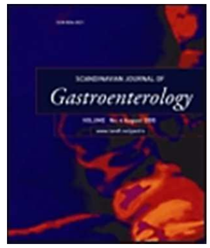

Patient radiation dose and fluoroscopy time during ERCP: a single-centre, retrospective study of influencing factors

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Patient radiation dose and fluoroscopy time during ERCP: a single-centre, retrospective study of influencing factors

Objectives Recently, both the number and the complexity with associated increased technical difficulty of therapeutic ERCP procedures have significantly increased resulting in longer procedural and fluoroscopy times. During ERCP, the patient is exposed to ionizing radiation and the consequent radiation dose depends on multiple factors. The aim of this study was to identify factors affecting fluoroscopy time and radiation dose in patients undergoing ERCP. ***Materials and methods*** Data related to patient demographics, procedural characteristics and radiation exposure in ERCP procedures (n=638) performed between August 2013 and August 2015 was retrospectively reviewed and analysed. Statistically significant factors identified by univariate analyses were included in multivariate analysis with fluoroscopy time (FT) and dose area product (DAP) as dependent variables. Effective dose (ED) was estimated from DAP measurements using conversion coefficient. ***Results*** The factors independently associated with increased DAP during ERCP were age, gender, radiographer, complexity level of ERCP, cannulation difficulty grade, bile duct injury and biliary stent placement. In multivariate analysis the endoscopist, the complexity level of ERCP, cannulation difficulty grade, pancreatic duct leakage, bile duct dilatation and brushing were identified as predictors for a longer FT. The mean DAP, FT, number of acquired images and ED for all ERCP procedures were 2.33 Gy·cm2, 1.84 min, 3 and 0.61 mSv, respectively. ***Conclusions*** Multiple factors had an effect on DAP and FT in ERCP. The awareness of these factors may help to predict possible prolonged procedures causing a higher radiation dose to the patient and thus facilitate the use of appropriate precautions.

Keywords: cholangiopancreatography, endoscopic retrograde; radiation exposure; radiation protection; fluoroscopy; multivariate analysis

Introduction

Endoscopic retrograde cholangiopancreatography (ERCP), used as a gold standard in the endoscopic treatment of pancreatobiliary disorders, continues to be one of the most complex and technically demanding gastrointestinal procedures [1-3]. This invasive procedure requires the use of fluoroscopy and therefore places both the patient and the endoscopy staff at risk of radiation-induced injury [4]. Risks associated with ionizing radiation include cataract, infertility, skin injury, hair loss, malignancy, and genetic effects [5].

During ERCP, the patient is exposed to the primary beam and consequently receives a higher radiation dose compared to endoscopy staff, whose major source of radiation exposure is caused by scattered radiation from the patient [6]. Over the years, both the number and the complexity with associated increased technical difficulty of therapeutic ERCP procedures have significantly increased resulting in longer procedural [7] and fluoroscopy times [8, 9]. Prolonged fluoroscopy time to the same skin area, irradiation through thick body masses as well as an extensive use of high-dose rate modes may produce a high radiation dose to the patient's skin and increase the risk of radiation-induced skin injury [10, 11]. Skin injury may occur if the skin dose exceeds a threshold dose of 2 Grey (Gy) for transient erythema [12]. Grey (Gy) is a unit of absorbed radiation dose, defined as 1 joule of energy deposited in 1 kilogram of mass (1 J/kg). According to International Commission on Radiological Protection (ICRP), ERCP procedure has the potential to impart skin doses exceeding 1 Gy [13].

In order to understand both the optimization of the radiation exposure in fluoroscopy procedures and minimizing the risk of radiation-induced injury, it is essential to be familiar with the factors influencing patient radiation dose [1, 6, 11]. Previously, it has been found that the type of x-ray unit, anatomical location of pathology, difficult cannulation, annual volume and experience of endoscopist, trainee involvement, complexity of procedure, sphincterotomy, stent insertion, balloon dilatation, stone extraction, and other interventions influenced on the exposure levels in ERCP [8, 9, 14-22]. A randomized trial by Uradomo et al. [22] showed that a behavioural intervention (time limiting the fluoroscopy to 3 seconds each time the foot-operated switch is depressed) was associated with a 16 % lower fluoroscopy time. Decreasing the distance between the endoscopy and fluoroscopy screens in the ERCP was also found to reduce a fluoroscopy time by 1.4 minutes [23].

Although several studies have been performed to identify factors associated with prolonged fluoroscopy time and increased radiation exposure in ERCP, these have not been completely clarified [19] and the impact of difficulty degree of ERCP procedure on patient radiation dose remains unclear. The aim of the present study was to determine factors affecting fluoroscopy time and radiation dose in patients undergoing ERCP in a single tertiary care hospital performing some 450-500 ERCPs annually.

Materials and methods

This study is a retrospective data review covering prospective data collection in an already running database, previously initiated for quality control and for scientific purposes in the endoscopy unit at Turku University Hospital, Finland. The database comprises data from ERCP including patients' demographics, indications for ERCP, cannulation time and cannulation methods, performed interventions and used techniques, post-ERCP diagnosis, total procedural time and the endoscopist. Similarly, the specific reason for possible unsuccessful procedure was registered. All consecutive patients undergoing ERCP between August 2013 and August 2015 were enrolled in this study.

The data of included consecutive ERCP patients (n=756) was complemented by radiation quantities, such as dose area product (DAP, Gy·cm²), fluoroscopy time (FT, min) and the number of radiographic images that were retrieved directly from Radiology Information System (RIS) and Picture Archiving and Communication System (PACS). DAP is a product of the air kerma (Gy) and exposed area of the skin (m²) providing a good estimation of the total radiation energy delivered to the patient during a procedure [15, 24]. Effective dose (ED) is an indicator of the risk for stochastic effects (cancer, genetic effects) [25] and ED (measured in Sieverts, Sv) was estimated from DAP measurements by a conversion coefficient of 0.26 mSv/(Gy·cm²) [26]. ED allows a comparison across different radiological procedures and various hospitals [25].

Based on clinical guideline from European Society of Gastrointestinal Endoscopy (ESGE), the cannulation in ERCP was considered being difficult if more than 5 minutes was spent attempting to cannulate following visualization of the papilla [27]. The cannulation difficulty was graded according to the time needed to achieve a successful selective deep cannulation as follows: <1 min (1=easy), 1-5 min (2=intermediate), >5 min (3=difficult). The cannulation time was measured by an assisting radiographer and counted from the first touch to papilla to a successful cannulation of the desired duct. Procedural complexity of ERCP was determined using the grading system proposed by the working group of the American Society for Gastrointestinal Endoscopy (ASGE) Quality Committee with scores ranging from 1 (simple ERCP) to 4 (the most complex ERCPs) based on clinical context and performed interventions [28]. The grades are defined as follows: grade 1 (biliary stent removal or exchange, brushing), grade 2 (biliary stone extraction <10 mm, treating biliary leaks, treating extrahepatic benign and malignant strictures), grade 3 (biliary stone extraction >10 mm, minor papilla cannulation, removing of internally migrated biliary stents, management of acute or recurrent pancreatitis, treating pancreatic strictures, removing mobile pancreatic stones and stones <5 mm, treating benign strictures in hilum and above) and grade 4 (removing internally migrated pancreatic stents, removing impacted pancreatic stones and stones >5 mm, intrahepatic stones, pseudocyst drainage, ampullectomy). Because of the small number of ERCP procedures of 4th degree appears in this data (n=5), the complexity grades 3 and 4 were combined into one group.

All ERCP procedures were performed for clinical symptoms or for pathologic findings detected in other examinations. Five experienced endoscopists performed the procedures and those performed by a trainee were excluded from the study. Patients were positioned on the left side for the ERCP and procedures were completed under conscious sedation with midatzolam and fentanyl administered by a nurse according to the instructions of the endoscopist. During ERCP, the fluoroscopy was operated by the endoscopist while fluoroscopy system was controlled by a radiographer. The same fluoroscopic system (MultiDiagnost Eleva, Philips Medical Systems, Best, The Netherlands) was used in ERCP throughout the study period, and it was equipped with a multipurpose C-arm and with an image intensifier. The dose measuring device was integrated into the equipment. During ERCP pulsed fluoroscopy with lowest possible pulse rate of 1.5 fps was used and the x-ray beam was modified by collimating the field size to the region of interest.

Statistical analysis was performed using the IBM SPSS Statistics for Windows, Version 22 (IBM Corp. 2013 Armonk, NY). Failed ERCP procedures and those with missing radiation exposure data were excluded from the final analysis. Categorical data were presented as frequency and percentage. Continuous data were expressed as mean ± standard deviation (SD), range, standard error (SE) or median with interquartile range (IQR) as indicated. Differences in continuous variables were tested using Mann-Whitney U-test or Kruskal-Wallis test for nonparametric data. Factors associated with increased FT and DAP in ERCP were evaluated by univariate analysis performed with a logarithmic transformation of the DAP and FT due to asymmetric distributions. Statistically significant variables were included in the multivariate analysis. Bonferroni adjustments were applied for all post-hoc tests to adjust p-values for multiple comparisons. A p value less than 0.05 was considered statistically significant.

Institutional review board approval was obtained at the Turku University Hospital. According to Finnish Medical Research Act [29], the retrospective nature of this study does not require the approval from local ethics committee. Data was anonymized before statistical analysis prohibiting subsequent patient identification.

Results

Altogether 638 out of 756 ERCP procedures were analysed in this study to determine factors affecting fluoroscopy time and radiation dose to patient, as the failed procedures (n=86) and those performed by a trainee (n=27) or with missing radiation exposure data (n=5) were excluded from the study. Common reasons for failed ERCP were unsuccessful cannulation (n=37, 43%) and gastroduodenal obstruction (n=26, 30%). 48% of the patients were male and the mean age for all patients was 66.0 years (Table 1). The main indication for ERCP was bile duct stone removal (n=261, 41%) followed by malignant strictures (n=100, 16%) and jaundice of unknown etiology (n=80, 13%). Most of the ERCP procedures (n=463, 73%) were carried out in patients with native papilla. The time needed to achieve a successful selective deep cannulation of the desired duct was <1 min in 40%, 1-5 min in 34% and >5 min in 26% of those ERCP cases where the time was recorded (n=537). The cannulation success rate was 95% in patients with free access to papilla. Typical findings in ERCP were bile duct stones (n=208, 33%), benign and malignant bile duct strictures (n=174, 27%) and normal anatomy (n=65, 10%). [Table 1 near here]

The results showed a large variation in radiation quantities (Table 2). The mean DAP, FT and number of radiographic images for all ERCP procedures were 2.33±1.79 (range 0.09-14.19) Gy·cm2, 1.84±1.56 (range 0.11-9.57) min and 3.02±1.83 (range 0-

11), respectively. A positive linear correlation was observed between DAP and FT (rs=0.73, $p < 0.01$), as well as between DAP and the number of radiographic images (rs=0.52, $p < 0.01$). The average ED of the ERCP patient was 0.61±0.47 (range 0.02-3.69) mSv. Male gender was associated with a greater radiation exposure (2.55 ± 1.92 Gy·cm2) compared to females (2.11 ± 1.65 Gy·cm2) and the difference was statistically significant (p=0.001). Patients who underwent ERCP for the first time received a lower radiation dose (2.21 ± 1.67 Gy·cm2) than those who had repeat ERCP (2.63 ± 2.06 Gy·cm2) procedure (p=0.036). FT was also significantly longer in the repeat ERCP than in the primary one (p=0.024). Moreover, patients with suspected ($p<0.001$) or diagnosed (p=0.01) bile duct injury had a higher radiation dose than those with bile duct stones. Similarly, post-ERCP diagnosis of pancreatic duct leakage was associated with a higher DAP ($p<0.001$) and longer FT (p=0.03). Increased image acquisition during ERCP was noted in patients with bile duct stricture ($p<0.001$) and bile duct injury ($p<0.001$). The mean of acquired images was also high in patients with pancreatic duct leakage (n=12), but statistical significance was not reached. [Table 2 near here]

The difficult cannulation with cannulation time exceeding 5 min was related to increased DAP and prolonged FT compared to those ERCP procedures with cannulation lasting between 1 and 5 min (DAP p=0.012; FT $p < 0.001$) or being under 1 min (DAP p=0.004; FT $p<0.001$). Based on ERCP complexity grading system, the majority (60%) of performed ERCP procedures in this study were of complexity grade 2 (Table 2). The grade 1 procedures constituted 20% and grade 3 and 4 combined were 21%. There was a significant difference in DAP between the ERCP complexity grades 1 and 3 (p=0.004) as well as between grades 2 and 3 ($p<0.001$). The same statistical difference was noted in FT for complexity grade 1 versus grade 3 ($p<0.001$) and complexity grade 2 versus 3 ($p<0.001$). The mean DAP (2.84±1.85 Gy·cm2) and FT (2.45±1.71 min) were highest in procedures of 3rd grade (Table 2). However, the mean DAP and FT did not increase in concert with the increase in complexity scale.

Three out of five endoscopists performed higher number of ERCP procedures of 3rd grade complexity and difference in relative proportion of difficult procedures was also observed between the endoscopists (Table 3). The mean FT was substantially longer in ERCP procedures performed by endoscopist 1 (2.11±1.87 min, p<0.001), 3 (1.81±1.40 min, p<0.001), 4 (1.79±1.58 min, p<0.001) and 5 (2.25±1.27 min, p<0.001) compared with endoscopist 2 (0.92±0.91 min). Regarding DAP, the differences between endoscopists did not reach the statistical significance. There were no significant differences in image acquisition between endoscopists either. In addition, it was found that DAP varied in ERCP depending on who of the ten radiographers was controlling the fluoroscopy system (p<0.001). The highest mean DAP was 4.06 ± 2.31 Gy·cm2 in procedures with involvement of radiographer 6. Nevertheless, there were no significant differences among radiographers in FT or procedural complexity of performed ERCP procedures (Fig. 1). [Table 3 near here] [Figure 1 near here]

The univariate and multivariate analysis with log-transformed data identified several factors as predictors for higher DAP (Table 4) and prolonged FT (Table 5) in ERCP. In univariate analysis, the variables that were found to be significantly associated with both radiation quantities were complexity level of ERCP, cannulation difficulty grade, bile duct stricture, bile duct injury and pancreatic duct leakage. Age, gender, radiographer involved in ERCP, jaundice and suspicion of bile duct injury were associated statistically only with DAP, whereas endoscopist performing ERCP was related only to FT. Multivariate modelling performed with DAP as dependent variable showed that clinical indication and post-ERCP-diagnosis were highly correlated, if included in the same model. Based on this, the indication was excluded from the final analysis. In addition, the types of interventions performed during ERCP were included directly in multivariate analysis. To assess the independent effect of certain variables on DAP and FT, a total of 3 models were selected in multivariate analysis for both dependent variables.

Multivariate analysis showed that gender (female vs male), age (<35 vs 36-65 years), radiographer (1 vs 2, 4, 5, 6, 9, 10), complexity level of ERCP (grade 2 vs 3) and cannulation difficulty grade (in all comparisons) were independently associated with increased DAP in all selected models (Table 4). Post-ERCP diagnoses such as bile duct stricture ($p<0.001$), cholangitis ($p=0.01$), bile duct injury ($p<0.001$) and other ($p=0.03$) were found to be associated with a higher DAP in the multivariate model 1, but when interventions were included in the model (model 2), only bile duct injury ($p<0.001$) remained significant. The biliary stent placement was the only intervention performed during ERCP that independently predicted a higher DAP.

Similarly, factors independently related to prolong FT (Table 5) in all selected models of multivariate analysis were endoscopist (in all comparisons), complexity level of ERCP (grade 2 vs 3) and cannulation difficulty grade (in all comparisons). Post-ERCP diagnoses such as bile duct stricture ($p=0.03$), cholangitis ($p=0.04$), bile duct injury ($p<0.001$) and pancreatic duct leakage ($p=0.02$) were associated with longer FT in multivariate model (model 1), but when interventions were included in the model (model 2), only pancreatic duct leakage ($p=0.03$) remained significant. Interventions like bile duct dilatation and brushing were identified by multivariate analysis as predictors for longer FT. Furthermore, the multivariate analysis revealed that biliary stent placement was also associated with longer FT, when the diagnosis was removed from the model (model 3). [Table 4 near here] [Table 5 near here]

Discussion

In recent years, there has been a growing interest generated by research in the field of radiation exposure of both the patient and medical staff during ERCP procedures, as it has been recognized that ERCP requires the same level of radiation protection practice as all other interventional radiological procedures [1, 3, 4, 6, 8, 9, 14-23, 30-37]. This study was performed to identify factors associated with FT and radiation dose measured by DAP in patients undergoing ERCP in a single tertiary care hospital. The factors independently associated with increased DAP during ERCP were gender, age, radiographer, complexity level of ERCP, cannulation difficulty grade, bile duct injury and biliary stent placement. Endoscopist, complexity level of ERCP, cannulation difficulty grade, pancreatic duct leakage, bile duct dilatation and brushing were identified by multivariate analysis as predictors for longer FT. The mean DAP, FT, number of acquired images and ED for all ERCP procedures were 2.33 Gy·cm2, 1.84 min, 3 and 0.61 mSv, respectively. Assuming a linear response at low doses, the combined detriment from stochastic effects has remained unchanged at around 5% per Sievert [25] and it follows that the lifetime cancer risk from ERCP is approximately 0.003%.

Previous studies investigating factors related to increased radiation exposure in patients during ERCP have been focused mainly on FT [8, 17, 19-21, 23, 37], only some studies have included DAP in the analysis [9, 15, 18, 38]. There is a good correlation between FT and DAP in ERCP according to the literature [30, 32, 34-36, 38], however in some studies a correlation was not found [4, 39]. FT is one of the features that determine radiation exposure, but as a surrogate measure, FT is not sufficient in monitoring patient radiation doses since it has several limitations [34, 40, 41]. For instance, some factors affecting DAP are not included in FT, such as patient size and position, imaging geometry, settings of the fluoroscopy equipment, collimation, magnification, angulation, acquisition images and filtration [20, 33, 34, 42]. The results of the present study also revealed that variables associated with increased DAP and prolonged FT in ERCP were partly different.

Male gender was associated with a higher DAP, likely attributable to the larger size of male patients. Larger patient size requires a higher radiation dose to obtain adequate image quality than the normal-sized patient [43]. Unfortunately, body weights of the patients were not registered at the time when original data was collected, as this information could have been provided an additional benefit for this study. Younger patients, i.e. under 35 years, received a lower radiation dose than the patients between 36 and 65 years, probably owing to simpler ERCP procedures performed in that age group and for better dose optimisation practice. In a previous study by Rodríguez-Perálvarez et al. [38] an independent association was observed between younger patients and a higher DAP in ERCP, however, the authors did not identify any logical explanation for it. It is essential to pay a special attention to the radiation protection of young patient, but as life expectancy increases, highlighting the benefits of radiation protection in the elderly is also important [44].

The observed significant differences in FT between endoscopists were likely related to procedural complexity in ERCP, as endoscopists who performed more ERCPs with a greater procedural complexity had a longer FT on average. There seemed to be differences in DAP among endoscopists as well, but they did not reach the statistical significance in this study. Differences in training, experience and individual practice patterns of endoscopists could also explain these variations in FT and DAP [37]. Previous studies have demonstrated that ERCP volume of endoscopist fewer than 200 procedures in the preceding year has been associated with a longer FT [20] and increased DAP [15]. In addition, an involvement of a trainee in ERCP procedures has been noticed to associate with increase in FT [16, 17, 20, 21]. The differences in DAP among radiographers are likely the result of different collimation practices during ERCP, since significant differences in FT or procedural complexity of performed procedures were not found. This association has not been reported previously. Even though a fluoroscopy system includes multiple settings that can be adjusted during ERCP, radiographers at our institution typically modify only the collimation. Collimation of the irradiated surface area to the region of interest is important, because it reduces the radiation exposure of the patient and improves image quality by limiting the amount of scattered radiation to the detector [45].

Bile duct injury was found to have a significant impact on DAP, which probably is related to increase in use of image acquisition during ERCP as high image quality is needed to visualize fine details and subtle contrast differences in the anatomy of interest. FT was also longer for patients with bile duct injury, likely due to additional interventions performed during ERCP, such as sphincterotomy and stent placement. This difference reached the statistical significance in univariate analysis and in one of the multivariate models. The same effect on DAP and FT was observed with diagnosis of pancreatic duct leakage, though association with FT was stronger. Multivariate analysis revealed that interventions such as bile duct dilatation and brushing predicted a longer FT in ERCP. Biliary stent placement was significantly related to higher DAP and an association between biliary stent placement and FT was also found in one of the multivariate models. All these significant variables have already been reported previously [8, 17-19, 21, 23, 37, 46] and without a doubt these interventions require fluoroscopy to confirm proper placement of instruments and to assist in the endoscopic therapy. The use of balloon catheter as a dilatator is often followed by cholangiogram, consequently requiring longer FT. One possible reason for the stronger association of the biliary stent placement with the DAP instead of FT is that the outcome of stent insertion is usually documented at our hospital by image acquisition.

Difficult and complex procedures typically take more time, require prolonged fluoroscopy time and therefore associate with a higher radiation dose [47]. Complexity level of ERCP and cannulation difficulty grade were both independently associated with a higher DAP and longer FT in present study. It seems that cannulation difficulty is a better predictor of the increase in DAP and FT than the grading system of ERCP complexity. Performed interventions during ERCP were somewhat associated with the complexity level of ERCP, since significant differences in DAP and FT were observed only between the complexity grades 2 and 3 (multivariate models 2 and 3). ASGE [28] complexity grading system was originally developed for a method of evaluating outcomes/adverse events based on the degree of procedural difficulty. In addition, this grading system does not take into consideration the number of interventions performed or the number of instruments used during ERCP as these both has been found to be significant and have an effect on FT [37]. Recently, a new “HOUSE” -grading scale for ERCP complexity was developed by Olsson et al. [48], which classified procedures into three classes in line with the modern endoscopic treatment procedures in ERCP.

In conclusion, multiple factors were found to affect DAP and FT in ERCP. The awareness of these factors may help to predict possible prolonged procedures causing a higher radiation dose to the patient and thus facilitate the use of appropriate precautions. This is particularly important in the complex cases, as difficult papillary cannulation and complexity level of ERCP were both independently associated with a higher DAP and longer FT. Minimizing patient radiation dose in ERCP remains an essential goal in the optimisation process and the endoscopist has the most significant role in the amount of fluoroscopy time used during ERCP. Optimization of patient exposure will consequently improve the radiation protection of the staff involved in ERCP procedures. A good radiation protection practice can be achieved through continuing education and training of medical staff as well as by ensuring quality of fluoroscopy equipment.

Disclosure of interest Paulina Salminen has received lecture fees from Merck and Lilly. The remaining authors declare that they have no conflicts of interest.

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Table 1 Patient demographics and procedural characteristics of 638 ERCP procedures

Variables	Total
Gender [n (%)]	
Female	330 (51.7)
Male	308 (48.3)
Age *(y)* [mean±SD]	66.0 ± 16.7
Indication [n (%)]	
Bile duct stones	261 (40.9)
Malignant strictures	100 (15.7)
Jaundice	80 (12.5)
Cholangitis	61 (9.6)
Chronic pancreatitis	28 (4.4)
Suspicion of bile duct injury	22 (3.4)
Pseudocyst	8 (1.3)
Stent removal or exchange	36 (5.6)
Other	42 (6.6)
Type of ERCP [n (%)]	
Primary ERCP	463 (72.6)
Repeat ERCP	175 (27.4)
Total cannulation time *(min, n=537)* [median (IQR)]	1.67 (0.49-5.2)
Post-ERCP diagnosis [n (%)]	
Normal anatomy	65 (10.2)
Bile duct stricture	174 (27.3)
Bile duct stones	208 (32.6)
Cholangitis	48 (7.5)
Chronic pancreatitis	26 (4.1)

Pseudocyst	6 (0.9)
Bile duct dilatation	20 (3.1)
Bile duct injury	22 (3.4)
Stent problems	16 (2.5)
Pancreatic duct leakage	12 (1.9)
Other	41 (6.4)
Types of interventions (n=1229) [n (%)]	
Sphincterotomy	366 (29.8)
Biliary stone extraction	314 (25.5)
Bile duct dilatation	135 (11.0)
Biliary stent placement	222 (18.1)
Biliary stent removal	70 (5.7)
Pancreatic sphincterotomy	21 (1.7)
Pancreatic stone extraction	3 (0.2)
Pancreatic duct dilatation	9 (0.7)
Pancreatic stent placement	22 (1.8)
Pancreatic stent removal	11 (0.9)
Brushing	34 (2.8)
Other	22 (1.8)
Total procedural time *(min, n=542)* [median (IQR)]	17.0 (12.0-25.0)

ERCP indicates endoscopic retrograde cholangiopancreatography, SD standard deviation, IQR interquartile range

Table 2 Dose area product (DAP), fluoroscopy time (FT) and radiographic images by different variables in 638 ERCP procedures

	DAP *(Gy·cm²)*		FT *(min)*		Radiographic images	
	mean±SD	median [IQR]	mean±SD	median [IQR]	mean±SD	median (range)
Overall *(n=638)*	2.33 ± 1.79	1.83 [1.20-2.90]	1.84 ± 1.56	1.37 [0.90-2.30]	3.02 ± 1.83	3.0 (0-11)
Gender						
Female *(n=330)*	2.11 ± 1.65	1.68 [1.12-2.60]	1.87 ± 1.50	1.39 [1.08-2.32]	2.82 ± 1.84	2.0 (0-11)
Male *(n=308)*	2.55 ± 1.92	2.14 [1.24-3.16]	1.81 ± 1.62	1.32 [0.53-2.31]	3.23 ± 1.80	3.0 (0-9)
Age (years)						
< 35 *(n=40)*	1.77 ± 1.18	1.51 [0.85-2.54]	1.46 ± 1.06	1.17 [0.52-2.20]	2.80 ± 1.80	2.0 (1-8)
36-65 *(n=223)*	2.62 ± 2.20	1.97 [1.25-3.27]	1.98 ± 1.75	1.42 [1.07-2.38]	3.17 ± 1.90	3.0 (0-11)
> 66 *(n=375)*	2.21 ± 1.54	1.78 [1.14-2.78]	1.80 ± 1.48	1.34 [0.59-2.28]	2.95 ± 1.79	3.0 (0-11)
Indication						
Bile duct stones *(n=261)*	1.97 ± 1.40	1.54 [1.09-2.41]	1.67 ± 1.38	1.29 [0.59-2.13]	2.21± 1.35	2.0 (0-9)
Malignant strictures *(n=100)*	2.24 ± 1.48	1.82 [1.18-3.01]	1.79 ± 1.55	1.39 [0.56-2.35]	3.33 ± 1.57	3.0 (0-8)
Jaundice *(n=80)*	2.71 ± 2.02	2.22 [1.30-3.14]	1.99 ± 1.57	1.54 [1.06-2.44]	3.34 ± 1.95	3.0 (1-11)
Cholangitis *(n=61)*	2.60 ± 2.21	2.12 [1.36-2.87]	1.80 ± 1.25	1.43 [1.07-2.27]	3.30 ± 1.68	3.0 (1-8)
Chronic pancreatitis *(n=28)*	2.61 ± 2.37	2.00 [1.28-3.37]	2.19 ± 1.74	1.94 [0.67-3.21]	3.46 ± 2.19	3.0 (0-11)
Suspicion of bile duct injury *(n=22)*	3.90 ± 2.65	3.61 [1.98-5.23]	2.25 ± 1.87	1.77 [1.34-2.37]	4.68 ± 1.56	5.0 (2-8)
Pseudocyst *(n=8)*	2.45 ± 1.85	1.75 [1.06-3.77]	2.26 ± 1.53	2.21 [0.68-3.95]	3.88 ± 2.23	3.5 (2-9)
Stent exchange or removal *(n=36)*	2.19 ± 1.65	1.38 [0.82-3.38]	2.15 ± 2.25	1.31 [0.49-3.39]	3.44 ± 2.05	3.0 (0-8)

Other *(n=42)*	2.68 ± 2.09	2.22 [1.30-3.49]	2.01 ± 1.97	1.19 [0.56-3.27]	3.83 ± 2.48	3.5 (1-11)
Type of ERCP						
Primary ERCP *(n=463)*	2.21 ± 1.67	1.80 [1.14-2.70]	1.74 ± 1.47	1.33 [0.58-2.19]	2.93 ± 1.81	2.0 (0-11)
Repeat ERCP *(n=175)*	2.63 ± 2.06	2.12 [1.19-3.53]	2.09 ± 1.75	1.45 [1.07-2.55]	3.25 ± 1.86	3.0 (0-11)
Primary endoscopist						
1 *(n=168)*	2.42 ± 2.09	1.69 [1.09-3.24]	2.11 ± 1.87	1.39 [1.01-3.06]	3.17 ± 2.10	3.0 (0-11)
2 *(n=59)*	1.88 ± 1.19	1.67 [0.92-2.39]	0.92 ± 0.91	0.52 [0.37-1.29]	3.27 ± 1.78	3.0 (1-11)
3 *(n=229)*	2.41 ± 1.81	2.04 [1.30-2.98]	1.81 ± 1.40	1.45 [1.07-2.29]	3.14 ± 1.76	3.0 (0-9)
4 *(n=132)*	2.24 ± 1.73	1.73 [1.07-2.50]	1.79 ± 1.58	1.31 [1.07-2.16]	2.63 ± 1.57	2.0 (0-9)
5 *(n=50)*	2.39 ± 1.31	2.24 [1.45-3.05]	2.25 ± 1.27	2.17 [1.40-3.16]	2.64 ± 1.74	2.0 (0-8)
Post-ERCP diagnosis						
Normal anatomy *(n=65)*	1.63 ± 1.06	1.34 [0.83-2.12]	1.18 ± 0.87	1.15 [0.48-1.43]	2.49 ± 1.64	2.0 (1-7)
Bile duct stricture *(n=174)*	2.37 ± 1.71	1.86 [1.23-2.80]	1.89 ± 1.59	1.43 [1.01-2.43]	3.64 ± 1.83	3.0 (0-11)
Bile duct stones *(n=208)*	2.10 ± 1.47	1.71 [1.14-2.56]	1.82 ± 1.43	1.34 [1.07-2.18]	2.22 ± 1.35	2.0 (0-9)
Cholangitis *(n=48)*	2.66 ± 2.40	1.88 [1.50-2.88]	1.82 ± 1.25	1.43 [1.09-2.44]	3.19 ± 1.62	3.0 (1-8)
Chronic pancreatitis *(n=26)*	2.62 ± 2.48	2.00 [1.07-3.37]	2.48 ± 2.27	1.97 [0.95-3.47]	3.23 ± 1.77	3.0 (0-7)
Pseudocyst *(n=6)*	2.19 ± 2.04	1.38 [0.90-3.36]	1.46 ± 1.50	0.82 [0.43-2.59]	3.33 ± 1.03	4.0 (2-4)
Bile duct dilatation *(n=20)*	2.13 ± 1.41	1.62 [1.10-2.80]	1.61 ± 1.52	1.09 [0.47-2.93]	3.60 ± 2.14	3.0 (1-9)
Bile duct injury *(n=22)*	4.04 ± 2.54	3.61 [2.38-5.23]	2.34 ± 1.84	1.77 [1.36-2.69]	4.77 ± 1.45	5.0 (2-8)
Stent problems *(n=16)*	2.28 ± 1.68	1.82 [0.96-3.37]	1.95 ± 1.82	1.11 [0.43-4.05]	2.69 ± 1.82	2.0 (0-7)
Pancreatic duct leakage *(n=12)*	3.66 ± 1.53	3.54 [2.38-4.44]	3.20 ± 1.95	3.23 [1.70-4.22]	4.25 ± 2.77	4.0 (1-11)

Other *(n=41)*	2.66 ± 2.20	2.15 [1.08-3.49]	1.88 ± 1.92	1.14 [0.51-2.35]	3.39 ± 2.32	3.0 (0-9)
Complexity level of ERCP						
1 *(n=125)*	2.22 ± 1.76	1.73 [0.98-2.78]	1.77 ± 1.71	1.31 [0.50-2.34]	3.46 ± 1.90	3.0 (0-9)
2 *(n=381)*	2.18 ± 1.76	1.74 [1.11-2.68]	1.65 ± 1.40	1.27 [0.58-2.17]	2.91 ± 1.80	2.0 (0-11)
3 *(n=132)*	2.84 ± 1.85	2.32 [1.40-3.67]	2.45 ± 1.71	2.02 [1.27-3.37]	2.89 ± 1.80	2.0 (0-11)
Cannulation difficulty of ERCP						
1 *(n=216)*	2.18 ± 1.71	1.67 [1.08-2.79]	1.61 ± 1.47	1.25 [0.52-2.15]	2.89 ± 1.80	2.0 (0-11)
2 *(n=181)*	2.20 ± 1.82	1.74 [1.13-2.65]	1.63 ± 1.40	1.25 [0.54-2.12]	2.98 ± 1.66	3.0 (0-8)
3 *(n=140)*	2.61 ± 1.63	2.24 [1.49-3.23]	2.28 ± 1.54	1.59 [1.23-3.16]	3.08 ± 1.80	3.0 (0-9)

ERCP indicates endoscopic retrograde cholangiopancreatography, *SD* standard deviation, *IQR* interquartile range

Table 3 The distribution of ERCP procedural complexity by endoscopist

		Complexity level of ERCP		
Endoscopist	Total	Grade 1	Grade 2	Grade 3
1	168	34 (20.2%)	90 (53.6%)	44 (26.2%)
2	59	9 (15.3%)	39 (66.1%)	11 (18.6%)
3	229	52 (22.7%)	139 (60.7%)	38 (16.6%)
4	132	18 (13.6%)	76 (57.6%)	38 (28.8%)
5	50	12 (24.0%)	37 (74.0%)	1 (2.0%)
Total	638	125 (19.6%)	381 (59.7%)	132 (20.7%)

ERCP indicates endoscopic retrograde cholangiopancreatography

Table 4 Univariate and multivariate analysis of factors influencing on dose area product (DAP) in 638 ERCP procedures

	Univariate analysis		Multivariate analysis					
			Model 1		Model 2		Model 3	
	log DAP *(Gy·m²)* [a]		log DAP *(Gy·m²)* [a]					
Variables	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]
Gender								
Female	0.53 (0.04)	*0.003*	0.64 (0.06)	*0.023*	0.79 (0.32)	*0.048*	0.83 (0.31)	*0.025*
Male	0.69 (0.04)		0.76 (0.06)		0.89 (0.32)		0.95 (0.31)	
Age (years)								
< 35	0.33 (0.11)	Ref	0.51 (0.11)	Ref	0.67 (0.33)	Ref	0.73 (0.33)	Ref
36-65	0.70 (0.05)	*0.004*	0.83 (0.06)	*0.008*	0.96 (0.32)	*0.022*	1.01 (0.31)	*0.026*
> 66	0.58 (0.04)		0.76 (0.06)	*0.048*	0.89 (0.32)		0.93 (0.31)	
Indication								
Bile duct stones	0.48 (0.04)	Ref		NI		NI		NI
Malignant strictures	0.59 (0.07)							
Jaundice	0.78 (0.08)	*0.008*						
Cholangitis	0.71 (0.09)							
Chronic pancreatitis	0.66 (0.13)							
Suspicion of bile duct injury	1.13 (0.15)	*<0.001*						
Pseudocyst	0.67 (0.24)							

Stent exchange or removal	0.49 (0.11)							
Other	0.72 (0.11)							
Type of ERCP								
Primary ERCP	0.58 (0.03)	NS		NI		NI		NI
Repeat ERCP	0.69 (0.06)							
Primary endoscopist								
1	0.58 (0.05)	NS		NI		NI		NI
2	0.46 (0.09)	Ref						
3	0.67 (0.05)							
4	0.56 (0.06)							
5	0.71 (0.10)							
Radiographer								
1	0.20 (0.07)	Ref	0.26 (0.08)	Ref	0.41 (0.32)	Ref	0.47 (0.32)	Ref
2	0.73 (0.06)	*<0.001*	0.86 (0.08)	*<0.001*	1.01 (0.32)	*<0.001*	1.06 (0.31)	*<0.001*
3	0.60 (0.18)		0.75 (0.21)		0.86 (0.38)		0.91 (0.38)	
4	0.69 (0.08)	*<0.001*	0.74 (0.10)	*<0.001*	0.89 (0.33)	*<0.001*	0.93 (0.32)	*<0.001*
5	0.71 (0.08)	*<0.001*	0.79 (0.08)	*<0.001*	0.92 (0.32)	*<0.001*	0.97 (0.31)	*<0.001*
6	1.26 (0.10)	*<0.001*	1.30 (0.10)	*<0.001*	1.46 (0.33)	*<0.001*	1.52 (0.32)	*<0.001*
7	0.21 (0.13)		0.33 (0.12)		0.48 (0.34)		0.51 (0.34)	
8	0.44 (0.06)		0.47 (0.08)		0.60 (0.32)		0.64 (0.31)	
9	0.79 (0.14)	*<0.001*	0.82 (0.13)	*<0.001*	0.94 (0.34)	*<0.001*	1.00 (0.33)	*<0.001*

10	0.68 (0.07)	*<0.001*	0.71 (0.90)	*<0.001*	0.85 (0.33)	*<0.001*	0.90 (0.32)	*<0.001*
Complexity level of ERCP								
1	0.52 (0.06)	*<0.001*	0.57 (0.08)	*<0.001*	0.78 (0.35)		0.83 (0.34)	
2	0.55 (0.04)	*<0.001*	0.60 (0.06)	*<0.001*	0.74 (0.32)	*0.014*	0.79 (0.32)	*0.018*
3	0.86 (0.06)	Ref	0.93 (0.08)	Ref	1.00 (0.30)	Ref	1.05 (0.29)	Ref
Cannulation difficulty of ERCP								
1	0.54 (0.05)	*0.002*	0.57 (0.06)	*<0.001*	0.70 (0.32)	*<0.001*	0.76 (0.31)	*<0.001*
2	0.56 (0.05)	*0.006*	0.65 (0.07)	*<0.001*	0.79 (0.32)	*<0.001*	0.84 (0.31)	*<0.001*
3	0.78 (0.06)	Ref	0.88 (0.07)	Ref	1.03 (0.32)	Ref	1.08 (0.32)	Ref
Post-ERCP diagnosis								
Normal anatomy	0.29 (0.08)	Ref	0.36 (0.09)	Ref	0.61 (0.34)	Ref		NI
Bile duct stricture	0.66 (0.05)	*<0.001*	0.72 (0.07)	*<0.001*	0.78 (0.33)			
Bile duct stones	0.54 (0.05)		0.53 (0.06)		0.77 (0.33)			
Cholangitis	0.72 (0.10)	*0.01*	0.76 (0.09)	*0.01*	0.88 (0.33)			
Chronic pancreatitis	0.64 (0.13)		0.60 (0.12)		0.76 (0.32)			
Pseudocyst	0.51 (0.28)		0.70 (0.26)		0.78 (0.43)			
Bile duct dilatation	0.57 (0.15)		0.54 (0.15)		0.80 (0.37)			
Bile duct injury	1.20 (0.15)	*<0.001*	1.24 (0.13)	*<0.001*	1.32 (0.35)	*<0.001*		
Stent problems	0.52 (0.17)		0.64 (0.18)		0.70 (0.37)			
Pancreatic duct leakage	1.22 (0.20)	*<0.001*	0.89 (0.20)		0.96 (0.36)			
Other	0.65 (0.11)		0.72 (0.10)	*0.03*	0.90 (0.33)			

Types of interventions						
Sphincterotomy	NI	NI	0.79 (0.32)		0.84 (0.32)	
Biliary stone extraction			0.86 (0.34)		0.91 (0.33)	
Bile duct dilatation			0.88 (0.33)		0.95 (0.33)	
Biliary stent placement			0.95 (0.34)	*0.027*	1.03 (0.33)	*0.004*
Biliary stent removal			0.79 (0.33)		0.85 (0.32)	
Pancreatic sphincterotomy			0.88 (0.34)		0.91 (0.33)	
Pancreatic stone extraction			0.79 (0.48)		0.86 (0.48)	
Pancreatic duct dilatation			0.79 (0.38)		0.84 (0.36)	
Pancreatic stent placement			0.96 (0.36)		1.06 (0.35)	
Pancreatic stent removal			0.89 (0.39)		0.95 (0.37)	
Brushing			0.88 (0.34)		0.96 (0.33)	

ERCP indicates endoscopic retrograde cholangiopancreatography, [a] distribution of DAP is presented on a logarithmic scale, [b] Bonferroni adjusted p-values, *SE* standard error, *Ref* reference category, *NS* not significant, *NI* not included

Types of interventions performed during ERCP were included directly in multivariate analysis

Table 5 Univariate and multivariate analysis of factors influencing on fluoroscopy time (FT) in 638 ERCP procedures

	Univariate analysis		Multivariate analysis					
			Model 1		Model 2		Model 3	
	log FT *(min)* [a]		log FT *(min)* [a]					
Variables	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]	mean (SE)	*p*-value [b]
Gender								
Female	0.34 (0.04)	NS		NI		NI		NI
Male	0.23 (0.05)							
Age (years)								
< 35	0.06 (0.13)	Ref		NI		NI		NI
36-65	0.34 (0.06)	NS						
> 66	0.27 (0.04)							
Indication								
Bile duct stones	0.21 (0.05)	Ref		NI		NI		NI
Malignant strictures	0.25 (0.08)	NS						
Jaundice	0.40 (0.09)							
Cholangitis	0.32 (0.11)							
Chronic pancreatitis	0.41 (0.16)							
Suspicion of bile duct injury	0.58 (0.18)							
Pseudocyst	0.53 (0.30)							

Stent exchange or removal	0.23 (0.14)							
Other	0.29 (0.13)							
Type of ERCP								
Primary ERCP	0.25 (0.04)	NS		NI		NI		NI
Repeat ERCP	0.39 (0.07)							
Primary endoscopist								
1	0.38 (0.06)	*<0.001*	0.58 (0.10)	*<0.001*	1.22 (0.41)	*<0.001*	1.50 (0.40)	*<0.001*
2	-0.42 (0.11)	Ref	-0.26 (0.11)	Ref	0.31 (0.41)	Ref	0.61 (0.39)	Ref
3	0.32 (0.05)	*<0.001*	0.45 (0.07)	*<0.001*	1.08 (0.41)	*<0.001*	1.39 (0.39)	*<0.001*
4	0.28 (0.07)	*<0.001*	0.37 (0.08)	*<0.001*	0.95 (0.41)	*<0.001*	1.22 (0.39)	*<0.001*
5	0.63 (0.11)	*<0.001*	0.83 (0.12)	*<0.001*	1.45 (0.42)	*<0.001*	1.72 (0.40)	*<0.001*
Radiographer								
1	0.14 (0.09)	Ref		NI		NI		NI
2	0.30 (0.08)	NS						
3	0.34 (0.23)							
4	0.35 (0.11)							
5	0.35 (0.10)							
6	0.53 (0.13)							
7	0.28 (0.17)							
8	0.14 (0.08)							
9	0.49 (0.18)							
10	0.30 (0.09)							

Complexity level of ERCP								
1	0.13 (0.07)	*<0.001*	0.19 (0.09)	*<0.001*	0.86 (0.44)		1.15 (0.43)	
2	0.21 (0.04)	*<0.001*	0.28 (0.07)	*<0.001*	0.92 (0.41)	*0.024*	1.20 (0.39)	*0.026*
3	0.65 (0.07)	Ref	0.71 (0.09)	Ref	1.23 (0.39)	Ref	1.51 (0.37)	Ref
Cannulation difficulty of ERCP								
1	0.13 (0.06)	*<0.001*	0.20 (0.07)	*<0.001*	0.79 (0.41)	*<0.001*	1.08 (0.39)	*<0.001*
2	0.18 (0.06)	*<0.001*	0.29 (0.07)	*<0.001*	0.92 (0.41)	*<0.001*	1.20 (0.39)	*<0.001*
3	0.61 (0.07)	Ref	0.69 (0.08)	Ref	1.31 (0.41)	Ref	1.58 (0.39)	Ref
Post-ERCP diagnosis								
Normal anatomy	-0.12 (0.10)	Ref	0.05 (0.11)	Ref	0.71 (0.43)	Ref		NI
Bile duct stricture	0.32 (0.06)	*<0.001*	0.41 (0.07)	*0.03*	0.95 (0.42)			
Bile duct stones	0.32 (0.06)	*<0.001*	0.28 (0.07)		0.87 (0.42)			
Cholangitis	0.33 (0.12)		0.51 (0.12)	*0.04*	0.90 (0.42)			
Chronic pancreatitis	0.48 (0.16)	*0.02*	0.49 (0.15)		1.19 (0.41)			
Pseudocyst	-0.02 (0.34)		0.13 (0.33)		0.86 (0.54)			
Bile duct dilatation	0.08 (0.19)		0.08 (0.19)		0.77 (0.46)			
Bile duct injury	0.66 (0.18)	*<0.001*	0.78 (0.17)	*<0.001*	1.23 (0.44)			
Stent problems	0.13 (0.21)		0.43 (0.23)		0.90 (0.47)			
Pancreatic duct leakage	0.93 (0.24)	*< 0.001*	0.90 (0.25)	*0.02*	1.76 (0.46)	*0.03*		
Other	0.21 (0.13)		0.26 (0.13)		0.89 (0.42)			
Types of interventions								
Sphincterotomy		NI		NI	1.01 (0.41)		1.28 (0.40)	

Biliary stone extraction	1.08 (0.43)		1.33 (0.41)	
Bile duct dilatation	1.13 (0.42)	*0.037*	1.43 (0.41)	*0.014*
Biliary stent placement	1.13 (0.43)		1.44 (0.41)	*0.008*
Biliary stent removal	1.08 (0.42)		1.36 (0.40)	
Pancreatic sphincterotomy	1.11 (0.43)		1.39 (0.41)	
Pancreatic stone extraction	1.12 (0.61)		1.33 (0.60)	
Pancreatic duct dilatation	0.94 (0.48)		1.40 (0.45)	
Pancreatic stent placement	1.01 (0.45)		1.40 (0.43)	
Pancreatic stent removal	1.07 (0.49)		1.54 (0.46)	
Brushing	1.29 (0.44)	*0.002*	1.56 (0.41)	*0.001*

ERCP indicates endoscopic retrograde cholangiopancreatography, [a] distribution of FT is presented on a logarithmic scale, [b] Bonferroni adjusted p-values, *SE* standard error, *Ref* reference category, *NS* not significant, *NI* not included

Types of interventions performed during ERCP were included directly in multivariate analysis

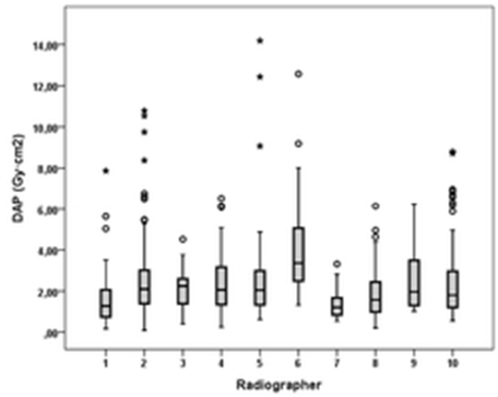

Fig. 1 The distribution of dose area product (DAP) by radiographer controlled fluoroscopy system during endoscopic retrograde cholangiopancreatography (ERCP)

21x16mm (300 x 300 DPI)