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Factors Affecting Radiation Exposure to Patients During ERCP

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Abstract: ***Introduction**: Endoscopic retrograde cholangiopancreatography (ERCP) is a common technique performed worldwide for the indications of cholangitis, biliary tract pathology and pancreatic duct disease. Fluoroscopy is a requisite during ERCP which involves varied doses of radiation exposure to both patient & the team involved. **Objective**: This study aims to measure the radiation exposure during ERCP and to identify patient and procedural factors associated with increased radiation exposure during ERCP. **Materials & Methods**: In this retrospective, single-center study of 375 patients who underwent ERCP between January to October 2023, we analyzed the influence of indication of ERCP and presence of native papilla on the following radiation exposure parameters - Cumulative radiation dose (mGy), dose area parameter (Gy-cm^2), total fluoroscopy time and number of fluoroscopy shots. Using SPSS version 24, statistical tests were performed. **Results**: The major indication for ERCP in our study was choledocholithiasis (55 %). The mean cumulative radiation dose was 44.54 ± 2.35 mGy, mean DAP 12.49 ± 0.77, average number of fluoroscopy shots 26.46 ± 1.04 and mean fluoroscopy time was 6.58 ± 4.06 minutes. Various indications like choledocholithiasis, benign biliary stricture, malignant biliary stricture and pancreatic duct stones were analyzed. There was a significant difference between ERCP quality indicators and indications. Among the indications, Benign biliary stricture had the highest cumulative radiation dose (60.94 ± 5.99 mGy), DAP (17.92 ± 2.61 Gy-cm^2) and number of fluoro shots (32.51 ± 2.82). Presence of prior sphincterotomy/native papilla did not significantly influence radiation parameters recorded in the study. **Conclusion**: The amount of radiation that a patient was exposed to was influenced by the nature of the indication, disease behavior and complexity of the ERCP procedure. Radiation dose parameters such as dose area parameters (DAP), median cumulative dose exposure and total fluoroscopy time can be used as ERCP quality indicators.*

Keywords: Choledocholitiasis, Pancreatitis, Biliary stricture, Cholangitis, Fluoroscopy

1. Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is an invasive endoscopic procedure that is commonly performed across the world for the management of hepatobiliary and pancreatic diseases with success rates of up to 90%[1]. With the recent advancement of non-invasive diagnostic tools, such as magnetic resonance imaging, magnetic resonance cholangiopancreatography, and endoscopic ultrasonography, ERCP has become an almost exclusively therapeutic procedure.

ERCP is a highly technical and demanding invasive procedure carrying a high potential risk of severe complications. The most common are pancreatitis, haemorrhage, perforation, cholangitis and other infectious complications. ERCP-related mortality rate is approximately 1% [2].

ERCP procedure requires fluoroscopic imaging and digital X rays to be performed to visualize the biliary tract and the pancreas, which makes it an interventional radiology procedure [3].

Medical radiation exposure is increasingly becoming a significant problem because of its frequent usage in different specialities of health care and associated potential carcinogenic effects.

ERCP procedure involves relatively high doses of radiation compared to other diagnostic radiological examinations. This is particularly the case for examinations that include therapeutic intervention, which may have effective doses of the order of that of an abdominal CT. The estimated cancer risk from a diagnostic ERCP was 1 in 6700 and from a therapeutic ERCP 1 in 1700. These risks are small but not insignificant[4].

Hence there is a need to establish diagnostic reference levels for radiation doses in ERCP procedure as per various societies. The International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency (IAEA), and the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) [5]. However, data regarding radiation doses during ERCP is scarce.

ASGE includes radiation dose and fluoroscopy time as part of its intra procedure quality indicators of ERCP. ESGE also recommended permissible radiation dose exposure levels in Endoscopy in 2012. However, they acknowledged in the same report that there is limited data available regarding radiation dose exposure levels during ERCP [5].

Reducing the fluoroscopy duration is the most effective and easiest method to minimize radiation exposure during ERCP. Fluoroscopy radiation depends on many factors such as indication of ERCP procedure, degree of difficulty of the

procedure, patient factors and endoscopic skills. A better understanding of which of these factors lead to increased fluoroscopy duration and radiation exposure during ERCP can help us in preparing better to reduce overall procedure time and radiation exposure.

The aim of this study was to analyze radiation doses to patients during ERCP procedures performed at our centre and to identify factors that lead to increased radiation exposure during the procedure.

2. Materials and Methods

1) Study Design

The present study is a retrospective single center study and was conducted at Yashoda Hospitals, Secunderabad. All consecutive patients who underwent ERCP during the period January 2023 to October 2023 were included in the study. The following patient data was collected – a) Demographic data – Name, age and gender, b) Procedure related data collected included indication of ERCP (which was classified into 4 categories i.e choledocholithiasis, malignant biliary stricture, benign biliary stricture and pancreatic duct stenting. ERCP procedures were also classified based on presence of native papilla or prior sphincterotomy status. The following radiation parameters were recorded for each patient undergoing ERCP: a) Cumulative radiation dose in milligray (mGy), b) Dose area parameter in Gray – centimeter^2, c) Total fluoroscopy time and Number of fluoroscopy shots. The study was approved by the institutional ethics committee. Informed consent was omitted due to the retrospective nature of the study.

2) Procedure

ERCP was performed for all patients for therapeutic indications. Preferred patient position was prone. Fujifilm ED-580XT duodenoscope was used to perform all the procedures. All ERCPs were performed under sedation with propofol and ancillary medications. ERCP team included the gastroenterologist, anesthetist, ERCP technician and his two assistants. Eight different gastroenterologists have performed ERCP for patients included in this study. All gastroenterologists involved in the study are experienced in ERCP procedure.

The X-ray fluoroscopy generator was a Philips Zenition 50 mobile C – arm unit. The radiation data related to ERCP are automatically recorded by a preinstalled equipment in the system. This unit automatically shows fluoroscopy duration and other radiation parameters included in the study. The fluoroscopy system was entirely operated by the attending radiology technician.

3) Outcome measurements and Statistical Analysis

The primary outcome of interest was radiation exposure during ERCP, which was determined by the following four parameters. a) Cumulative radiation dose in milligray (mGy), b) Dose area parameter in Gray – centimeter2, c) Total fluoroscopy time and number of fluoroscopy shots. Additionally, the association between indication of ERCP, prior sphincterotomy status and patient radiation exposure was determined.

4) Statistical Analysis

Software used was SPSS version 24. A confidence interval of 95% was taken, hence P value <0.05 is considered significant. Statistical tests performed were: one-way ANOVA and Independent t-test.

5) Consent for ERCP procedure

Written informed consent was obtained from all patients before the procedure in accordance with guidelines set forth by the institutional board of the hospital. All ERCP procedures were therapeutic and were done under sedation provided by an anesthesiologist and with a fixed setup for the patient.

3. Results

A total of 375 patients who underwent ERCP were included in the study. All patients underwent ERCP for therapeutic indications only. Mean age of the patients included in the study was 53.03 ± 16.03 years. 58 % of the patients in the study were men.

Table 1: Baseline characteristics of the patients

Characteristic	n (%)/ Mean ± SD
Age (years)	53.03 ± 16.03
Sex	
Male	216(57.6)
Female	159(42.4)

The major indication for ERCP in our study was choledocholithiasis in 55% of patients. The different types of indications for which ERCP procedures included in the study were undertaken is shown in Table 2. Radiation dose parameters recorded in our study were highly variable and are depicted in table 3

Table 2: Indications for ERCP

Parameter	n (%)
Indication	
Choledocholithiasis	207 (55.2)
Benign biliary stricture	75 (20)
Malignant Biliary stricture	54 (14.4)
PD stone	39 (10.4)

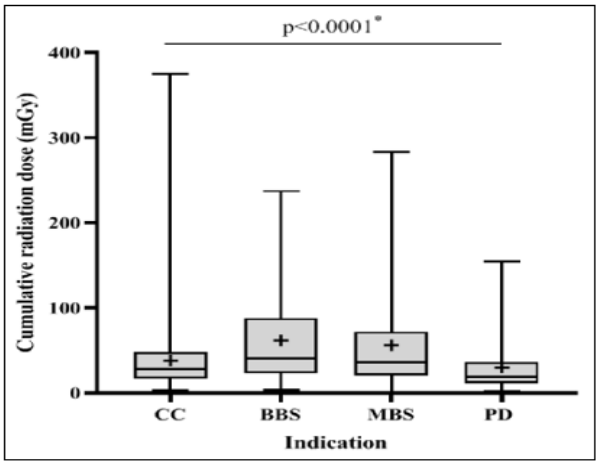

Figure A: Cumulative Radiation Dose Exposure Based on Indication

Table 3: Descriptives of Radiation, DAP, Fluoroscopy, No. of Fluoro Shots

Parameter	Minimum	Maximum	Mean ± SD
Radiation(mGy)	1.23	375	44.54 ± 2.35
DAP(Gy-cm^2)	0.343	176	12.49 ± 0.77
Fluoroscopy (Minutes)	0.1	14.9	6.58 ± 4.06
No. of shots	2	163	26.46 ± 1.04

Mean cumulative radiation dose was 44.54 ± 2.35 mGy. Maximum cumulative radiation dose was 375 mGy and minimum dose was 1.230 mGy. Mean DAP recorded in the study was 12.49 ± 0.77 Gy-cm^2. Average number of fluoroscopy shots applied were 26.46 ± 1.04.

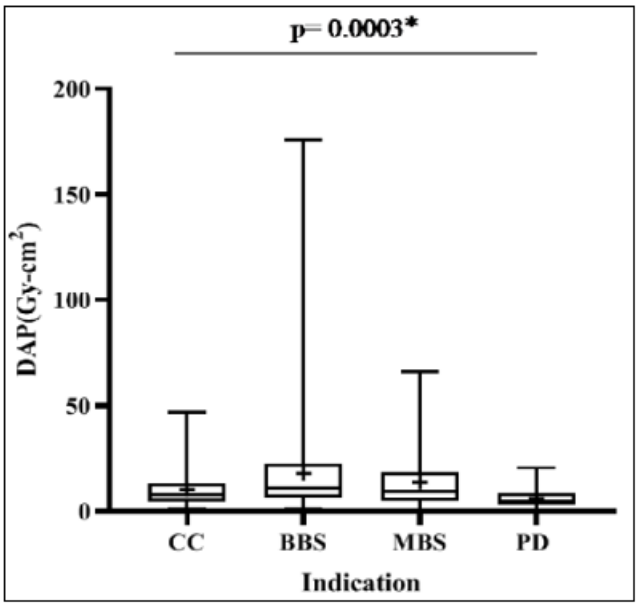

Figure B: DAP Based on Indication

Mean fluoroscopy time in the study was 6.58 ± 4.06 minutes. However, this was highly variable. Shortest duration of fluoroscopy time was only 0.01minutes where only a single fluoroscopy shot was used. Longest duration of fluoroscopy time used was 14.90 minutes for a case with difficult cannulation.

In our study, the indication for which ERCP was performed significantly influenced cumulative radiation dose, dose area product and number of fluoroscopy shots used. This is shown in table 4.

Table 4: Radiation, DAP, Fluoroscopy, No. of Fluoro Shots Based on Indication

Indication	Radiation Dose mGy	DAP	Fluoroscopy Gcm^2 time in minutes	No. of Fluro Shots
Choledocholithiasis	38.13 ± 2.61	11.01 ± 0.84	6.70 ± 3.98	24.14 ± 1.21
Benign biliary stricture	60.94 ± 5.99	17.92 ± 2.61	6.35 ± 4.33	32.51 ± 2.82
Malignant biliary stricture	57.55 ± 8.35	14.77 ± 1.98	6.23 ± 4.21	29.44 ± 3.23
PD stone	28.99 ± 4.93	6.71 ± 0.82	6.85 ± 3.88	23.03 ± 2.84
P value	<0.0001*	0.0003*	0.804	0.0083*

Test used: One-way ANOVA
*Statistically significant difference was found in radiation dose, DAP, and No. of fluro shots based on indication.

Patients who underwent ERCP for malignant and benign biliary strictures had significantly more radiation exposure in terms of cumulative radiation dose in milligray, dose area parameter in Gray – centimeter^2 and number of fluoroscopy shots compared to those who underwent ERCP for choledocholithiasis and pancreatic duct therapy. Fluoroscopy time however was not significantly different based on indication.

Presence of native papilla did not influence radiation dose exposure parameters measures in the study. This is shown in Table 5. Test used: Independent t test.

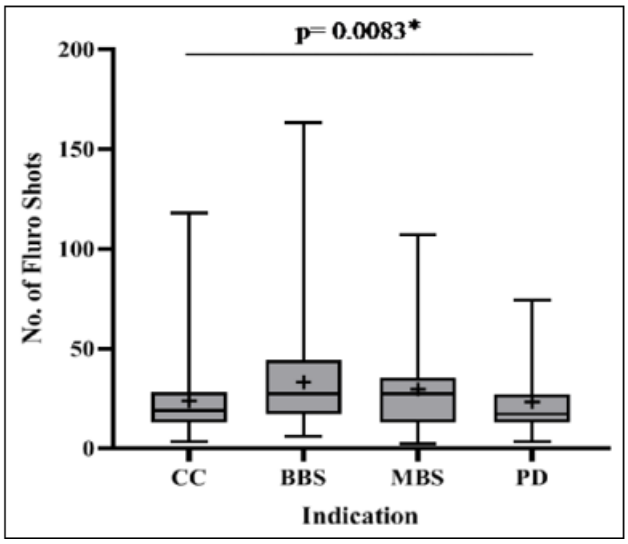

Figure C: No. of Fluoro Shots Based on Indication

Table 5: Radiation, DAP, Fluoroscopy, No. of Fluro Shots Based on Sphincterotomy Procedure

Parameter	With sphincterotomy procedure	Without sphincterotomy procedure	P value
Radiation	41.57 ± 2.78	48.27 ± 3.97	0.1571
DAP	11.16 ± 0.67	14.16 ± 1.53	0.0553
Fluoroscopy time in minutes	6.80 ± 4.08	6.30 ± 4.04	0.241
No. of shots	24.76 ± 1.15	28.61 ± 1.86	0.0679

Statistically significant difference was not found in radiation, DAP, fluoroscopy, No. of fluoro shots based on procedure.

4. Discussion

Medical radiation exposure to patients has been increasing over the years and is a potential concern for risk of cancer[5]. Even low dose radiation exposure has been shown in some studies to have carcinogenic potential due to stochastic effect [6,7] Radiation exposure to medical and para medical staff is also a major concern. Radiation safety culture is a major issue that needs addressing at the institutional and administrative level.

The major interventional procedure in Medical Gastroenterology practice that requires the use of medical radiation is ERCP. It requires fluoroscopy for imaging of the pancreaticobiliary system and hence the procedure involves radiation exposure to patients and medical staff. ERCP is being performed widely all across India in a number of centers.

Optimising radiation dose exposure during ERCP would mean limiting the radiation dose to as low as reasonably achievable (ALARA principle). The European Society of Digestive Endoscopy developed guidelines for minimizing radiation exposure of patients and physicians during endoscopy[8]. However before trying to minimize radiation we must have dose reference levels for radiation exposure in ERCP against which we can compare the radiation dose exposure occurring in different ERCP centres[9].

There is a dearth of data regarding dose reference levels for radiation exposure during ERCP in India.

In our present study we have measured four radiation dose exposure parameters to assess the amount of radiation that a patient is being exposed to during ERCP at our centre which is a tertiary care hospital. Mean cumulative radiation dose, dose area product and fluoroscopy time recorded in our study are similar to values recorded in previous studies [1,2,3,10-17]. Number of fluoroscopy shots applied were higher in our study compared to previous studies. However, the duration of each fluoroscopic shot was less in our study.

The dose of radiation exposure to patients during ERCP depends on a number of factors including patient related factors, indication of procedure, complexity of procedure steps, radiation equipment used etc.

In our study we evaluated the influence of indication of procedure and presence of native papilla/prior sphincterotomy status on the dose of radiation exposure to patients during ERCP.
The indication for which ERCP was performed significantly influenced the radiation dose exposure in our study. Patients who underwent ERCP for benign and malignant biliary stricture had significantly more radiation dose exposure in terms of Mean cumulative radiation dose, Dose area product and number of fluoroscopy shots used in comparison with those who underwent ERCP for choledocholithiasis and pancreatic duct therapy. In a study conducted by Hayash et al, radiation dose exposure parameters similar to those in our study were significantly higher in patients undergoing ERCP when the indication for procedure was proximal malignant biliary obstruction as compared to distal malignant biliary obstruction and choledocholithiasis[5]. Chi Hyuk Oh, et al showed that those patients who underwent ERCP for malignant biliary obstruction required significantly more fluoroscopy time than those who underwent ERCP for other indications [18]. In this study fluoroscopy time during ERCP was significantly higher in those patients with a high BMI (BMI >27.5kg/m2). Fluoroscopy time was also higher if complex ERCP procedure steps like mechanical lithotripsy and needle-knife use were performed [18].

In our study the presence of a prior sphincterotomy did not affect radiation dose parameters during ERCP in comparison to those patients undergoing ERCP who had a native papilla. Hayash et al also found that presence of native papilla did not affect radiation dose exposure parameters in their study[5]

Prior studies have shown high-volume endoscopists can achieve lower radiation exposure due to shorter procedure times [19-22]. In our study all the endoscopists are experienced ERCP operators and perform a similar yearly volume of ERCP procedures, so this distinction could not be made.

There are a few limitations of the present study that we would like to acknowledge

Present study is a retrospective analysis of a single centre ERCP database.

Influence of difficulty of ERCP procedure on radiation dose parameters based on ASGE grading was not taken into consideration. Effect of individual steps of ERCP on radiation dose parameters like needle knife use, mechanical lithotripsy etc was not included in the study. This could have provided more insight into the factors leading to the wide variability in radiation dose parameters in different studies. Impact of patient related factors like BMI on radiation dose parameters also could have been included.

Overall, having an understanding of patient and ERCP procedure related factors that can affect radiation dose exposure can help reduce radiation exposure to patients during ERCP with prior planning. Multicentre prospective studies are required on this topic to establish dose reference levels and publish well established guidelines on optimizing radiation exposure during ERCP. Future studies should also focus on differences in radiation exposure with different processing engines and optimizing the use of radiation equipment (C - arm machines). Radiation exposure to ERCP staff during the procedure is another topic that needs to be explored in future studies.

5. Conclusion

Fluoroscopy performed during ERCP adds to a patient cumulative medical radiation dose exposure during the course of his life. Dose of radiation exposure during ERCP is highly variable and depends on a number of procedure related factors. A prior understanding of ERCP procedure related factors that influence radiation dose exposure to patients can help a physician to reduce radiation dose exposure during the ERCP procedure with prior planning.

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