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ASSESSMENT OF RADIATION DOSES RECEIVED BY PATIENTS DURING ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAPHY ACCORDING TO DISEASE LOCATION

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ABSTRACT

Objective

During endoscopic retrograde cholangiopancreatography (ERCP) patients are exposed to ionizing radiation. Radiation dose depends upon multiple factors. Our goal was to assess fluoroscopy time (FT), radiation doses and effective dose (ED) during ERCP according to the condition that is being treated.

Materials and methods

A descriptive study of 369 consecutive ERCPs from January 2017 to June 2019. Patient demographic and procedure data were collected.

FT, cumulative dose area product (DAP), fluoroscopy DAP, DA fluoroscopia, air Kerma, and number of radiographs. ED was estimated using specific conversion factors.

Results

Mean age was 73.34 years. A total of 193 subjects were male. Mean FT was 4.56 ± 0.17 min. Cumulative DAP was 2056.73 ± 188.83 cGycm^2, fluoroscopy DAP was 1722.90 ± 82.26 cGycm^2, and air Kerma was 85.84 ± 4.93 mGy. The number of radiographs was 2.10 ± 0.07. Mean ED was 5.34 ± 0.49 mSv.

FT was statistically significantly longer for choledocholithiasis (CL), proximal malignant biliary stricture (PMBS), and distal malignant biliary stricture (DMBS) versus others (OT). Cumulative DAP was higher for PMBS (p < 0.002). FT, cumulative DAP, fluoroscopy DAP, and air Kerma values were significantly higher for complicated CL as compared to simple CL. ED was higher for CL, DMBS and PMBS, but only significantly so (p < 0.002) for PMBS.

Conclusions

FT for ERCP is variable. It increases with exploration difficulty, thus being longer in case of PMBS, as well as with the amount of radiation received by the patients and ED.

Keywords

Radiation, fluoroscopy time, ERCP, effective dose.

Abbreviations

ERCP: endoscopic retrograde cholangiopancreatography

ICRP: International Commission on Radiological Protection

FT: fluoroscopy time

DAP: dose area product

ED: effective dose

CL: choledocholithiasis

DMBS: distal malignant biliary stricture

PMBS: proximal malignant biliary stricture.

OT: other

LNT: linear no-threshold

ESGE: European Society of Gastrointestinal Endoscopy

ASGE: American Society for Gastrointestinal Endoscopy

ACG: American College of Gastroenterology

INTRODUCTION

Patient exposure to ionizing radiation is associated with an increased risk of cancer and genetic damage. Such exposure has grown over the past few decades, seemingly related to an increase in the use of CT scans, nuclear medicine, and interventional radiology procedures (1).

In gastroenterology several endoscopic procedures are carried out under radiographic control, including endoscopic retrograde cholangiopancreatography (ERCP), interventional endoscopic ultrasound, enteroscopy, and stent placement.

Since ERCP requires exposure to radiation, the latter should be reduced to the lowest level still allowing a safe and short procedure according to the "as low as reasonable" principle (2).

The World Gastroenterology Organisation recommends collecting the dose area product (DAP) and fluoroscopy time (FT) during ERCP (3).

FT is the cumulative time—in minutes—during which the x-ray device is running. DAP is the product of absorbed radiation dose times exposed surface area, expressed in Grays per cm^2. It provides a fine estimation of the total radiation administered to the patient along the procedure, and strongly correlates with FT (4,5).

In order to better estimate the radiation a patient receives the DAP may be converted to effective dose (ED) (6). This is the measure of exposure to radiation. It is used by the International Commission for Radiologic Protection (ICRP) to establish annual radiation limits, namely 20 mSV per year (2). The ICRP recommends education and training for gastroenterologists who use ionizing radiation in order to reasonably optimize its use. They also recommend the use of pulsed fluoroscopy, a configuration where the x-ray beam is repeatedly switched on and off at a pre-established rate (e.g., 4, 8, 15 "pulses" per second) while the operator has the pedal depressed (2). This technology limits FT and is usually utilized together with the "last image hold" mode, a function that saves the last image visualized during pulsed fluoroscopy, and may obviate the need for radiographs.

The goal of this study was to assess FT and DAP in our ERCPs according to the condition being treated. A secondary goal was to assess effective dose (ED) as an stochastic risk marker in our patients.

MATERIALS AND METHODS

This was a cross-sectional, descriptive study of prospectively collected data. All consecutive patients who underwent ERCP from January 2017 to June 2019 were enrolled. Procedure and patient demography data were collected, as were procedure indication and final diagnosis.

Only two endoscopists with over 15 years' experience with the technique participated. Patients were placed in the prone position with the endoscopist on the left side of the fluoroscopy table. A radiology technician was in the room for all procedures, and controlled both fluoroscopy and x-ray taking following endoscopist indications. ERCPs were peformed under deep sedation administered by an anethetist. Patients signed an informed consent form.

A Philips Eleva Exam system (Philips Medical Systems, Nederland B.V.) with the x-ray tube under the table. Endoscopes were Olympus brand.

Efforts were made to minimize patient doses by limiting FT (and fluoroscopy was indicated only when strictly necessary). Pulsed fluoroscopy and collimation were used to reduce exposed surface area. Efforts were also made to keep the distance from patient to image receptor (flat-panel receptor) at a minimum, and magnification was avoided. We reduced the number of x-ray images by using the "last image hold" function.

At the end of the procedure FT, cumulative DAP, fluoroscopy DAP, air Kerma, ad number of x-ray films were recorded. These data were collected directly from the radiology system software.

ED, a risk indicator for stochastic effects, was measured in Sv. It was estimated based on DAP using a conversion coefficient of 0.26 mSv/Gy cm^2 (according to the latest weighting factor values included in NCPR Report 160) (5).

ERCPs were classified according to the eventually established condition into: choledocholithiasis (CL), proximal malignant biliary stricture (PMBS), distal malignant biliary stricure (DMBS), and other (OT), which included an assortment of conditions such as stent replacement, fistula, benign stricture, etc.

Furthermore, CL was divided into simple procedures (stones ≤ 10 mm or ≤ 2 stones), and complicated procedures (stones > 11 mm or ≥ 3 stones).

The study was approved by the hospital's medical research ethics committee.

Data were analyzed using the IBM SPSS Statistics, version 24.0 for Windows, software package. Quantitative variables are reported as mean and standard error, and qualitative variables according to frequency distribution. The Kolmogorov-Smirnov test was used to assess normality. Pearson's Chi-squared test was used to analyze associations between qualitative variables. When the number of cells with expected values lower than 5 was greater than 20 %, Fisher's exact test or the likelihood ratio were used for variables with more than two categories. Comparisons between quantitative variables were carried out with a one-factor ANOVA or non-parametric Kruskal-Wallis test. Statistical significance was considered for p-values < 0.05.

RESULTS

Data were collected from 369 consecutive ERCP procedures. Mean patient age was 73.34 years (26-103). The sample included 193 (46.9 %). First-time ERCPs amounted to 226 procedures. A naïve papilla was present in 238 (64.4 %) patients (Table 1).

A group of 229 (62 %) patients had CL, 58 (15.7 %) DMBS, 23 (6.2 %) PMBS, and 59 (15.9 %) an assortment of conditions making up the OT group (biliary stent removal/replacement, 18; biliary fistula, 5; benign stricture, 10; pancreatic disorders, 8; sphincter of Oddi dysfunction, 2; biliary sphincterotomy, 6; and failed cannulation, 10).

Mean ERCP FT was 4.56 ± 0.17 min. Cumulative DAP was 2056.73 ± 188.83 cGycm^2, mean fluoroscopy DAP was 1722.90 ± 82.26 cGycm^2, and air Kerma was 85.84 ± 4.93 mGy. Mean number of x-rays was 2.10 ± 0.07 (Table 1). X-ray taking represents 16.23 % of DAP as received by patients during ERCP. No differences in value between fluoroscopy DAP and cumulative DAP were found on comparing patients according to age (≤ 70 years vs > 70 years) or gender. Mean ED for all ERCPs was 5.34 ± 0.49 mSv.

LFT, cumulative DAP, fluoroscopy DAP, air Kerma, x-ray number, and ED results for the different groups are listed in table 2.

When assessing ERCP FT in the various groups statistically significantly higher values were seen for CL, PMBS and DMBS as compared to OT. Concerning cumulative DAP, it was higher in all groups versus OT, but the difference was statistically significant only

for PMBS (p < 0.002). Fluoroscopy DAP was also higher in all groups than in OT, but statistical significance only applied to the CL group (p < 0.022). The number of x-ray films that were taken was similar for all groups.

FT, cumulative DAP, and fluoroscopy DAP values, as well as air Kerma, were significantly higher for complicated versus simple CL.

ED was higher in the CL, DMBS, and PMBS groups than in OT, but only significantly so for PMBS (p < 0.002).

DISCUSSION

In our study we used a mean fluoroscopy time of 4.56 min for ERCP. According to multiple study reports it is estimated that patients undergo fluoroscopy for 2 to 16 min during ERCP (7-10). This wide variation results from the fact that some studies only deal with diagnostic procedures whereas others include both diagnostic and therapeutic ones. We have only included patients undergoing therapeutic procedures, who had previously been assessed with specific imaging tests (cholangio-MRI/CT), and had ERCP indicated. The primary factors affecting FT were not explicitly established, but were seemingly related to a combination of case complexity, endoscopist experience, and possibly the role of trainee physicians in ERCP (11-13).

In this research we used significantly longer FTs for all higher-complexity ERCPs, most particularly for PMBS (5.45 min; p = 0.019) and complicated CL (6.06 min; p = 0.000). Findings similar to ours have been reported by other authors. Thus, Choi et al (13), in 127 ERCPs, found fluoroscopy times of 12.6 min for the management of lesions at the common hepatic duct bifurcation, and of 4.86 min for extrahepatic biliary disorders, with a mean of 6.9 min for all procedures. Something similar was seen in the study by Hayash S et al (14) in 1,157 cases, which also showed that condition type affects FT—specifically, proximal biliary stricture required a longer time than distal biliary stricture or choledocholithiasis.

Mean DAP for all ERCPs in this study was 2056.73 ± 188.83 cGycm^2. Since our ERCP procedures were only performed for therapeutic purposes, cumulative DAP was relatively lower than in prior studies, which reported DAPs around 30-150 Gy cm^2 for therapeutic ERCP (7,8,10,15,16). This lower value in our institution mat result from various reasons. First, our procedures were performed by only two endoscopists with

over 15 years of experience. Administered radiation during ERCP is significantly lower when the procedure is performed by an experienced endoscopist (17,18). Secondly, the number of x-rays taken during ERCP may play a significant role. We took a mean of 2 radiographs per procedure, which represents 16 % of total DAP. In prior studies radiation dose from x-rays represented 10-35 % of total radiation dose (4,7). Also the use of pulsed fluoroscopy may have played a role, since the images-per-second adjustment may significantly impact total dose, as may doing without magnification and oblique viewing. A study using the "single-frame fluoroscopy" technique (a combination of pulsed or continuous fluoroscopy and last image hold mode) found a most significant reduction in radiation dose. Mean DAP during a therapeutic ERCP procedure might amount to 360 cGycm^2 (19).

The findings in our study are consistent with the well-documented notion that radiation measurements are higher for more complicated procedures. Thus, we found that for PMBS DAP was higher than for the rest of conditions, though only significantly so when compared to the OT group. Prior studies found that the management of biliary conditions at the proximal level resulted in higher radiation doses for patients (13,14). Other studies classified ERCPs according to procedure difficulty level, and observed that DAP and FT increased as difficulty increased, with grade-4 ERCPs exhibiting the highest values (17)

EDs of 6.6 up to 12.4 mSv have been reported for therapeutic ERCP (4,7,8,20,21). More recently, Liao et al (17) showed improved levels by reporting values between 2.09 and 3.9 mSv. Other authors have also found values lower than 3 mSv (22), and by eliminating continuous fluoroscopy and x-ray taking Churrango et al (19) obtained mean values of 0.94 mSv. However, we recorded EDs at 5.34 ± 0.49 mSv, similar to those obtained by Olgar et al (8). Decreased exposure to patient radiation may result from multiple factors, including technological advances in fluoroscopy equipment, improved endoscopes and endoscopic materials as used for ERCP, better endoscopist training, and greater endoscopist involvement in understanding radiation-associated risks.

The ICRP suggests nominal probability coefficients for stochastic cancer and genetic damage risk using a linear no-threshold (LNT) model for a dose < 100 mSv (2). The LNT

model shows that, even for minute doses, an increase in cancer risk is induced, which may eventually lead to a patient developing cancer. The coefficient for the general population is 5.5×10^{-2} Sv^{-1}. Applying this formula to the mean ED recorded in our patients, which was 5.34 mSv, the lifetime cancer risk for an ERCP procedure would be ≈ 0.029 %.

The American Society for Gastrointestinal Endoscopy (ASGE), American College of Gastroenterology (ACG), and European Society of Digestive Endoscopy (ESGE) recommend that FT and radiation dose be recorded in all ERCPs as a procedure quality indicator (23,24). Furthermore, the ESGE recommends that recorded DAP values be used for the study of the values provided by different endoscopists in the same institution and between institutions, and to compare them with the available regional and national data concerning diagnosis reference levels (DRL) (24).

DRLs play a key role in the optimization process of fluoroscopic procedures, and serve as a guideline for good clinical practice. In addition, DRLs help identify the fluoroscopy equipment, protocols and practices that may be resulting in the dosing of unusually high radiation levels to patients. Because of all the above, it is important that radiation doses administered be routinely, regularly recorded, and then compared to DRLs. If no national DRLs are available, the establishment of local DRLs based on local practice would be an option (25).

To conclude, FT for ERCP is variable and increases with difficulty level, being longer for PMBS, with the amount of radiation administered, and with ED. There is room for improvement in radiation levels by suppressing x-rays. Also, we believe it necessary that a conversation be started with hospital radioprotection units in order to implement measures to reduce radiation dosing by adjusting radiology systems to optimize their operation, and by providing gastroenterologists and endoscopists with training courses to have them become involved in how radiation is used in the safest way for both patients and themselves. Availability of DRLs, even if initially local, may also help with improvement. Additional studies are needed to establish DRLs at a national level, and the DAP for a wide-ranging sample of patients during ERCP.

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Table 1. Characteristics of patients and procedures

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AGE (mean ± SD)	73.34 ± 14.59
SEX (male) (%)	193 (49.6 %)
First ERCP (%)	226 (61.2 %)
NAÏVE PAPILLA (%)	238 (64.4 %)
CL (%)	229 (62 %)
DMBS (%)	58 (15.7 %)
PMBS (%)	23 (6.2 %)
OT (%)	59 (15.9 %)
TF (mean ± SE)	4.56 ± 0.17
CUMULATIVE DAP (mean ± SE)	2056.73 ± 188.83 (cGycm2)
FLUOROSCOPY DAP (mean ± SE)	1722.90 ± 82.26 (cGycm2)
KERMA (mean ± SE)	85.84 ± 4.93 (mGy)

| ED (mean ± SE) | 5.34 ± 0.49 (mSv) |

Mean ± SD: mean ± standard deviation. Mean ± SE: mean ± standard error. CL: choledocholithiasis. DMBS: distal malignant biliary stricture. PMBS: proximal malignant biliary stricture. OT: other. DAP: dose area product. ED: effective dose.

Table 2. Radiation timing and dosing for different conditions

	FT (min)	CUMULATIVE DAP Gycm²	FLUOROSCOPY DAP cGycm²	KERMA mGy	No. XRs	ED mSv
CL	4.97±0.2 5.38±0.47	2072.66±181.53	1821.94±111.53	94.93±7.35		2.2±0.1
SIMPLE	3.90±0.28 4.83±0.80	1859.89±309.04	1437.77±123.47	74.47±10.01		2.0±0.1
COMPLICATED	6.06±0.38** 5.97±0.50	2296.38±193.01	2234.31±181.26§	116.17±10.53		2.4±0.1
DMBS	4.40±0.41 7.11±2.48	2738.06±956.12	1850.34±232.92	81.84±9.31		1.9±0.1
PMBS	5.45±0.72 7.42±1.18	2856.63±456.63	2196.41±381.41	124.55±22.39		2.2±0.4
OT	2.78±0.22* 2.71±0.28††	1043.78±110.04†	1120.40±105.23‡	45.56±3.96‖		1.9±0.1

Mean ± standard error. CL: choledocholithiasis. DMBS: distal malignant biliary stricture. PMBS: proximal malignant biliary stricture. OT: other. FT: fluoroscopy time in minutes. ED: effective dose. *p = 0.019 OT vs DMBS; p < 0.001 OT vs CL; p = 0.001. OT vs PMBS. †p = 0.002 OT vs PMBS. ‡p = 0.022 OT vs CL. §p = 0.000 complicated vs simple CL. ‖ p=0,021 OT vs CL. ¶p < 0.004 complicated vs simple CL. **p < 0.000 complicated vs

simple. ††p = 0.002 OT vs PMBS.