ORIGINAL ARTICLE

Annals of Gastroenterology (2012) **25,** 338-344

A prospective analysis of factors influencing fluoroscopy time during therapeutic ERCP

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Abstract

Background Fluoroscopy time (FT) in endoscopic retrograde cholangiopancreatography (ERCP) has a linear relationship with radiation exposure to endoscopist, personnel and patients. The aim of this prospective study was to investigate the factors influencing the FT during ERCP.

Patients and Methods Between January 2010 and August 2011, patients with naïve papilla undergoing therapeutic ERCP were included in the study. Patient and procedural factors affecting fluoroscopy duration were investigated.

Results During the study period 549 ERCP records were included in the final analysis. The mean procedural time and FT were 19.53±7.61 min and 48.82±26.43 sec, respectively. There was no effect of age or gender on FT. Univariate analysis showed choledocholithiasis (+17.92 sec; 95%CI: 12.73-23.11, p<0.001), multiple stones (+21.21 sec; 95%CI: 14.31-30.35, p<0.001), stone size >10 mm (+27.514 sec; 95%CI: 16.62-35.71; p<0.001), precut technique (+12.46 sec; 95%CI: 6.32-18.60; p<0.001), periampullary diverticulum (+33.36 sec; 95%CI: 28.49-38.23; p<0.001), mechanical lithotripsy (+31.14 sec; 95%CI: 24.67-37.61; p<0.001) and mechanical lithotripsy plus stent placement (+42.41 sec; 95%CI: 31.93-52.89; p<0.001) to be associated with longer FT. Multivariate analysis identified choledocholithiasis (+13.24 sec; 95%CI: 4.44-22.04; p=0.003), multiple stones (+19.51 sec; 95%CI: 11.72-26.78; p<0.001), stone size >10 mm (+23.95 sec; 95%CI: 14.35-29.45; p<0.001), needle-knife papillotomy (+17.26 sec; 95%CI: 7.77-26.75; p<0.001), periampullary diverticulum (+21.99 sec; 95%CI: 17.81-26.16; p<0.001) and mechanical lithotripsy plus stent placement (+20.39 sec; 95%CI: 7.38-33.40; p=0.002) to prolong FT.

Conclusions The identified factors influencing the FT may help endoscopists take appropriate precautions during ERCP to significantly decrease FTs.

Keywords endoscopic retrograde cholangiopancreatography, fluoroscopy time

Ann Gastroenterol 2012; 25 (4): 338-344

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Conflict of Interest: None

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Received 26 January 2012; accepted 25 March 2012

Introduction

The use of fluoroscopy to aid endoscopic procedures including endoscopic retrograde cholangiopancreatography (ERCP) and other interventions, places both the patient and the endoscopy staff at risk of radiation-induced injury [1-4]. Previous reports have demonstrated a linear relationship between radiation dose and fluoroscopy duration, thus limiting fluoroscopy time is one of the simplest and most modifiable methods of reducing radiation exposure during ERCP [5,6]. An audit [7] of radiation exposure to personnel performing ERCP found that both patients and staff are exposed to a significant level of radiation. This was equivalent to an estimated additional lifetime fatal cancer risk of between 1 in 3,500 and 1 in 7,000 [7]. The awareness of hospital doctors about radiation exposure and associated cancer risk is poor [8]; chronic exposure to X-ray, in spite of the relative low dose, can lead to potentially threatening conditions such as bone marrow malignancies and other solid cancers.

Factors associated with prolonged fluoroscopy duration have been delineated recently, but these have not been validated [9]. In this respect, there is a scarcity of data [10-12] regarding the factors influencing radiation exposure to patients and staff during ERCP.

The aim of the present study was to characterize patient and procedure-related factors associated with increased fluoroscopy duration.

Patients and Methods

Study design

This was an observational, prospective study with consecutive ERCPs performed on 549 patients in a tertiary referral center of therapeutic endoscopy in Northern Greece between January 2010 and August 2011. The research proposal was approved by the Institutional Review Board of Research and Ethics Committee of G. Gennimatas General Hospital of Thessaloniki.

Patients

Patients undergoing therapeutic ERCP on an inpatient or outpatient basis were eligible for enrollment in the study. Exclusion criteria were: age under 18 years, pregnancy or breast feeding, previous endoscopic sphincterotomy (ES), upper gastrointestinal (GI) obstruction, cancer, severe hypoxemia with ventilation/perfusion imbalance, acute myocardial infarction within three months prior to the procedure, coagulopathy and platelet count less than 50,000/mm^3, and refusal to participate in the study.

A thorough clinical history was completed and physical examination was performed for all patients emphasizing the indication for ERCP, history of systemic diseases, drug intake and acute pancreatitis. Each patient or his/her relatives gave written informed consent after receiving verbal and written explanations about ERCP and possible post-procedure complications.

ERCP procedure

All procedures were performed by an experienced pancreatobiliary endoscopist (PK) by using a standard therapeutic duodenoscope**.** The fluoroscopy x-ray unit used during all ERCPs was Prestige SI, GE Medical Systems, Milwaukee, WI, USA. ERCP was performed under conscious sedation with midazolam and pethidine. Hyoscine-n-butyl (Buscopan, Boehringer, Ingelheim Ltd, UK) or glucagon was used as smooth muscle relaxants at the endoscopist's discretion. Arterial oxygen saturation, heart rate and blood pressure were monitored using automated devices. ERCPs were performed with the patients in the supine position. For ductal opacification, contrast medium (50% sodium meglumine amide triazoate diluted in distilled water) was used. Pancreatograms were graded according to the extent of pancreatic opacification: main pancreatic duct, first class branches, secondary branches or acinarization. The cannulation of the common bile duct (CBD) was attempted firstly with a sphincterotome (Clever-Cut, Olympus, Athens, Greece). In case of failure of CBD cannulation within 5 min, a hydrophilic guidewire (Jagwire 0.035′′, Microvasive, Athens, Greece) was introduced for an additional 5 min. If both techniques failed, a precut papillotomy was attempted. ES was performed with blended current (cut 45W, coagulation 30W) using an Olympus electrosurgical unit (PSD-30, Olympus, Tokyo, Japan). The length of ES depended on the indication: small for stent placement or as large as possible for choledocholithiasis.

Data collected by the endoscopist conducting the procedure were: specific details concerning the procedure, including the presence of periampullary diverticulum, type of precut papillotomy (conventional needle knife, suprapapillary fistulotomy, transpancreatic septotomy), type of therapy performed, total procedure time and fluoroscopy duration.

Definitions

The total procedure time was recorded via screen recording time, from endoscope insertion until its withdrawal. Fluoroscopy time was recorded by a radiologist.

The definition of post-ERCP complications and the grading of their severity were based on consensus criteria [13].

Study outcomes

The primary endpoint of the study was to investigate the factors influencing the fluoroscopy time in therapeutic ERCP.

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, version 16.0, Chicago, IL, USA). Categorical variables were analyzed with chi-squared and Fisher's exact tests, as appropriate, while continuous variables were expressed as means with standard deviation (SD) and analyzed using the Student *t* test. Factors associated with increased fluoroscopy time during ERCP were examined by univariate and multivariate analyses and calculated with odds ratio (OR) with 95% confidence interval (CI), using a logistic regression method. Statistical significance was set at $p<0.05$.

Results

We analyzed 549 ERCPs performed at our hospital during the aforementioned period. Patient characteristics are demonstrated in Table 1. 57.2% were women and the mean age of the patients was 68.86±14.64 years. The main indication for therapeutic ERCP was choledocholithiasis (78.5%) followed by malignant pathology (9.3%) and 109 patients (19.9%) presented periampullary diverticulum (Table 1). Table 2 shows the procedure characteristics. All cases were performed with the patients under conscious intravenous sedation. Cannulation of CBD was achieved with sphincterotome (61%), sphincterotome plus hydrophilic guidewire (23.3%) and a precut technique was needed in 82 patients (15%). In four patients (0.7%) CBD cannulation was unsuccessful despite the fact that a precut technique was performed. The type of treatment performed is demonstrated in Table 2. The mean procedure and fluoroscopy time was 19.53±7.61 min and 48.82+26.43 sec, respectively. There was no effect on mean procedure and fluoroscopy time when the cases were analyzed with respect to age or gender.

Univariate analysis (Table 3) showed that the factors that significantly increased the fluoroscopy time were: choledocholithiasis (+17.918 sec; 95%CI: 12.728-23.108, p<0.001), multiple stones (+21.21 sec; 95%CI: 14.31-30.35, p<0.001), stone size >10 mm (+27.514 sec; 95%CI: 16.62-35.71; p<0.001), precut technique (+12.458 sec; 95%CI: 6.32-18.596; p<0.001), needle-knife papillotomy (+17.762 sec; 95%CI: 9.15-26.374; p<0.001), suprapapillary fistulotomy (+12.512 sec; 95%CI: 0.421-24.603; p=0.043), periampullary diverticulum (+33.36 sec; 95%CI: 28.489-38.231; p<0.001), mechanical lithotripsy (+31.138 sec; 95%CI: 24.667-37.609; p<0.001) and mechanical lithotripsy plus stent placement (+42.405 sec; 95%CI: 31.925-52.886; p<0.001). In a multivariate analysis, the factors (Tables 4 & 5) that significantly increased fluoroscopy time were: choledocholithiasis (+13.24 sec; 95%CI: 4.442-22.037; p=0.003), multiple stones (+19.51 sec; 95%CI: 11.72-26.78; p<0.001), stone size >10 mm (+23.95 sec; 95%CI: 14.35-29.45; p<0.001), needle-knife papillotomy (+17.26 sec; 95%CI: 7.769-26.751; p<0.001), presence of periampullary diverticulum (+21.988 sec; 95%CI: 17.814-26.162; p<0.001) and mechanical lithotripsy plus stent placement (+20.388 sec; 95%CI: 7.377-33.398; p=0.002).

Post-ERCP pancreatitis presented in 7 patients and was mild or moderate; all these patients were treated conservatively. Post-ES bleeding was observed in 5 patients and they were all successfully treated with injection of adrenaline (1:10,000) or adrenaline plus electrocoagulation. Deaths related to ERCP and cardiopulmonary complications directly attributed to ERCP were not observed.

Table 1 Patients' characteristics

	N (%)
No of patients	549 (100)
Age (mean±SD)(years)	68.86±14.64
Gender (male/female)	235/314 (42.8/57.2)
Indication for ERCP	
Choledocholithiasis	431 (78.5)
>1 stones	253
Stone size (mean±SD)(mm)	8.57±5.44
Malignant pathology	51 (9.3)
Biliary leak	21 (3.8)
Pancreatitis	12 (2.2)
Others	34 (8.9)
Presence of periampullary diverticulum	109 (19.9)

Table 2 Procedure characteristics

	N (%)
Cannulation	
Sphincterotome	335 (61)
Sphincterotome plus guidewire	128 (23.3)
Precut technique	82 (15)
Needle-knife	38 (6.9)
Transpancreatic	25 (4.6)
Suprapapillary fistulotomy	19 (3.5)
Failed	4 (0.7)
Treatment	545 (99.3)
ES+ stone extraction (basket, balloon)	338 (61.6)
ES only	31 (5.6)
ES+ mechanical lithotripsy	58 (10.6)
Plastic stent placement	77 (14)
ES+ mechanical lithotripsy+plastic stent placement	23 (4.2)
Metal stent placement	16 (2.9)
Total procedure time (mean±SD)(min)	19.53±7.61

ES, endoscopic sphincterotomy

Discussion

Therapeutic ERCP remains a significant weapon in the armamentarium of endoscopists and is the main source of radiation exposure for endoscopists and personnel involved in the procedure [2,14]; exposure to radiation during ERCP could have adverse effects on the endoscopic team members and patients. Therefore, further investigation to identify factors influencing the fluoroscopy time during ERCP may help the endoscopist to predict which procedures are associated with prolonged fluoroscopy duration and may lead to appropriate

Table 3 Univariate analysis of factors influencing fluoroscopy time during therapeutic ERCP

Variable	β coefficient	p-value	95% CI	
			Lower limit	Upper limit
Female sex	1.423	0.535	-3.075	5.921
Choledocholithiasis	17.918	<0.001	12.728	23.108
>1 stones	21.214	<0.001	14.314	30.355
Stone size >10 mm	27.514	<0.001	16.621	35.714
Malignancy	-3.218	0.408	-10.857	4.421
Biliary leak	-21.145	<0.001	-32.851	-9.439
Pancreatitis	-25.037	0.001	-40.06	-10.013
Cholecystectomy	3.716	0.107	-0.811	8.243
Sphincterotome	-7.31	0.002	-11.816	-2.805
Sphincterotome+ guidewire	0.627	0.815	-4.625	5.878
Precut technique	12.458	<0.001	6.32	18.596
Needle knife	17.762	<0.001	9.15	26.374
Suprapapillary	12.512	0.043	0.421	24.603
Transpancreatic	0.441	0.935	-10.2	11.083
Periampullary diverticulum	33.36	<0.001	28.489	38.231
Stone extraction	-9.336	<0.001	-13.855	-4.817
ES only	-27.718	<0.001	-37.042	-18.395
Mechanical lithotripsy	31.138	<0.001	24.667	37.609
Plastic stent placement	-12.446	<0.001	-18.751	-6.141
Mechanical lithotrispy+stent placement	42.405	<0.001	31.925	52.886
Metallic stent placement	8.461	0.182	-3.977	20.898

p-value<0.05: presence of statistically significant difference
ES, endoscopic sphincterotomy

precautions. Radiation dose has a direct linear relationship with fluoroscopy time [2,15] and is theoretically dependent on many factors including: type of procedure (diagnostic or therapeutic), skill of endoscopist, presence of deformed upper GI anatomy (i.e. Billroth II operation), stent insertion, lithotripsy, biopsies, use of a needle-knife, additional wires other than the standard, balloon catheter and involvement of a gastroenterology fellow, thereby prolonging fluoroscopy duration [10-12].

The findings from this prospective observational study suggest that fluoroscopy is directly related to various measures of case complexity. More specifically the use of a lithotriptor plus stent placement was associated with a significant increase in fluoroscopy time in univariate (Table 3) and multivariate (Tables 4 & 5) analyses, respectively, because they are often used for the treatment of difficult CBD stones. Moreover, we observed that the presence of periampullary diverticulum was associated in both analyses with a significant increase ($p<0.001$) in fluoroscopy time because increased size and number of CBD stones and use of mechanical lithotripsy with/without stent placement were encountered. A precut technique to achieve CBD cannulation is usually used as a second-line access technique when conventional methods have failed, and is often associated with prolonged procedure time and longer duration. In univariate analysis the three types of precut techniques were found to significantly increase the fluoroscopy time (Table 3). However, multivariate analysis (Table 4) showed that only the needle-knife papillotomy was associated with prolonged fluoroscopy duration. To our knowledge, this is the first study concerning periampullary diverticula and type of precut technique and their relationship to fluoroscopy time. The presence of choledocholithiasis as well as multiple duct stones and stone size >10 mm were found to be associated in both analyses with increased fluoroscopy duration because more difficult procedures (mechanical lithotripsy with/without stent placement) are used to treat multiple and larger CBD stones.

The lower rate of mean fluoroscopy time (48.82±26.43 sec) in our study in contrast to two recent studies [10,11] (mean fluoroscopy time 284.4 sec and 6.77 min, respectively) is related to the fact that, i) in our study, all procedures were performed by a very experienced pancreatobiliary endoscopist (PK), in contrast to both of the above-mentioned studies in which a significant number of procedures were performed

Table 4 Multivariate analysis of factors influencing fluoroscopy time during therapeutic ERCP

Variable	β coefficient	p-value	95% CI	
			Lower limit	Upper limit
Choledocholithiasis	13.24	0.003	4.442	22.037
>1 stones	19.515	<0.001	11.723	26.783
Stone size >10mm	23.953	<0.001	14.351	29.446
Biliary leak	-8.181	0.091	-17.681	1.32
Pancreatitis	2.277	0.735	-10.954	15.509
Sphincterotome	-8.012	<0.001	-11,801	-4.223
Precut technique	3.98	0.324	-3.939	11.899
Needle knife	17.26	<0.001	7.769	26.751
Suprapapillary	8.109	0.15	-2.929	19.146
Periampullary diverticulum	21.988	<0.001	17.814	26.162
Stone extraction	-17.307	0.002	-28.067	-6.546
ES only	-29.709	<0.001	-41.191	-18.227
Mechanical lithotripsy	10.23	0.068	-0.75	21.211
Plastic stent placement	-14.203	0.002	-23.112	-5.294
Mechanical lithotrispy+stent placement	20.388	0.002	7.377	33.398

p-value<0.05: presence of statistically significant difference
ES, endoscopic sphincterotomy

Table 5 Significant variables in multivariate analysis

Variable	Increase in fluoroscopy duration (sec)	95%CI
Choledocholithiasis	13.24	4.442-22.037
>1 stones	19.515	11.723-26.783
Stone size >10mm	23.953	14.351-29.446
needle-knife papillotomy	17.26	7.769-26.751
Periampullary diverticulum	21.988	17.814-26.162
Mechanical lithotripsy + stent placement	20.388	7.377-33.398

by trainees, and ii) good collaboration with the radiographer. Radiation doses to ERCP patients are significantly lower with experienced endoscopists [11,16]. This is further demonstrated when comparing our data (Table 6) with those of Kim *et al* [11]. The use of a lithotriptor alone and the use of a guidewire did not significantly alter the fluoroscopy time in multivariate analysis in contrast to the data of Kim *et al* where trainees in ERCP were involved. On the other hand we need to stress out that the radiologist should only perform fluoroscopic screening as required by the endoscopist, who should indicate clearly when no more screening is needed. From our experience it is clear that a relatively large amount of unnecessary exposure is delivered when no strict arrangements are made between endoscopist and radiologist.

The advantage of our study is the prospective design that allows accurate recording of specific details concerning the procedure, fluoroscopy duration and post-ERCP complications. On the other hand, because there is an inverse relationship between fluoroscopy time and endoscopist's experience, the limitation of this series is that all procedures were performed by an experienced endoscopist in a tertiary referral center, thereby eliminating factors such as the endoscopist's limited experience and factors related to the procedure that might have an impact on the procedure and fluoroscopy time; therefore our excellent results on fluoroscopy duration must be viewed in the context of a single endoscopist with a high degree of expertise and cannot be extrapolated.

In view of the aforementioned data, fluoroscopy duration and radiation reduction methods should be prospectively investigated and integrated into ERCP training programs

Table 6 Variables in multivariate analysis

Variable	Katsinelos *et al*			Kim *et al*		
	Increase in fluoroscopy duration (sec)	95%CI	p	Increase in fluoroscopy duration (sec)	95%CI	p
Sphincterotome + guidewire	0.627	-4.625	5.878	93	1.5-184.2	0.046
Lithotriptor	10.23	-0.75-21.211	0.068	344.4	55.86-603	0.019
Needle-knife	17.26	7.769 - 26.751	<0.001	266.4	132-400.2	0.00
Stenting	-14.203	-23.112- -5.294	0.002	186.6	114.6-258	0.00

considering, concurrently, clinical aspects detected in the present series such as difficult papillary cannulation, more complex therapeutic intervention or presence of periampullary diverticulum, which can prolong the fluoroscopy time and increase the dose received by the patient. In this regard, gastroenterologists involved in ERCP procedures could work at specialized centers performing multiple procedures daily, in all circumstances in which fluoroscopic and/or x-ray equipment is used, endoscopists should minimize the risks to patients, themselves, and other members of the staff. Radiation-induced cancer risk is reasonably low but is expected to fall further in the coming years with the participation of more experienced endoscopists and the advent of new technologies.

In conclusion, the identification of parameters influencing the fluoroscopy time during ERCP may help the endoscopist to predict which procedures are associated with prolonged fluoroscopy duration and may lead to appropriate precautions.

Summary Box

What is already known:

- There is a linear relationship between radiation dose and fluoroscopy duration during endoscopic procedures
- Patients and staff are exposed to a significant level of radiation during ERCP, equivalent to an estimated additional lifetime fatal cancer risk of between 1 in 3,500-7,000
- Although several factors (diagnostic or therapeutic procedure, endoscopist's skill, deformed upper GI anatomy, stent insertion, lithotripsy, biopsies, use of a needle-knife, additional wires other than the standard, balloon catheter) have been implicated in prolonged fluoroscopy duration during ERCP, these have not been completely clarified

What the new findings are:

- Fluoroscopy is directly related to various measures of case complexity
- Multivariate analysis has demonstrated that choledocholithiasis, multiple CBD stones, stone size >10 mm, needle-knife papillotomy, presence of periampullary diverticulum and mechanical lithotripsy significantly prolong fluoroscopy
- Fluoroscopy time can be significantly lower when ERCP is performed by skilled endoscopists

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