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MONITORING OF SURFACE RADIATION DOSE TO PATIENTS AND PERSONNEL DURING ERCP FOR OPTIMIZATION OF INSTITUTIONAL PRACTICE

Radiology

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ABSTRACT

Endoscopic Retrograde Cholangio-Pancreatography (ERCP) uses ionizing radiation and hence associated with radiation hazards. The present study analyses the prospective estimates of the radiation doses received by patients and personnel during ERCP, optimizes the radiation dose during therapeutic ERCP, estimates the risk for personnel and patients and compares the doses with available data and reference levels. Dose Area Product (DAP) measurements were used to estimate the effective dose (ED) to patients undergoing ERCP. A DAP meter was fitted to the x-ray tube before each of the ERCP procedure. 60 ERCP procedures of therapeutic intent are evaluated. All the procedures were performed on Allengers HF fluoroscope. The procedure completion time observed varied between 10 minutes to 35 minutes with a median of 20 minutes. Optically Stimulated Luminescence Dosimeters (OSLDs) were used to measure radiation exposure to the abdomen, thyroid surface, forehead and hands of the personnel performing the procedure and center of anterior and posterior body surface of the patient undergoing the procedure. Median dose to abdomen, thyroid surface, forehead and hands measured for personnel. The diagnostic reference level for ERCP in the study is 13.82 Gy.cm2 (75th percentile DAP) while the UK DRL is 16.7 Gy.cm2. Routine radiation dose monitoring is a valuable tool for reducing both patient and staff radiation doses. The ERCP type (diagnostic or therapeutic), fluoroscopic parameters and the complexity of each clinical case will definitely affect radiation dose received. The number of procedures performed routinely plays a vital contribution to the cumulative dose to the personnel.

KEYWORDS

ERCP, DAP, OSLD, DRL, LLE

INTRODUCTION

Ionizing radiation such as X-rays and gamma rays cause ionization in the medium through which they pass. The ionization produced can lead to DNA damage or cell death. Though it gas significant benefits in medical imaging; it also has associated with a risk of developing adverse effects such as tissue reactions and carcinogenesis. The population exposure from medical X-rays contributes approximately 14% of the average annual population dose. More than 95% of human exposure to man-made ionizing radiation results from diagnostic and interventional radiology. Endoscopic Retrograde Cholangio pancreatography (ERCP) uses endoscopic and radiological guidance to accomplish diagnosis and therapy of biliary and pancreatic disorders. ERCP is one the most complicated gastrointestinal procedures routinely performed. In addition to endoscopic skills it requires the ability to interpret radiologic images in real time. Recent data indicate that ERCP is becoming a major therapeutic strategy for biliary disease in developed and developing countries. ERCP is a combination of upper endoscopy and fluoroscopy for diagnostic and therapeutic purposes to examine the pancreatic and hepatobiliary tract. During the last decades ERCP had proved to be very useful in diagnosis, however the introduction of new, non-invasive imaging modalities, such as magnetic resonance cholangiopancreatography and Endoscopic Ultrasonography (EUS), have led the ERCP to be mainly used for therapeutic purposes.

Ionizing radiation is a well-established risk factor for cancer. Since medical exposure has been justified, due to the potential benefit to the patient, there are no prescribed dose limits to the patients; however, the principles of radiation protection have to be followed. During the performance of ERCP, a large number of X-ray fluoroscopy and digital radiographs are performed, making it an interventional radiological (IR) procedure. ERCP is highly technical and depends on endoscopist experience. The use of fluoroscopy to aid ERCP places both the patient and the endoscopy staff at risk of radiation-induced injury. Radiation dose to patients during ERCP depends on many factors, and the endoscopist cannot control some variables, such as patient size, procedure type, or fluoroscopic equipment used. High quality ERCP outcomes and limitation of ERCP-related complications depend on good training. It is essential to establish the appropriate conditions for radiography in all circumstances, in order to avoid unnecessary exposure of patients and staff to potentially harmful radiation. This means that precautions should be taken to keep the radiation dose to both the personnel participating in ERCP procedures and to patients as low as reasonably achievable (ALARA) principle. With increasing public awareness and concern surrounding radiation risks, it is crucial that procedures be performed according to the ALARA principle. ERCP requires radiation exposure to the patient which should be kept to the lowest level to allow the procedure to be completed safely in accordance with the "as low as reasonably achievable" principle.

The International Commission on Radiological Protection (ICRP) has recommended dose limits for occupational exposure in order to reduce the probability of cancer and to prevent the tissue reaction effects. Examiners can reduce the occupational exposure to radiation by using the principles based on distance, time, and shielding. The operator selects equipment and methods to ensure that for each medical exposure, the dose of ionizing radiation to the individual undergoing the exposure is as low as reasonably achievable (ALARA) and consistent with the intended diagnostic or therapeutic purpose. However, despite the fact that endoscopic retrograde cholangiopancreatography (ERCP) requires fluoroscopic and radiographic exposures, which impose radiation risks to patients and staff, the exposure of gastroenterologists and patients to ionizing radiation and the associated potential cancer risk have been assessed in only a few studies. The purpose of this study has been to determine the occupational doses of ionizing radiation and to estimate the related risks to the patients and staff at gastroenterology department.

The International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency has introduced diagnostic reference levels (DRLs) to optimize the radiation exposure (RE) from medical imaging. However, the ICRP states the difficulty of applying the DRL concept to interventional procedures because the RE level depends on the individual clinical circumstances and the complexity of the procedure. There are two types of expression for quantities of radiation, those that express the concentration of radiation at some point, or to a specific tissue or organ, and those that express the total radiation delivered to a body. Exposure indicators usually measured in ERCP are absorbed dose, as a measure of radiation concentration, two measures of total radiation (effective dose and dose area product) and fluoroscopy time. Absorbed dose is the measure used to quantify the concentration of radiation energy actually absorbed in a specific tissue. This is the measure that is most directly related to biological effects. ERCP procedures is essential not only in order to optimize the techniques and protocols in each centre, but also to manage the probably increasing radiation dose delivered to patients. The radiation

dose from fluoroscopy varies with different variables. Fluoroscopy time is a quantitative measure that adds to duration as the patient undergoes fluoroscopy during ERCP. Fluoroscopy time has been proposed as a quality measure for ERCP; however, it is but one of several factors that determine radiation exposure. Another variable is dose–area product (DAP, expressed as Gy.cm^2), which is the product of the dose absorbed and the area irradiated. It is an estimation of the entire dose of radiation the patient receives and is thought to correlate with long-term biological risk from radiation exposure. It is automatically calculated by the fluoroscopy machine based on the radiation dose and the surface area being imaged. Dose values can be in the traditional unit of the rad or the SI unit of the gray (Gy). Effective dose is a very useful radiation quantity for expressing relative risk to humans, both patients and other personnel. Dose-area product (DAP) provides a good estimation of the total radiation energy delivered to a patient during a procedure and is strongly correlated to the fluoroscopy time. It is the most practical measure for monitoring the radiation delivered to patients. DAP is just the product of the air kerma, in Gy or mGy, and the exposed area in cm^2 (Gy.cm^2). However, RE depends on several factors, including the difficulty of the procedure, the systematization or setting of the fluoroscopy unit, and the awareness of physicians monitoring the doses reported. When fluoroscopy is used to assist ERCP, the shortest fluoroscopy time possible is recommended. Fluoroscopy time is shorter when ERCP is performed by an endoscopist who has many years' experience of performing ERCP and carried out a large number of ERCPs in the preceding year.

OBJECTIVES

The primary objective of this study was to evaluate the effectiveness of a practical dose reduction measure for endoscopic retrograde cholangiopancreatography (ERCP) and to ensure the radiation dose is maintained in line with well-established international reference levels.

MATERIALS AND METHODS

The ERCPs were carried out using an over couch Allengers HF fluoroscope with a 30 cm diameter image intensifier and a high-frequency generator. The collimator diaphragms are automatically set to the size of the cassette inserted in the tray. Total filtration of the X-ray beam was 4.0 mm Al. Patients referred for ERCP examination were included without setting any restrictions on patient weight, sex or clinical condition. Written informed consent was obtained from all patients in accordance with guidelines set forth by the institutional board of the hospital. The ethics and research committee approved the study and a written consent was obtained from all patients prior to the procedure. All ERCP procedures were therapeutic and were done under sedation provided by an anesthesiologist and with a fixed setup for the patient. This meant that each patient remained in the same position, so the same anatomical area was exposed during the entire examination. The techniques were performed by a single endoscopist with more than 3 decades of experience. The X-ray equipment was controlled by the radiographer who remained in the control room and performed fluoroscopy and radiography according to the requirements of the endoscopist. The endoscopist was positioned next to the patient, behind two articulated ceiling suspended lead equivalent protective screens, during the whole procedure, wearing a two piece (front and back) protection apron 0.25 mm lead equivalent, a lead collar and lead protective glasses. Endoscopist was also monitored using a personal monitoring badges such as thermos luminescence dosimetry (TLD). Optically simulated luminescent dosimeter (OSLD) were used for measuring doses in this study. Five envelopes were used to abdomen, thyroid surface, forehead and hands of the personnel performing the procedure and center of anterior and posterior body surface of the patient undergoing the procedure. During the procedure, the OSLD were kept in the required positions and were stuck in place with adhesive tape. The operators performed the investigations as their daily practice with a protocol that is designed to minimize patient and examiner exposure.

Patient data included the radiation exposure in terms of Dose Area Product (DAP, in Gy.cm^2), fluoroscopy time (T, in min) and the radiation dose measured for personal. The present study has some limitations. First, we used data from only one center. Statistical analysis was performed on dose area product. Organ and surface dose to specific radiosensitive organs was carried out.

The Fluoroscopy Time and DAP were calculated by the fluoroscopy machine. FT, and DAP were automatically recorded for each procedure by the fluoroscopy device based on the numerical dose determination method. PCXMC dose calculations (Version 2.0.1.4), was used for the Monte-Carlo simulations. The data recorded for all procedures included patient body characteristics (age, sex, height, weight and body mass index (BMI) (weight/height^2), tube voltage (kV), tube load (mAs), and fluoroscopic data: kV, tube current (mA), total screening time, clinical indication, start and end time. During the procedure, the OSLD were kept in the required positions (entrance of the radiation [at intersection point of the X-ray beam axis with the entrance surface of the patient], exit of radiation and thyroid gland) and were stuck in place with adhesive tape. The operators performed the investigations as their daily practice with a protocol that is designed to minimize patient and examiner exposure.

Staff Dose Assessment

One experienced gastroenterologists performed all the procedures. Regarding gastroenterologist, the radiation dose was monitored using personnel monitoring badges such as TLD. The staff used a 0.25 mm lead equivalent thick apron, full wrap-around protection. The assistant used 0.50 mm lead equivalent thickness, frontal protection. Neither a protective eyeglass nor thyroid collar were worn by either of the staff. The examiner radiation dose in gastroenterology departments is routinely monitored by TLD dosimeters. All procedures were performed with the examiners at the same locations. The nurses remained outside the X-ray room during the exposure; therefore, there was no need for radiation dose measurements. A lead barrier of 0.50 mm lead equivalent was placed on the side of the gastroenterologist to reduce radiation scatter to the examiners standing to the side of the fluoroscopy couch. ERCP was performed with an Allegers HF Fluoroscope machine. During the procedure, radiographic and fluoroscopic images were obtained after injection of contrast medium. Since the contrast medium normally remained in the biliary tree for several minutes following removal of the duodenoscopy, a post procedure antero-posterior projection was also obtained, if required, for further evaluation of the stent placement or residual stones. Radiological and clinical records of ERCP performed in these periods were retrospectively reviewed.

OSLD Measurements

Optically stimulated luminescence dosimeters (OSLDs) have a number of advantages in radiation dosimetry making them an excellent dosimeter for in vivo dosimetry. The measurement was carried by using OSL system by Landauer Inc., The OSLD system uses Al_2O_3: C Nano Dot TM as an active radiation detector and InLight TM microStar ® as a readout assembly. Inter-detector response, energy, dose rate, field size and depth dependency of the detector response were evaluated for all available clinical range of photon beam energies in radiotherapy.

Radiation Dose Monitoring In Ercp

Radiation dose monitoring in patients undergoing diagnostic or IR procedures has been widely adopted in clinical practice, but data on patient doses during ERCP are very scarce. Gastroenterologists who are involved in ERCP procedures may work at specialized centers and may perform multiple procedures daily. In all circumstances in which fluoroscopic and/or x-ray equipment is used, gastroenterologists should minimize the risks to patients, themselves, and other members of the staff. The dose limit that is recommended by the International Commission on Radiological Protection (ICRP) and adopted by most countries is 20 mSv/year. For situations where the annual dose limit exceeds 20 mSv, it is recommended that the dose should not exceed 50 mSv in any particular year or 100 mSv over 5 years. This dose limit is based on the calculation of radiation risk over a full working life from the age of 18 years to 65 years (47 years) at the rate of 20 mSv per year, Despite the relatively low risk of radiation-induced injury, endoscopist should be aware that all exposure carries a cumulative risk. It is estimated that patients receive about meadian 20 min of fluoroscopy during ERCP, with therapeutic procedures taking significantly longer. Our Studies have found that meadian values of DAP was 9.77 Gy/cm^2.

Personal Protection And Radiation Safety

The primary source of radiation to endoscopy personnel is radiation scattered from the patient, not the primary x-ray beam. Positioning staff as far away from the patient as possible is essential in limiting exposure. If an endoscopy staff member is standing 1 m from the patient, the radiation exposure for that individual is 1/1000 the patient's exposure. Shielding is required for all staff in the fluoroscopy unit. Aprons containing lead shielding 0.5 mm thick are standard in most fluoroscopy units and block more than 90% of scattered radiation.

Optically clear lead glasses can reduce the operator's eye exposure by 85% to 90%. There are no mandatory requirements for either thyroid shields or leaded glasses, although many have recommended that thyroid shields should be used routinely and leaded glasses should be used by individuals with high caseloads.

Fluoroscopic Examinations And Acquisition Parameters

DAP is defined as the absorbed dose multiplied by the X-ray beam cross sectional area at the point of measurement. Our fluoroscopic machine was equipped with a DAP meter. Dose-area product (DAP) provides a good estimation of the total radiation energy delivered to a patient during a procedure and is strongly correlated to the fluoroscopy time. It is the most practical measure for monitoring the radiation delivered to patients. DAP is just the product of the air kerma in Gy or mGy, and the exposed area in cm^2 ($Gy.cm^2$). The DAP was shown on the live screen in the examination room, on the data display in the examination room, and on the console monitor in the control room. The DAP meter was calibrated at regular intervals

Statistical Analysis

Statistical analysis was performed with commercially available statistical software PCXMC dose calculations (Version 2.0.1.4), was used for the Monte-Carlo simulations.

Relevant variables known to have an association with DAP were included in the model. Age, body mass index (BMI), fluoroscopy time, number of spot images taken, and ERCP difficulty grade were added into the regression model as predictors.

RESULTS

The use of fluoroscopy to aid ERCP, places both the patient and the endoscopy staff at risk of radiation-induced injury. ERCP is highly technical and depends on the endoscopist experience. Radiation dose to patients during ERCP depends on many factors, and the endoscopist cannot control some variables, such as patient size, procedure type, or fluoroscopic equipment used. Previous reports have demonstrated a linear relationship between radiation dose and fluoroscopy duration. When fluoroscopy is used to assist ERCP, the shortest fluoroscopy time possible is recommended. Factors associated with prolonged fluoroscopy duration have been delineated recently, but these have not been validated.

The patient doses in ERCP can be optimized by the presence of an experienced interventional endoscopist in the team by reducing the fluoroscopic time and reduction of radiographic images. The radiation absorbed doses to the different organs are relatively low reasons be the high level of experience and the proper use of radiation protection measures. Proper use of lead curtains and lead aprons is important in reducing the personnel dose. Furthermore, the examiner should put on a lead wrap-around protective apron, since he is not facing the scattered radiation.

The sample included 60 ERCP procedures and reviewed. A summary of the results in comparison with published literature is shown in Table 1.

Table – 1 Time And Dap Values

Author	No. of cases	Median T min	Median DAP Gy.cm2
Present Study	60	2.2	9.77
Tsapaki et al.	1632	3.5	15.6
Hadjiconstanti et al.	15	2.1	1.7
Tsapaki et al.	200	4.4	7.8
Saukko et al.	227	2.7	5.83
Seo et al.	126	4.52	27.35
Liao et al.	331	3.4	9.56
Tsapaki et al.	157	2.6	3.1
Rodriguez et al.	340	2.75	9.4
IAEA part E	10	3.3	11.1
IAEA part F	39	1.7	23.6
Tsalafoutas et al.	21	7.1	48.9
Buls et al.	54	8.3	60.3

The procedure completion time observed varied between 10 minutes to 35 minutes. The mean DAP was 9.7 $Gy.cm^2$. 60 patients who underwent therapeutic ERCP at the medical college and hospital were consecutively enrolled in this study. Although all 60 ECRP procedures were performed by a single, well experienced endoscopist, using the same X-ray imaging system, additional factors, such as behavior modification during the procedure and the complexity of each clinical case definitely affect radiation dose. The number of procedures per endoscopist, the ERCP type (diagnostic and therapeutic) and, mainly, the complexity of each clinical case affect staff radiation dose too. DAP and T values of the present study appeared to be close to those reported in similar studies in the literature. Quarterly endoscopist radiation dose was negligible due to the high level of experience and the proper use of all radiation protection equipment of the endoscopic gastroenterology department.

The radiation dose received by the personnel such as endoscopist, resident, and technologist are very less and it is with in tolerance level. The mean radiation dose to the unprotected parts of the gastroenterologist was higher for the hand (0.0086cGy) due to the scatter radiation from the protective barrier (lead apron). However, in current study the effective dose for the right wrist of the technologist is very high (0.0437) as compared to the dose received by the endoscopist and resident respectively (0.0086 and 0.0306). Comparisons of thyroid and abdomen doses for endoscopist, resident and technologist is shown in Table 2.

Table – 2 Radiation Doses Measured For Personnel

Personnel	Abdomen cGy	Forehead cGy	Left Wrist cGy	Right Wrist cGy	Thyroid Surface cGy
Endoscopist	0.0047	0.0069	0.0072	0.0086	0.0081
Resident	0.0085	0.0093	0.0187	0.0306	0.0132
Technologist	0.0105	0.0204	0.0159	0.0437	0.0100

DISCUSSION

The two basic principles of radiation protection of the patient as recommended by the International Commission on Radiological Protection (ICRP) are justification of practice and optimization of protection, including the consideration of dose reference levels. Justification is the first step in radiation protection. It is accepted that no diagnostic exposure is justifiable without a valid clinical indication, no matter how good the imaging performance may be. Every examination must result in a net benefit for the patient. Once a diagnostic examination has been clinically justified, the subsequent imaging process must be optimized. The optimal use of ionizing radiation involves the interplay of three important aspects of the imaging process: the diagnostic quality of the radiographic image, the radiation dose to the patient, and the choice of radiographic technique. ERCP is nowadays mainly a therapeutic endoscopic procedure that under fluoroscopy guidance provides treatment in various benign and malignant diseases of biliary and pancreatic ducts. Radiation dose to patients during ERCP depends on many factors. Some factors are related to the endoscopist, including fluoroscopy time, number of digital spot images taken, and use of collimation. The endoscopist cannot control some variables, such as patient size or procedure type.

The patient body characteristic data were comparable to the mean values reported in the literature. The median screening time in the present study is 20 min, which was more than that previously reported by Naidu et al. It is estimated that patients receive about 2-16 min of fluoroscopy during ERCP. It is important to note that; Larkin et al. and Buls et al. estimated that fluoroscopic exposure contributes 90% of patient total dose during ERCP. In agreement with the aforementioned studies, strong correlation was found between the ESD and screening time. Therefore, fluoroscopic time can be a good indicator of dose if radiographic images are controlled. As expected, no significant correlation was found between patient dose, patient characteristics, and exposure factors, but it should be noted that dose does depend on the complexity of the procedure. Storing fluoroscopic images could reduce the number of radiographs; this may decrease the image quality but not the yield of the procedure. Selection of the low dose fluoroscopic mode and good patient positioning prior to the procedure could also reduce the radiation dose. Moreover, adequate filtration of an X-ray beam can substantially reduce patient dose up to 70% by improving the quality of the beam while largely maintaining adequate image quality.

As ERCP involves direct irradiation of some of the internal and radiosensitive organs, equivalent doses for specific organs were estimated as illustrated in table2. Optically Stimulated Luminescence

Dosimeters (OSLDs) were used to measure radiation exposure to the abdomen, thyroid surface, forehead and hands of the personnel performing the procedure and center of anterior and posterior body surface of the patient undergoing the procedure. Median dose to abdomen, thyroid surface, forehead and hands measured for personnel are tabulated in Table 2. Thyroid surface dose (TSD) was estimated by direct placement of the OSLD s to organ site. The measured endoscopist, resident, technologist doses (cGy) are comparable as presented in table 2. As expected, the technologist was more exposed than the endoscopist. The use of full wrap-around apron is more effective due to the full coverage of the back and waist area, than the frontal protection one. The mean radiation dose to the unprotected parts of the gastroenterologist was higher for the hand (0.0086cGy) due to the scatter radiation from the protective barrier (lead apron). However, in current study the effective dose for the right wrist of the technologist is very high (0.0437) as compared to the dose received by the endoscopist and resident respectively (0.0086 and 0.0306). Dose differences to examiners can be explained in the light of patient dose differences and examiners' location and the utility of radiation barriers. These variations could be attributed to the X-ray machine characteristics and to projections used to derive the effective dose from ESD. However, it offers a good and simple indicator of effective dose estimation. This variation of patient dose is due to differences in the protocols and exposure factors, X-ray equipment, patient pathology, field of view, geometry and examiners experience.

The probability of cancer due to radiation dose depends on organ dose, age and tissue weighting factor, which represent the relative contribution of that organ or tissue to these effects. The risk of exposure induced cancer death estimated for patients in the present study is $8.86x10^{-4}$ (1 in 1200) which is similar to the findings of Larkin et al. and Naidu et al. who have estimated the risk of radiation-induced cancer between 1 in 1700 ($6x10^{-4}$) to 1 in 3500 ($3x10^{-4}$) per procedure. The risk of exposure induced cancer death and loss of life expectancy (LLE) estimated for the endoscopist, resident and assistant were $3.86x10^{-5}$ (1 in 26000), 6 minutes; $9.05x10^{-5}$ (1 in 12000), 6 minutes and $1.09x10^{-4}$ (1 in 9200), 12 minutes respectively. Since the procedure is obviously justified, the risk of cancer is used as an indicator of the radiation detriment. Radiation dose reduction can be achieved by wearing the protective eyeglasses and thyroid shields that significantly attenuate scatter radiation. However, the practitioners believe that the use of lead glasses impairs vision and so increases the exposure time and that lead gloves are inconvenient.

DAP is a more accurate indicator of patient radiation exposure during ERCP than FT, but did not emphasize the indication or degree of procedure difficulty. Therefore, the present study not only aimed at measuring the DAP and FT during ERCP, but also at correlating radiation exposure with different indications and degrees of difficulty, with comparison between different operation techniques. Factors affecting radiation dose, in addition to gastroenterologist's experience, include patient body habitus, use of copper filtration, and distance of patient to the radiation source, magnification, oblique views and spot images.

CONCLUSION

The use of fluoroscopy to aid ERCP, places both the patient and the endoscopy staff at risk of radiation-induced injury. ERCP is highly technical and depends on the endoscopist experience. Radiation dose to patients during ERCP depends on many factors, and the endoscopist cannot control some variables, such as patient size, procedure type, or fluoroscopic equipment used. Previous reports have demonstrated a linear relationship between radiation dose and fluoroscopy duration. When fluoroscopy is used to assist ERCP, the shortest fluoroscopy time possible is recommended. Factors associated with prolonged fluoroscopy duration have been delineated recently, but these have not been validated. The patient doses in ERCP can be optimized by the presence of an experienced interventional endoscopist in the team by reducing the fluoroscopic time and reduction of radiographic images. The radiation absorbed doses to the different organs are relatively low reasons be the high level of experience and the proper use of radiation protection measures. Proper use of lead curtains and lead aprons is important in reducing the personnel dose. The available data is not enough to establish local reference levels, but this could be a baseline for the optimization of dose with regard to avoiding unnecessary radiation risks.

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