all patients was 68 years, ranging from 11 to 102 years. Women were on average 6 years older than men in this study. The mean and range of BMI of the patients was 26.4 kg/m^2 and 15.6–44.5 kg/m^2, respectively. Males were slightly heavier and taller than females. Patients' body characteristics are presented in Table 1.

The results show a large variation in patient radiation dose, fluoroscopy time and as well as in the number of digital radiographs. During ERCP patients received on average 5.15 Gy cm^2 radiation dose. The highest reported DAP value in this study was 57.00 Gy cm^2. The mean fluoroscopy time was relatively short (2.4 min), ranging from 0.03 to 22.2 min. A predetermined limit of 5 min of fluoroscopy time was exceeded in about 10% of all ERCP examinations. Radiation dose and fluoroscopy time distributions did not exhibit a normal distribution, as shown in Fig. 1 and Fig. 2. The number of digital radiographs taken under ERCP varied from zero to 14 images. The average number of digital radiographs was 2.5. Table 2 presents the patient exposure data in ERCP in terms of DAP, fluoroscopy time and number of digital radiographs. A strong linear correlation was observed between the dose area product (DAP) and fluoroscopy time ($r = 0.74$).

The result showed that as expected, patients received a larger radiation dose in therapeutic ERCP compared to diagnostic ERCP. In ERCP examinations of therapeutic nature the DAP was higher and fluoroscopy time significantly longer than in diagnostic procedures. However, the differences between the therapeutic and diagnostic

Table 1
Patients' body characteristics including age, weight, height and BMI ($N = 227$).

	Age (Year)	Weight (kg)	Height (cm)	BMI (kg/m^2)
Min	11	30	132.0	15.6
Max	102	130	193.0	44.5
Mean	68.3	75.1	168.7	26.4
Median	73.0	75.0	169.0	25.5
Standard deviation	16.8	16.4	10.0	5.3