

Low-dose pulsed vs standard pulsed fluoroscopy during ERCP to reduce radiation without change in image quality: Prospective randomized study



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ABSTRACT

Background and study aims Endoscopic retrograde cholangiopancreatography (ERCP) poses the risk of radiation exposure (RE) to patients and staff and increases the risk of adverse biological effects such as cataracts, sterility, and cancer. Newer fluoroscopy equipment (C-Arm) provides options to limit radiation in the form of lower radiation dose and frame rate or time-limited “pulsed” settings. However, the impact of lower settings on image quality has not been assessed, and no standard protocol exists for fluoroscopy settings used during ERCP.

Patients and methods This was a single-center, double-blind, prospective randomized study of consecutive adult patients undergoing standard-of-care ERCP at a tertiary academic medical center. Patients were randomized into two groups: 1) standard-dose pulsed and 2) low-dose pulsed. Pulsed mode (8 fps) was defined as x-ray exposure either in the manufacturer standard-dose or low-dose settings limited to 3 seconds each time the foot-operated switch was depressed.

Results Seventy-eight patients undergoing ERCP were enrolled and randomized. No difference in age, gender, or body mass index was found between the two groups. No significant difference in image quality was found between standard-dose and low-dose fluoroscopy ($P = 0.925$). The low-dose group was exposed to significantly less radiation when compared with standard-dose ($P < 0.05$). Fluoroscopy time (minutes) was similar in both groups (2.0 vs 1.9), further suggesting that group assignment had no impact on image quality or procedure time.

Conclusions Low-dose pulsed fluoroscopy is a reliable method that substantially reduces radiation without compromising image quality or affecting procedure or fluoroscopy times. This underscores the need for standardization in ERCP fluoroscopy settings to limit radiation exposure.

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Introduction

Endoscopic retrograde cholangiopancreatography (ERCP) is a diagnostic and therapeutic tool that utilizes endoscopy paired with radiographic guidance in patients with pancreatic and biliary diseases. Although it is routinely performed, ERCP still carries the risk of radiation exposure (RE) to patients or medical staff [1].

Ionizing radiation in high doses may cause cell death, while low doses are more likely to damage the DNA of irradiated cells [2, 3, 4, 5, 6]. Deterministic effects of RE, such as erythema or cataract, have a threshold dose below which the biological response is not observed, and thus, they are more common in longer procedures with more RE [6, 7, 8, 9]. Radiation doses under 50 mSv do not cause any immediate issues, but rather, they may lead to the development of cancer in the exposed and genetic defects in their future offspring [4, 5, 6, 7]. The risk of these levels of RE are not well quantified, and thus, cannot be deemed as negligible in clinical practice [10, 11, 12]. Consequently, when the nature of a procedure necessitates RE to the patient, it should be kept as low as reasonably achievable [13].

Personal protection equipment such as lead aprons, thyroid collars, glasses, and other kinds of shields also has been utilized to protect patients and staff from RE [14]. In addition, newer fluoroscopy equipment provides options to limit radiation delivery in the form of lower radiation dose and frame rate or time-limited “pulsed” settings. Pulsed settings have been utilized and have demonstrated successful reduction in RE in many fields including orthopedics, neurosurgery, anesthesia, interventional radiology, vascular surgery, urology, and cardiology [15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28]

. The angle or positioning of the C-Arm has been shown to impact the level of radiation to the surgeon, and lung and colon cancers appear to be the greatest risks to surgeons [29].

In the field of gastroenterology, studies have also examined the potential benefit of different fluoroscopic and imaging techniques aimed at reducing RE such as dedicated stationary fluoroscopy units vs. C-Arm or time-limited fluoroscopy, enhancing ERCP performance using 3D-ERCP in biliary diseases, and additional benefits of shielding [30, 31, 32]. However, the impact of using lower radiation settings such as time-limited fluoroscopy, specifically on image quality in ERCP, has not been assessed. Currently, there is no standard protocol for fluoroscopy settings used during ERCP. The present study aimed to report image quality results of low-dose time-limited “pulsed” fluoroscopy compared with standard-dose time-limited “pulsed” fluoroscopy in patients undergoing clinically indicated standard-of-care ERCP and whether low-dose time-limited “pulsed” provides adequate imaging.

Patients and methods

Study design and ethics approval

This study was approved by the Clinical Institutional Review Board (IRB) (IRB- HP-00098356) as a double-blind, randomized (1:1), prospective study of patients undergoing standard-of-care ERCP at the University of Maryland Medical Center. The

IRB determined the study to be an assessment of quality outcomes given no additional patient interventions, and no existing standardized fluoroscopy protocol, and therefore, registration of the study as a clinical trial was not required. This study was conducted in accordance with the Helsinki Declaration and clinical research rules established by CONSORT.

Sample size

Based on previous fluoroscopy studies, a sample-size calculation before the initiation of the study identified a requirement of 40 patients per group to measure a 20% difference in mean imaging quality with a power of 0.80. Given the expectation of a 5% difference, we exceeded the calculated sample-size calculation required to account for incomplete or missing data and projected patient withdrawal from study protocol [15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28].

Participants and informed consent

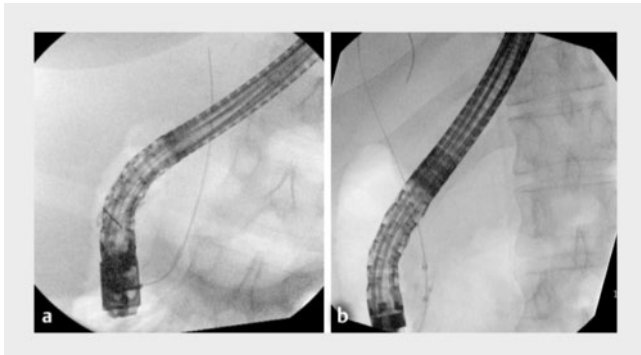
Consecutive patients undergoing standard-of-care ERCP were included from April 2022 to June 2022. Participants were excluded for altered anatomy such as Roux-en-Y, requiring the use of either surgical manipulation or additional equipment (e.g. balloon assisted ERCP), pregnancy, unable to provide consent/lacked a durable power of attorney, or age \geq 89 years.

Phantom model

Prior to patient enrollment, to ensure equipment calibration and confirm changes in fluoroscopic dose delivery, a phantom model was used to measure the kilovoltage peak (kVp) and milliamperage (mA) output from the C-Arm in the standard-dose and low-dose pulsed settings. Entrance skin exposure (ESE) and scatter RE measurements were taken using a 12 in \times 12 in \times 6 in acrylic phantom to simulate patient tissue. (Supplemental Fig. 1). During a change in the fluoroscopy technique from standard-dose pulsed to low-dose pulse, a measurable decrease in mA was observed, which resulted in a decrease in ESE (R/min) and scatter radiation (milliroentgens per hour (mR/hr)) measured at various positions in the room (Supplemental Table 1 and Supplemental Table 2). As we switched from the standard-dose pulsed to the low-dose pulsed setting, we observed no reduction in high-contrast resolution (line pairs per millimeter [LP/mm]) (Supplemental Fig. 2, Supplemental Fig. 3).

Randomization

Patients were randomized (1:1) under the maximally tolerated imbalance (MTI) procedure using the Clinical Trial Randomization Tool web application developed by the National Cancer Institute and the National Institutes of Health. The enrollment and assignments were performed by the advanced endoscopy fellow. Patients were randomized into two groups: Group 1 standard-dose time-limited “pulsed” fluoroscopy (n = 41) and Group 2 low-dose time-limited “pulsed” fluoroscopy (n = 37). The OEC Elite C-Arm (General Electric, Boston, Massachusetts, United States) was used in all procedures. Pulsed mode (8 fps) was defined as x-ray exposure either in the manufacturer standard-dose or low-dose settings limited to 3 seconds each time the foot-operated switch is depressed. The C-Arm fluoroscopy



► **Fig. 1** Fluoroscopy images low-dose pulsed vs. standard pulsed. **a** Low-dose pulsed. **b** Standard pulsed.

setting was set prior to the start of the procedure by the unblinded advanced endoscopy fellow. Following the procedure, the blinded attending interventional endoscopists (clinical experience range 7–25 years) were asked to rate real-time image quality using a Likert scale: 1 (excellent) – expected pancreaticobiliary anatomical structures and pathological findings visible at 100%; 2 (good) – expected pancreaticobiliary anatomical structures and any pathological findings visible between 99% – $\geq 75\%$; 3 (fair) – expected pancreaticobiliary anatomical structures and any pathological findings visible between $\leq 75\%$ and 25%; 4 (poor) – expected pancreaticobiliary anatomical structures and any pathological findings visible $< 25\%$; 5 (unacceptable) – pancreaticobiliary landmarks not visible at all (► **Fig. 1** and ► **Fig. 2**).

Data collection

Immediately after each procedure, image quality rating, FT, patient, and procedure-related data, and protocol deviation were recorded on a standard data collection form. Procedure data included indication, technical components (i.e. successful, failed, or not attempted: cholangiography, sphincterotomy, pancreatography, stone extraction, dilation, minor papilla, stent insertion/exchange), and procedure duration (from endoscope insertion to removal)

Statistical analysis

Population demographic and clinical characteristics were recorded and compared based both on group assignment (► **Table 1**) and native vs non-native papilla (► **Table 2**). The mean and interquartile ranges (IQR) were calculated for all quantitative variables (which excluded sex) and Welch's *t*-test was performed to assess observed differences in variable means (► **Table 1** and ► **Table 2**); the median was also used to calculate fluoroscopy time due to the distribution of the fluoroscopy time variable. Sex differences between groups were assessed using a Fisher's exact test (► **Table 1**). Mixed multiple linear regression was used to model predictors of fluoroscopy time and image quality while controlling for multiple confounders and individual error due to participant variation (► **Table 2**), while one-way ANOVA was used to assess differences in image quality and fluoroscopy time based on the indication (► **Table 3**). Asso-

| Likert Scale – Image Quality | |
|------------------------------|--|
| Points | Definition of Image Quality |
| 1 (excellent) | Expected pancreaticobiliary anatomical structures and pathological findings visible at 100 % |
| 2 (good) | Expected pancreaticobiliary anatomical structures and any pathological findings visible between 99 % – $\geq 75\%$ |
| 3 (fair) | Expected pancreaticobiliary anatomical structures and any pathological findings visible between $< 75\%$ and 25 % |
| 4 (poor) | Expected pancreaticobiliary anatomical structures and any pathological findings visible $< 25\%$ |
| 5 (unacceptable) | Landmarks not visible at all |

► **Fig. 2** Likert Scale.

ciations between cohort features and fluoroscopy time (► **Table 4**) were estimated using Generalized Linear Modeling (GLM). The Gaussian family was used for all variables except sex, for which Binomial family was employed. Statistical analyses were carried out with R version 4.0.4, using the “stats,” “vctrs,” and “nlme” packages [33, 34, 35].

Results

Cohort description and demographic and clinical characteristics

Eighty-two participants undergoing ERCP at the University of Maryland Medical Center were enrolled and randomized into two groups: Group 1 standard-dose pulsed ($n = 42$) and Group 2 low-dose pulsed fluoroscopy ($n = 40$). A total of four cases were switched from study protocol to standard-dose continuous fluoroscopy due to poor image quality, standard ($n = 1$), low ($n = 3$), and thus excluded. For the excluded cases, changes in fluoroscopic settings were made in a sequential fashion as defined, with the standard group switched to continuous fluoroscopy and low switched to standard-dose pulsed followed by continuous fluoroscopy (mean image quality rating: fair: 3.2 vs. 3, respectively). The remaining 78 participants were analyzed, standard ($n = 41$), and low ($n = 37$). The mean age of participants was 58.8 years and the majority were male (64.1%), with an average body mass index (BMI) of 27.4 (► **Table 1**). No significant differences in these demographics were found between the groups. Both groups had a similar mean American Society for Gastrointestinal Endoscopy (ASGE) ERCP complexity grade (group 1 = 2.19 vs. group = 2.2). Those in the standard group were exposed to an average of 5.63 mA of current compared with 2.77 mA in the low group, with no difference in kVp of the x-ray or total procedure time. Mean fluoroscopy time was lower in the low group ($P = 0.036$). However, this was a result of the mean skewing from one participant in the standard group who received approximately 14 minutes of fluoroscopy exposure due to technically difficult case (ASGE ERCP Grade 3). Therefore, a more precise measurement accounting for the

► **Table 1** Baseline characteristics of randomized cohort.

| | Cohort (n = 78) | Group 1 (n = 41) | Group 2 (n = 37) | P value |
|---|--------------------|------------------------|-------------------------|-----------|
| Age (mean, IQR) | 58.8 (46, 72) | 56.9 (43,71) | 61.0 (51,72) | 0.261 |
| Sex (m) | 50 (64.1%) | 23 (56.1%) | 27 (73.0%) | 0.492 |
| BMI (mean, IQR) | 27.4 (23.1,30.0) | 28.2 (23.1,31.0) | 26.6 (23.1,29.1) | 0.293 |
| mA (mean, IQR) | 4.34 (1.95,4.70) | 5.63 (3.70,6.10) | 2.77 (1.60,2.20) | 7.074e-05 |
| Fluoroscopy time in minutes (mean, median, IQR) | 3.10 (1.25,3.50) | 3.81, 2.00 (1.33,3.97) | 2.29, 1.94 (0.915,3.36) | 0.036 |
| kVp (mean, IQR) | 88.2 (83.0,94.0) | 87.6 (83.3,94.0) | 88.8 (83.3,94.8) | 0.616 |
| Total procedure time (mean, IQR) | 28.2 (15.8,34.5) | 29.2 (15.0,34.0) | 27.1 (16.0,34.5) | 0.640 |
| ASGE ERCP Grade | 2.2 (2,3) | 2.19 (2,3) | 2.21 (2,3) | 0.901 |

IQR, interquartile range; BMI, body mass index; ASGE, American Society of Gastrointestinal Endoscopy; ERCP, endoscopic retrograde cholangiopancreatography.

► **Table 2** Fluoroscopy time and image quality based on procedure type.

| | CBD stone (native) (n = 32) | Biliary/PD stricture (native) (n = 22) | Biliary/PD stricture (non-native) (n = 19) | PD/bile leak (native) (n = 5) | P value |
|------------------------------------|--------------------------------|--|--|----------------------------------|---------|
| Cohort fluoroscopy time (minutes) | 1.76 (0.88–2.68) | 1.88 (1–44–3.73) | 1.89 (1.18–2.76) | 4.45 (3.15– 7.53) | 0.411 |
| Cohort image quality | 1.00 (1.00– 2.00) | 1.00 (1.00–1.00) | 1.00 (1.00–1.00) | 1.00 (1.00–1.25) | 0.092 |
| Fluoroscopy time Group 1 (minutes) | 1.76 (1.18– 2.36) | 2.00 (1.47– 3.97) | 1.35 (1.15–2.80) | 8.01 (5.06–10.95) | 0.361 |
| Fluoroscopy time Group 2 (minutes) | 1.73 (0.88– 3.19) | 1.7 (1.36–3.24) | 2.00 (1.77– 2.63) | 4.45 (3.98–4.93) | 0.315 |
| Image quality Group 1 | 1.00 (1.00– 2.00) | 1.00 (1.00–1.00) | 1.00 (1.00–1.00) | 1.50 (1.25–1.75) | 0.008 |
| Image quality Group 2 | 1.00 (1.00– 2.00) | 1.00 (1.00–1.50) | 1.00 (1.00– 2.00) | 1.00 (1.00–1.00) | 0.752 |

CBD, common bile duct; PD, pancreatic duct.

► **Table 3** Impact of previous pancreaticobiliary intervention or sphincterotomy on fluoroscopy time and image quality.

| | Native papilla (n = 56) | Non-native papilla (n = 22) | P value |
|----------------------------------|----------------------------|--------------------------------|---------|
| Age (mean, IQR) | 59.0 (45,71) | 58.5 (50,73) | 0.903 |
| Sex (m) | 32 (57.1%) | 15 (68.2%) | 0.446 |
| BMI (mean, IQR) | 27.1 (23.1,29.9) | 28.1 (24.3,30.6) | 0.528 |
| mA (mean, IQR) | 4.16 (2.00,4.70) | 4.71 (1.85,4.65) | 0.567 |
| Fluoroscopy time (mean, IQR) | 3.15 (1.33,3.63) | 2.96 (1.18,2.76) | 0.812 |
| kVp (mean, IQR) | 87.2 (83.0,93.0) | 90.4 (84.0,94.8) | 0.139 |
| Total procedure time (mean, IQR) | 30.5 (16.0,36.0) | 22.6 (11.5,30.0) | 0.0475 |

IQR, interquartile range; BMI, body mass index.

outlier is reported in the median fluoroscopy time for standard of 2.00 minutes vs. 1.94 minutes for low. Overall, the primary result did not reveal a significant difference in the mean image

quality score between the groups (1.37 vs. 1.38, $P = 0.925$), and no difference in real-time image quality was observed in those

► **Table 4** Mixed multiple linear regression assessing predictors of image quality in participants.

| Factor | β coefficient | P value |
|--|---------------------|---------|
| BMI | 0.015 | 0.231 |
| mA | -0.030 | 0.268 |
| Group 2 (relative to Group 1) | -0.272 | 0.358 |
| Fluoroscopy time | 0.039 | 0.093 |
| kVp | 0.001 | 0.869 |
| Complexity | -0.025 | 0.820 |
| Interaction between mA and Group 2 (relative to Group 1) | 0.043 | 0.391 |
| Interaction between fluoroscopy time and Group 2 | 0.089 | 0.214 |

BMI, body mass index.

who receive standard-dose vs low-dose pulse fluoroscopy (► **Fig. 1**).

On further analyses, each parameter was assessed as a predictor of fluoroscopy time using a series of univariate GLMs to ensure unaccounted for relationships were not unknowingly prolonging fluoroscopy time in a subset of participants. While each additional minute of procedure time was associated with an extra 3.93 seconds of fluoroscopy time ($P < 0.001$), age, sex, BMI, mA used, and kVp of the x-ray, were found not to have a statistically significant relationship with fluoroscopy time. However, interval increases in ASGE complexity grade were associated with a 1.28-minute increase in total fluoroscopy time. A mixed linear model was used to assess the difference in image quality (measured by the Likert scale) between the standard and low groups. This model accounted for fluoroscopy time, amount of x-ray current (measured in mA), the voltage of the x-ray beam (measured in kVp), and was controlled for BMI, complexity, and interactions between assigned group and fluoroscopy time, as well as group exposure to radiation (► **Table 4**). Overall, no significant relationship was found between image quality and any of the assessed factors, while accounting for changes in radiation current exposure and fluoroscopy time, further suggesting that group assignment had no impact on image quality.

Neither native papilla nor procedure indication are predictive of fluoroscopy time. Nearly 72% of participants had native papillae (no prior sphincterotomy or pancreaticobiliary intervention). To investigate the impact of non-native papillae on fluoroscopy times or image quality, characteristics of those with or without native papillae were assessed (► **Table 3**). Total procedure time was observed to be lower in the group with non-native papillae ($P = 0.048$); however, no difference in age, sex, BMI, fluoroscopy time, RE (mA), or kVp of the x-ray was observed. Further, given that the rate of procedures performed for non-native papillae was similar between the standard and low groups, a history of non-native papillae was considered un-

likely to impact results. Fluoroscopy time and image quality were also assessed and found not to be significantly different regardless of procedure indication (► **Table 2**).

Discussion

Our study aimed to report image quality results of low-dose time-limited “pulsed” fluoroscopy compared with standard-dose time-limited “pulsed” fluoroscopy in patients undergoing clinically indicated standard-of-care ERCP. We found that there was no statistical or clinical difference in image quality between group 1 and group 2 at the univariate level (1.37 vs. 1.38, $P = 0.925$), nor when accounting for multiple potential confounders (a difference of 0.272 less in Likert scale image quality in group 2, $P = 0.358$). Median fluoroscopy time did not significantly differ between groups; only RE differed between groups, with significantly less exposure occurring for participants in group 2 (5.63 vs 2.77 mA, $P < 0.0001$). Based on physician-reported image quality and phantom modeling, our results show that low-dose pulsed fluoroscopy is a reliable method that substantially reduces radiation to a clinically significant degree without compromising image quality or affecting procedural or fluoroscopy times.

Our findings further add to the results of previous studies that have evaluated and advocated for the use of low-dose pulsed fluoroscopy in other radiological procedures. Sabat et al. evaluated low-dose pulsed fluoroscopy versus standard-dose continuous fluoroscopy during fluoroscopically-guided lumbar punctures and found low-dose pulsed fluoroscopy significantly reduces RE by about 600% compared with standard-dose continuous fluoroscopy, thus dramatically reducing RE without impacting the image quality or technical success rate [36]. Similarly, Badawy et al. evaluated the utilization of ultra-low pulse rate fluoroscopy in routine transfemoral diagnostic coronary angiography and found no reduction in diagnostic clarity, no increase in fluoroscopy time, and up to a 58% reduction in Dose Area Product (DAP) [37]. Furthermore, it has been reported that ERCPs performed by low-volume endoscopists are associated with significantly higher RE to patients, compared with those performed by high-volume endoscopists (HVEs) despite the fact that procedures performed by HVEs are of greater complexity [38]. In our study, we included a range of endoscopists with varying volumes and experience.

In our study, we used kilovoltage peak (kVp) and milliamperage (mA) as conduit indicators of radiation dose. Internationally, Kair Kerma (AK, mGy) or Kerma Area Product (KAP, Gy cm^2) have been widely adopted as internationally standardized measures of radiation dose exposure [39]. However, kVp and mA have been reported as appropriate inferences of radiation dose, because the reported radiation dose increases proportionally with increasing kVp and mA [40]. We believe that our study still highlights an accurate representation of radiation dose exposure using reported kVp and mA, and acknowledge its limitation in the standardized reporting of widely accepted international radiation dose measurements.

As the utility of ERCP and endoscopic ultrasound-guided techniques continues to expand, it is imperative to assess RE in

these novel procedures [41]. While our study provides evidence for the efficacy of low-dose pulsed fluoroscopy during ERCP, it is important to note some limitations. First, our study had a relatively small sample size, which may limit the generalizability of our findings, particularly on the basis of procedure indication, and indication may turn out to be a significant predictor of fluoroscopy time in larger samples. In addition, our study did not assess individual radiation dose exposure to patients and staff in order to assess long-term outcomes such as radiation-induced cancer risk. However, we propose that those patients who would benefit the most from low-dose pulsed fluoroscopic technique are average-weight patients undergoing ASGE ERCP Grade 1–2 [42]. Furthermore, this was a single-center experience at an academic tertiary hospital where ERCP was performed by dedicated interventional gastroenterologists using institution-specific fluoroscopic equipment; therefore, results may vary between institutions and may not be applicable to community hospital settings. Despite the endoscopists being unaware of the group assignment, the assessment of image quality relied on a Likert scale, which could potentially introduce response bias. It is noteworthy that the high-contrast resolution (LP/mm) of the phantom model, serving as an objective indicator of spatial resolution, demonstrated similarities between the two groups. However, it is important to mention that this particular aspect was not explicitly examined within the context of individual cases or fluoroscopic images. Therefore, future multicenter studies are needed to investigate the long-term safety, efficacy, and reproducibility of low-dose pulsed fluoroscopy during ERCP along with its impact on image quality.

Conclusions

In conclusion, our study provides important insights into the impact and application of low-dose pulsed fluoroscopy on image quality and RE in patients undergoing ERCP. This study suggests that low-dose pulsed fluoroscopy reduces RE to a clinically impactful degree without compromising image quality, underscoring the need for a standardized protocol for fluoroscopy in ERCP. While further research is needed, our findings suggest that low-dose pulsed fluoroscopy can be a useful tool for reducing RE during ERCP without compromising imaging quality or procedure integrity.

Conflict of Interest

The authors declare that they have no conflict of interest.

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