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Assessment of patient dose and radiogenic risks during endoscopic retrograde cholangiopancreatography

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HIGHLIGHTS

- Radiation dose was measured for patients during ERCP procedures.
- Radiogenic risk per ERCP procedure was estimated.
- Patient ESAK is low compared to previous studies in the light of the current practice.
- Patient dose was decreased significantly in the last two decades due to advancement in imaging technology and protocols.

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ABSTRACT

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive technique that has been used for over 30 years in the diagnosis and management of pancreaticobiliary disorders. The objectives of this study were to evaluate the patient entrance surface air kerma doses (ESAK) and estimate the organ and effective doses during ERCP in three hospitals in Khartoum. A total of 55 patients were examined in three hospitals in Khartoum state, Sudan. Calibrated thermoluinescent dosimeters (TLD) were used to measure patients' ESAK. Organ and effective doses were estimated using National Radiological Protection Board (NRPB) software. The overall mean of ESAK for all ERCP procedures was 42.4 mGy. The mean patient ESAK in Fedail (A), Soba (B) and Ibn sena (C) hospitals were 26.7 mGy, 26.0 mGy and 72.4 mGy, respectively. The effective doses in three hospitals were 1.60, 1.56 and 2.67 mSv in that order and the overall mean effective dose was 1.94 mSv. Patient radiation doses vary widely among the hospitals. Patient ESAK is low compared to previous studies in the light of the current practice. Patient dose was decreased significantly in the last two decades.

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) which is a diagnostic and therapeutic procedure has impacted significantly the management of patients with pancreatico-biliary disorders. It was first described in 1968 (McCune et al., 1968). ERCP procedure, which uses a combination of endoscopy and fluoroscopic imaging, accounts for 8.5% of all fluoroscopically guided diagnostic and interventional procedures in the USA, with a mean effective dose of 4.0 mSv per procedure. It contributes 4.0–5.0% to the total collective dose from fluoroscopically guided interventions (WGO, 2010). The procedure is associated with a considerable radiation exposure for patients. The patient doses per procedure ranges from 55.0 to 347.0 mGy for entrance surface air kerma (ESAK) and from 3.0 mSv up to 20.0 mSv effective dose (WGO, 2010; ICRP, 2010; NCRP, 2009; Boix and Lorenzo-Zúñiga, 2011; Ho et al., 2014; Liao et al., 2015; Saukko et al., 2015). It has been estimated that patients are irradiated for approximately 2.0–16.0 min which accounts for almost 70% and $>90\%$ of the dose for diagnostic and therapeutic ERCP procedures, respectively (Boix and Lorenzo-Zúñiga, 2011, Ho et al., 2014). The knowledge of the absorbed radiation dose to the organs of a patient undergoing a

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procedure involving radiation is essential in order to evaluate the detriment of the procedure; which in turn is needed to evaluate the net benefit from the procedure (ICRP, 2010). The benefits of properly performed procedures almost always outweigh the radiation risk experienced by an individual. Nevertheless, unnecessary exposure to radiation can produce avoidable risk. Attention of patient dose measurement was increased recently, some studies has been published regarding patient doses in countries with level one health care (Boix and Lorenzo-Zúñiga, 2011; Ho et al., 2014, Sulieman et al., 2011; Dumonceau et al., 2012; Tsapaki et al., 2011; Noto et al., 2011; Jorgensen et al., 2010; Savides, 2012; Tsalafoutas et al., 2003; Alzimami et al., 2013; Rodríguez-Peralvarez et al., 2011; Buls et al., 2002). Furthermore, the European Society of Gastrointestinal Endoscopy (ESGE) (Dumonceau et al., 2012) recommended reporting patient radiation doses in a national database due to limited information regarding diagnostic reference levels (DRLs) for ERCP procedures. The available data on patient doses is quite limited in comparison with the importance and the frequency of the procedure. In addition to that, some of the available data on patient doses in ERCP is generally outdated because of the changes in X-ray systems, image receptors, and hardware that have taken place over the past decade. In Sudan, ERCP procedure is carried out in 5 gastroenterology departments, two governmental hospitals and three private hospitals (Ali et al., 2010). All ERCP departments are located in Khartoum, the capital of Sudan. Therefore, the average number of ERCP procedure is expected between 3000 and 5000 procedure per year, based on the current workload.

To our knowledge, no study has been published regarding patients doses during ERCP procedures in Sudan. The current study intends to evaluate the patient ESAK, to estimate the organ and effective doses during ERCP in three hospitals in Khartoum, Sudan.

2. Materials and methods

2.1. Thermoluminescent dosimetry

A total of 144 thermoluminescent dosemeters, (TLD–GR200A) circular chips of lithium fluoride (LiF:Mg,Cu,P) were used in this study. Prior to measurements, all TLDs were calibrated according to the protocol for the range of energies used in the study (Sulieman et al., 2007). The calibration was performed under reproducible reference condition using the Toshiba Rotande model (T6-6TL-6) against ionization chamber (PTW.CONNY II) connected to radiation monitor controller at 100 cm SSD, 75 kVp and 20 mA s, which is the average energy used during ERCP procedures. Both the chamber and electrometer were calibrated for the energy range 30–120 kVp at the national standard laboratory.

For the TLD and chamber irradiation, a Polymethyl- methacrylate (PMMA) calibration test bed was constructed having dimensions of $30 \times 30 \times 10$ cm^3, which simulates the patient's lateral and backscatter conditions. The first PMMA slab was used to accommodate the TLD chips in an array of slots 10×10. Each TLD was identified by its position in the array. TLDs been annealed prior to the irradiation in patient dose measurements. Individual calibration factors were obtained by irradiating the entire group to the same dose. The measured signal of each TLD was divided by the mean signal of the group. This process was repeated three times to reduce the effect of statistical variations and to determine the stability and reproducibility of the signal. TLDs with sensitivity within 3% were used in this study. All the TLD chips had the same thermal history. The calibration cycle was carried out every month.

The TLD signal profile was obtained using an automatic TLD reader (Fimel PCL3, France) in an atmosphere of inert nitrogen. The read-out was at a 155 °C preheat temperature and the signal was acquired from 155 °C to 260 °C .

2.2. X-ray machines

Three X-ray machines were used in this study: (i) General purpose fluoroscopic X-ray machine equipped with under couch tube; at Fedail Hospital (A) (Toshiba model KXO-15 E) while the range of the tube voltage is 40–120 kVp with a total filtration of 3.5 mm Al for machine A, (ii) Digital fluoroscopy C -arm (SIRE MOBIL COMPACT L, Siemens-Germany. The X ray tube in the C -arm machine located in the lower portion of C-arm and the image intensifier is on the upper portion with ability to capture the last fluoroscopic image on the monitor after X-ray exposure is terminated. The range of the tube voltages is 40–125 kVp, with a total filtration of 4.0 mm Al for Soba University hospital X ray machine (B) and (iii) X-ray machine (Shimadzu Shimavision EX Quatra-2005) equipped with over couch tube with remote control and under couch image intensifier at Ibn Sena Hospital (C). The tube voltage range is 40–140 kVp with a total filtration of 2.5 mm Al for machine C. Pulsed fluoroscopy was used during the procedures was used in machine A and B while in machine C, continuous fluoroscopy is used. All X ray machines were controlled by technologist during ERCP procedures. All machines had already passed the routine quality control tests performed by Sudan Atomic Energy Commission.

2.3. Patient dose measurement

Fifty five patients were examined in this prospective study (25 patients in hospital A, 11 patients in hospital B and 19 patients in hospital C). Patients were categorized into three groups in accordance with their hospital. The ethics and research committee approved the study and an informed consent was obtained from all patients prior to the procedure. ESAK (mGy) was directly measured using 3 TLDs placed on the patients' skin surface at the point of insertion of the central axis beam using white polyethylene plastic foil, to protect the TLDs from dust and dirt. During the procedure the TLDs were kept in the required position and were fixed in place with adhesive tapes. TLDs were repositioned during the procedure and always kept at the center of the field. All staff performed the procedures according to their routine practice. During the procedure, the patient is placed on an X-ray couch in the left anterior oblique position. Radiographic and fluoroscopic images were obtained after injection of contrast medium.

The data recorded for all procedures included: patient body characteristics (age, sex, height, weight and body mass index (BMI) (weight/height^2)), radiographic data: tube voltage (kV), tube load (mA s), number of images, and fluoroscopic data: tube voltage (kV), tube current (mA), total screening time and clinical indication and clinical indication of ERCP procedure.

2.4. Estimation of absorbed organ doses and effective doses

ESD was used to estimate the organ equivalent dose (H) using software provided by the National Radiological Protection Board (NRPB–SR262) (Hart et al., 1998). The Monte Carlo code is used for dose calculation are simulated by hermaphrodite mathematical phantom representing an average adult patient (with a mass of 70.9 kg and a height of 174 cm and BMI of 23.12 kg/m^2. For each radiographic projection, normalised doses are presented for 26 organs or tissues and 3 regions of the body (head, trunk and legs), along with the effective dose as defined by ICRP 103 (ICRP 103, 2008). The data are provided for 40 x-ray spectra ranging from 50 kVp to 120 kVp and from 2.0 mm A1 to 5.0 mm A1 total beam filtration. The doses are normalised to both ESAK (mGy) and kerma area product (KAP(Gy cm^2)) units. However, as specific

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