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Ocular and the whole body radiation exposure during endoscopic retrograde cholangiopancreatography

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ABSTRACT

Objective: This study aimed to analyze the average whole body radiation exposure, which changes significantly according to during endoscopic retrograde cholangiopancreatography (ERCP) difficulty and to determine whether an ocular protection device must be used by analyzing applied ocular radiation.

Material and Methods: Patients >18 years of age in whom an ERCP had been indicated were prospectively included in the study.

Results: A total of 1173 patients were included. Increased applied radiation dose significantly correlated with increased shot rate (Rho= 0.789, p< 0.001), ERCP duration (Rho= 0.487, p< 0.001), cost (Rho= 0.129, p< 0.001), and LOS (Rho= 0.109, p< 0.001). The whole body, skin, and eye radiation exposure doses were found to be lower than the recommended limit per year (20 mSv/year).

Conclusion: Limit of ocular radiation exposure during ERCP did not exceed the recommended annual limit (20 mSv/year), and it was also detected to be much lower than that. Therefore, the use of ocular visors is not recommended.

Keywords: Endoscopic retrograde cholangiopancreatography, radiation exposure, fluoroscopy duration

INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is a crucial diagnostic and treatment tool for hepatobiliary system disorders. However, a reliable procedure could not be achieved without using fluoroscopy. The radiation dose applied to the patients depends on many factors. The experience of the operator and technician, the features of the patient and fluoroscopy device, and the protective devices used are stated with regard to these factors. In some studies, the amount of radiation exposure has been found to be correlated with procedure type and fluoroscopy duration. Nevertheless, some factors related to long-term fluoroscopy have recently been described, but they cannot yet be confirmed (1). It was found that other staff were exposed to a lesser degree of radiation when compared to the operator with respect to radiation distance (2). However, the operator's exposure to radiation can still be considerably limited by using protective devices (2). Our aim was to analyze the average whole body radiation exposure, which changes significantly according to the ERCP difficulty, and to determine whether an ocular protection device must be used by analyzing applied ocular radiation.

MATERIAL and METHODS

Patients

Patients >18 years of age in whom an ERCP is indicated were prospectively included in the study between November 2019 and November 2022. Sedation was applied by an anesthesiologist via continuous monitoring. Demographics, additional diseases, and adverse events that occurred during the ERCP procedure were electronically recorded. A complete blood count (CBC) and comprehensive biochemistry tests were obtained both prior to and after the ERCP procedure. A

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pancreatitis prophylaxis was administered for all patients via intravenous Ringer lactate infusion and intramuscular non-steroid anti-inflammatory drug. Informed consent was obtained from all patients, and the whole data gathered were anonymized.

Procedure and Radiation Measurement

All procedures were performed by the same operator in the gastroenterological ERCP unit of the hospital. A lateral decubitus position was used. Advanced protective devices were used against radiation, including lead visors around the patient's table and upper to the C-arm and between the patient and the operator, other than routine lead aprons and thyroid shields.

Data regarding patients with respect to ampulla position, cannulation time, total procedure duration, procedure difficulty (easy-moderate-hard), type of periampullary diverticula, total number of fluoroscopic shots, total radiation dose, and adverse events were prospectively recorded. Dosimeters, including the whole body and ocular devices used by both the operator and two other staff, were periodically evaluated by a special organization (Radat Laboratory Services). A video-recorded C-arm fluoroscopy system producing 12.5 Hz pulses (BV Pulsera, Philips, Amsterdam, the Netherlands) was used in the study. Voltage and flow duration were automatically determined. An experienced technician applied the fluoroscopic shots according to the operator's requests. Cumulative radiation exposure was calculated and presented as mSv per hour. Our study was approved by the ethics board .

Statistical Analysis

All values are represented as mean ± standard deviation (SD), 95% confidence intervals (95% CI), percentages, medians with interquartile ranges (IQR) as appropriate. Distribution normality was analyzed with the Kolmogorov-Smirnov and Shapiro-Wilk tests properly. Differences respecting ERCP difficulty were tested with one-way ANOVA or Kruskal-Wallis test appropriately. A p value of <0.05 was accepted as significant. All analyzes were calculated with Jamovi® (2.3.26), an open and free statistics program, provided for free.

RESULTS

A total of 1173 patients were included into the study. Mean age was 54 ± 18, 61 ± 19, and 65 ± 17 years in the easy, moderate, and hard ERCP groups, respectively (p= 0.023). Female rates were detected to be 23%, 34%, and 43% in separate three groups (p≤ 0.001). No clinically meaningful, albeit statistically significant, differences were found between groups (Table 1).

Table 1. Group features according to the difficulty in achieving ERCP

	Easy (n= 305)	Moderate (n= 418)	Hard (n= 450)	p	$P_{easy-moderate}$	$P_{easy-hard}$	$P_{moderate-hard}$
Sex (F), n (%)	110 (23)	166 (34)	206 (43)	**0.023**	0.579	**0.022**	0.169
Age* (year)	54 ± 18	61 ± 19	65 ± 17	**<0.001**	**<0.001**	**<0.001**	**<0.001**
CC, n (%)	2 (1)	10 (2)	31 (7)	**<0.001**	0.168	**<0.001**	**0.005**
Leakage, n (%)	4 (1)	6 (1)	10 (2)	0.554	0.989	0.635	0.665
Row ERCP, n (%)	1 (0.5)	12 (3)	71 (16)	**<0.001**	**0.030**	**<0.001**	**<0.001**
Diverticulum, n (%)	30 (10)	49 (12)	75 (17)	**0.014**	0.702	**0.021**	0.094
Stent impl., n (%)	34 (15)	74 (37)	77 (43)	**<0.001**	**<0.001**	**<0.001**	0.509
Sphincterotomy, n (%)	238 (78)	348 (83)	340 (76)	**0.019**	0.181	0.711	**0.014**
Sclerotherapy, n (%)	10 (3)	51 (12)	61 (14)	**<0.001**	**<0.001**	**<0.001**	0.823
WBC* ($x10^3$/cc)	6.2 ± 2.0	6.4 ± 2.1	6.8 ± 3.1	**0.020**	0.713	**0.017**	0.077
GGT* (U/L)	188 ± 175	220 ± 203	197 ± 212	0.062	0.059	0.809	0.222
Bil* (mg/dL)	0.67 ± 0.86	0.80 ± 1.1	1.1 ± 2.0	**<0.001**	0.318	**<0.001**	**0.021**
ALP* (U/L)	218 ± 163	262 ± 194	259 ± 205	**0.022**	**0.036**	0.058	0.980
ALT* (U/L)	88 ± 105	77 ± 78	54 ± 68	**<0.001**	0.325	**<0.001**	**<0.001**
AST* (U/L)	55 ± 72	49 ± 63	40 ± 42	**<0.001**	0.529	**0.003**	**0.026**
Amylase* (U/L)	68 ± 74	94 ± 201	70 ± 123	**0.049**	**0.039**	0.946	0.090
LOS* (day)	3 [2-5]	4 [2-6]	6 [3-9]	**<0.001**	**0.011**	**<0.001**	**<0.001**
Pre-cat, n (%)	4 (1)	20 (5)	102 (23)	**<0.001**	**0.027**	**<0.001**	**<0.001**
Duration* (min)	17 ± 5	25 ± 7	35 ± 13	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Shot*	15 [9-21]	22 [14-34]	29 [12-57]	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Radiation dose*	6.8 ± 5.7	11.2 ± 10.1	16.3 ± 17.8	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Cost* (₺)	2473 ± 1837	3657 ± 3598	6605 ± 12657	**<0.001**	**<0.001**	**<0.001**	**<0.001**

ALP: Alkaline phosphatase, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, Bil: Bilirubin, CC: Cholangiocarcinoma, F: Female, GGT: Gamma-glutamyl transferase, Impl: Implantation, LOS: Length of stay, Pre-cat: Pre-catheterisation, ₺: Turkish lira, WBC: White blood count.
*mean ± SD, ** median [IQR]. Bolds indicates statistical significance.

Table 2. Correlation matrix							
		Radiation dose	**Shot**	**Duration**	**LOS**	**Cost**	**Age**
Radiation dose	**Rho**	-					
	p	-					
Shot	**Rho**	0.789*	-				
	p	**<0.001**	-				
Duration	**Rho**	0.487*	0.506*	-			
	p	**<0.001**	**<0.001**	-			
LOS	**Rho**	0.109*	0.094*	0.215*	-		
	p	**<0.001**	**0.002**	**<0.001**	-		
Cost	**Rho**	0.129*	0.073*	0.180*	0.693*	-	
	p	**<0.001**	**0.013**	**<0.001**	**<0.001**	-	
Age	**Rho**	0.056	0.132*	0.198*	0.108*	0.092*	-
	p	0.058	**<0.001**	**<0.001**	**<0.001**	**0.002**	-

LOS: Length of stay.
* Sign and bold indicates statistical significance.

According to results, it seemed that harder ERCP did not only mean the more accompanying cholangiocarcinoma, leakage, row ERCP, diverticulum, stent implantation rate, sphincterotomy, sclerotherapy but also increased LOS, pre-cat rate, ERCP duration, shot rate, total radiation dose, and the cost (Table 1). According to correlation analysis, increased applied radiation dose was significantly correlated with increased shot rate (Rho= 0.789, p< 0.001), ERCP duration (Rho= 0.487, p< 0.001), cost (Rho= 0.129, p< 0.001), and LOS (Rho= 0.109, p< 0.001) (Table 2, Figure 1). The whole body, skin, and eye radiation exposure doses were found to be lower than the recommended limit per year (20 mSv/year) (Figures 2, 3).

DISCUSSION

ERCP is a technical issue and depends on the operator's experience. Applied radiation during ERCP is multifactorial, and features of the operator and the patient, the type of the procedure, and other equipment may not be controlled. It is recommended that fluoroscopy duration be the shortest that could be achieved (1).

ERCP has also been performed recently via computed tomography (CT) technology. Although an ERCP via CT can facilitate the procedure in patients with hard ductal anatomy, it may elongate not only the duration of the procedure and the radiation but also require a contrast injection. A lower degree of radiation exposure has been detected in patients who have undergone a conventional ERCP procedure while compared to patients having an ERCP procedure via CT (2).

The eyes are a highly sensitive part of the human body, and radiation exposure may cause cataract formation (3). The minimum long-term exposure to trigger cataract formation is 2500 mSv (3). International guidelines recommend against exceeding a limit of 20 mSv/year for ocular radiation exposure (4). The radiation exposure of the operators working in high-volume centers (>200 procedures per year) and performing hard and complicated ERCP procedures must be cautiously assessed. Limitation by using lead-supported glasses might be logical in these circumstances (5).

Recent studies show the importance of radiation assessment. Although standard protection systems are routinely used for the skin, thyroid, and whole body against radiation exposure, knowledge about using ocular protection against radiation exposure is vague (6). Recently, it was shown that ocular cataractogenesis may be triggered by a lower radiation dose than previously considered (6). Radiation spread through fluoroscopy may cause cytotoxic cell damage in various tissues (7). Early reactions can occur in tissues with high metabolic demand, while late reactions take place in resistant tissues such as vessels and bones (8). On the other hand, immune system damage almost always occurs (8).

ERCP may be performed both in the supine and left lateral de cubitus (LDD) positions. It has been shown that ERCP performed in the LDD position is as safe as in the supine one (9). Ocular radiation exposure of the ERCP staff was found to be lower in the ERCP procedure performed in supine position while compared to in LDD position. The body thickness differences between two positions are accused of causing this phenomenon (7). Another study with patients who underwent an ERCP performed in the LDD position reported harder technical issues for operators who got used to performing ERCP in supine positions and more cardio-respiratory adverse events (3). Still, we consider the difficulty of the procedure to be more important than the body's thickness.

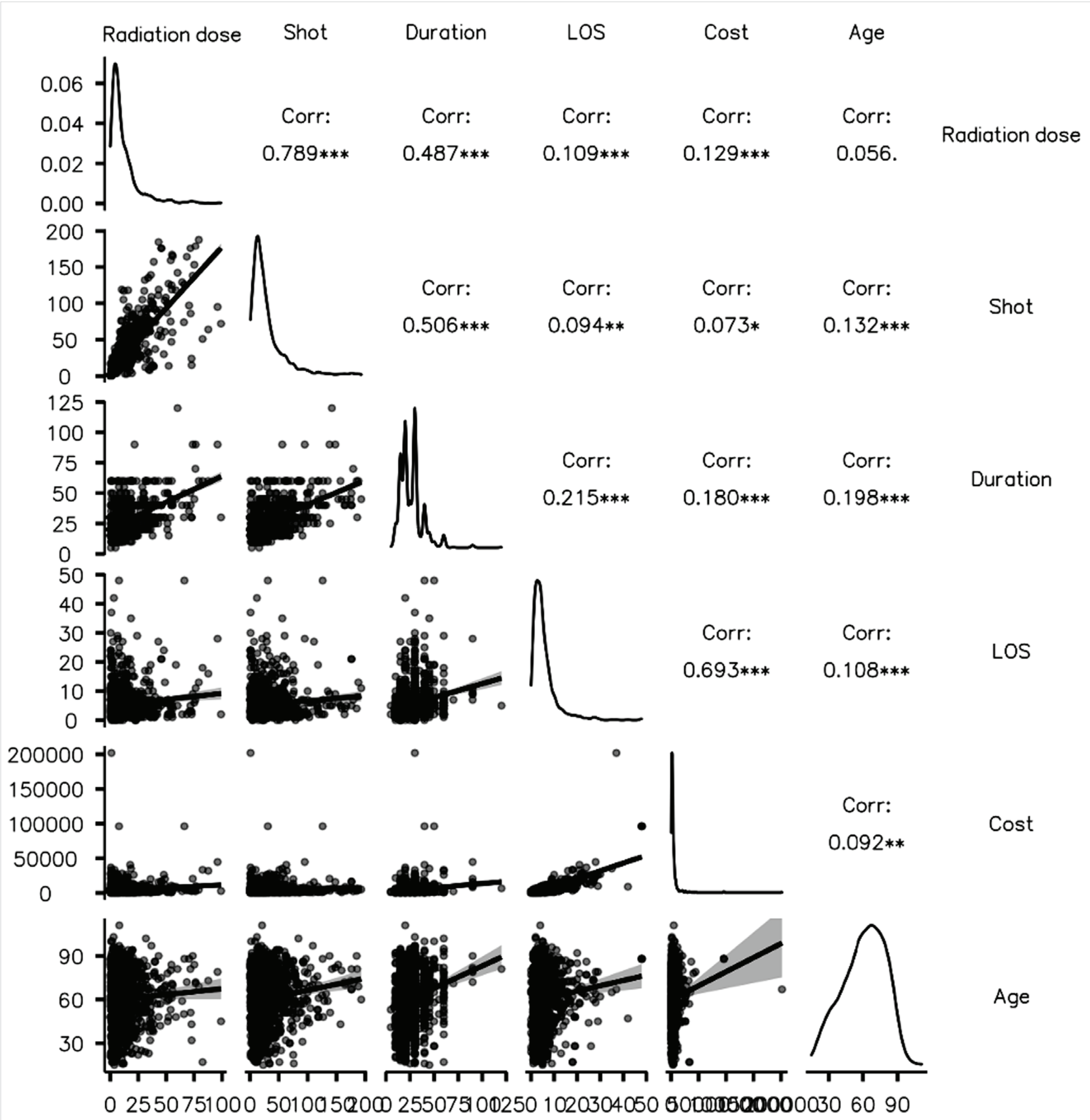

Figure 1. Correlation matrix depicting association among age, shot, duration, cost, and length of stay (LOS).
*p< 0.05, **p< 0.01, ***p< 0.001.

In the ERCP procedure, lead visors are mandatory for the operators; however, the use of the ocular protection devices is optional. In some studies, the duration of fluoroscopy (hour) to extend a recommended limit of ocular radiation exposure (10 mSv) was stated as 59.41 hours for operators and 88.17 hours for other staff (10). Then ocular protection devices have to be used by the operators in line with these results. However, according to our study, even the operators did not get close to the recommended level of the ocular radiation dose. Furthermore, it has been calculated that 100 times more ERCP procedures are needed to reach that limit.

Radiation dose exposure during ERCP is closely associated with fluoroscopy duration, and it may become longer in difficult cases (11). Another important factor is the experience of the operator and the technician (11). It is known that fluoroscopy's duration is shorter in the hands of experienced operators (11). Understanding the basics of radiation and using protective devices can help reduce stress on the team (12). Moreover, novel technologies provide features that might reduce radiation exposure. Still, the main factor preventing radiation exposure is a standard exposure time for ERCP (13).

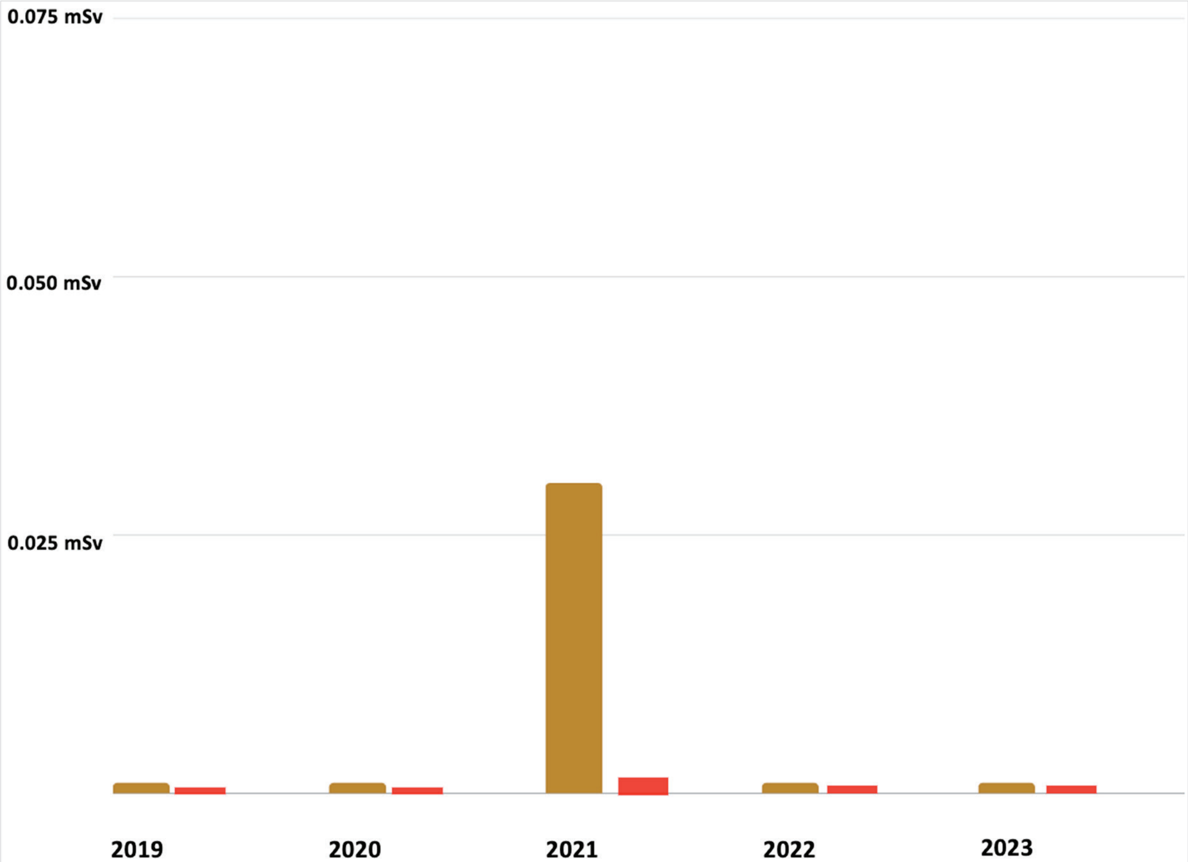

Figure 2. Eye radiation exposure through the years gone by for the operator (brown) and accompanying two nurses (red-mean value).
*A maximum of 20 mSv per year is the determined limit value according to provision of laws.

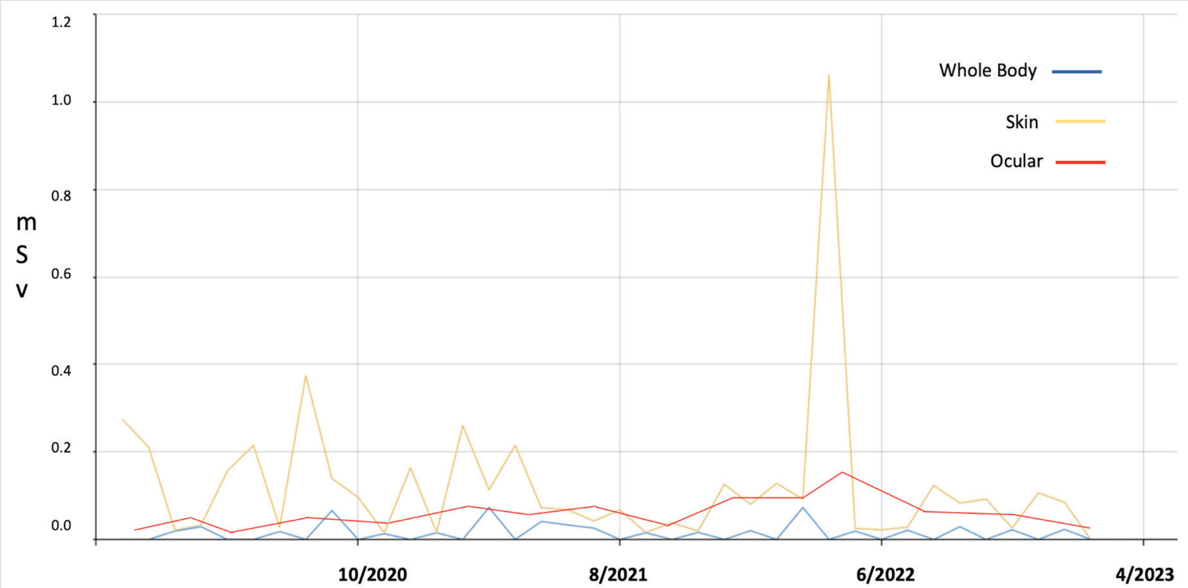

Figure 3. The whole body and skin radiation exposure through the years gone by for the operator (number before forward slash sign means the month of the year). Red line delineates the mean radiation exposure of two accompanying nurses (avarage of the whole body and skin radiation).
*A maximum of 20 mSv per year is the determined limit value according to provision of laws.

The radiation exposure of the staff working in an ERCP unit must be within acceptable limits. Unfortunately, some research has shown that staff might have be exposed to a higher level of radiation than that reported in the literature (14). Thus, the ERCP procedure's radiation doses and protective precautions are still a matter of debate. On the other hand, the radiation dose of patients for a diagnostic ERCP procedure is a mean of 14-26 Gy.cm^2, while it may increase to 67-89 Gy.cm^2 for a therapeutic procedure (15).

Indeed, there are also some studies investigating the radiation exposure of anesthesiologists. In a great number of studies, it has been shown that anesthesiologists, who were at least 1.5 meters away from the C-arm, did not expose themselves to radiation, or at least exposed themselves to only a minimal level of radiation (16). However, it has to be kept in mind that 1.5 meters of distance is the sensitivity limit of dosimeters. Understanding the basics of radiation and using protective devices can help reduce the possible harm to which the team might be exposed (16,17). In our hospital, working schedules are arranged in a shift formation that we consider another protective factor for the staff against radiation.

Although total body and thyroid lead visors are mandatory, the use of ocular protection devices is still a matter of debate. In fact, our prospective study highlights two important points. Does a standard body radiation dosimetry device provide reliable information regarding ocular radiation exposure, and what is the limit of fluoroscopy duration that makes it necessary to use an ocular protective device? According to our study, body radiation dosimetry results are in line with those of ocular devices, and almost 100 times more ERCP procedures than the current ERCP unit's work are needed to make an ocular protection device mandatory (Figures 2,3). This result also suggests a reevaluation to the recent guidelines.

The current study also has some limitations. To begin with, having only one center's experience makes our results not generalizable. However, considerable data, including more than a thousand patients, makes us believe it is clinically meaningful. Another point is that the only LDD position used in our study makes it impossible to compare our results with a supine position. Furthermore, the procedures were performed by a single experienced operator, hence results may vary according to the operators with different experiences. Lastly, we have analyzed only an 18-month duration, which limits our ability to comment on the chronic adverse events of the radiation exposure. It seems more advanced, structured prospective studies are needed.

CONCLUSION

Radiation exposure during ERCP is associated with fluoroscopy duration and the difficulty of the procedure. The exposure of radiation to the operators may be reduced significantly by using protective devices. In the current study, the ocular radiation limit did not only did exceed the recommended annual limit (20 mSv/year) but it was also detected to be much lower than that. Therefore, the use of ocular visors is not recommended.

Ethics Committee Approval: This study was obtained from Kahramanmaraş Sütçü İmam University Faculty of Medicine Clinical Research Ethics Committee (Decision no: 01, Date: 23.03.2022).

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - All of authors ; Design - All of authors; Supervision - All of authors; Data Collection and/or Processing - All of authors; Analysis and/or Interpretation - All of authors; Literature Search - All of authors; Writing Manuscript - All of authors; Critical Reviews - All of authors.

Conflict of Interest: The authors have no conflicts of interest to declare.

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ORİJİNAL ÇALIŞMA-ÖZET
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Endoskopik retrograd kolanjiyopankreotografi sırasında oküler ve tüm vücut radyasyon maruziyeti

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ÖZET

Giriş ve Amaç: Amaç, endoskopik retrograd kolanjiyopankreotografi (ERCP) zorluğuna göre önemli ölçüde değişen tüm vücut radyasyon maruziyetinin ortalamasını analiz etmek ve uygulanan oküler radyasyonu analiz ederek oküler koruma cihazı kullanılması gerekip gerekmediğini belirlemektir.

Gereç ve Yöntem: Endoskopik retrograd kolanjiyopankreotografi endikasyonu olan 18 yaş üstü hastalar prospektif olarak çalışmaya dahil edildi.

Bulgular: Çalışmaya toplam 1173 hasta dahil edildi. Artan uygulanan radyasyon dozu; artan radyografik çekim sayısı (Rho= 0,789, p< 0,001), ERCP süresi (Rho= 0,487, p< 0,001), maliyet (Rho= 0,129, p< 0,001) ve yatış süresi (Rho= 0,109, p< 0,001) ile anlamlı olarak ilişkilidir. Tüm vücut, cilt ve göz radyasyonuna maruz kalma dozlarının yıllık önerilen limitin (20 mSv/yıl) altında olduğu tespit edildi.

Sonuç: Endoskopik retrograd kolanjiyopankreotografi sırasında oküler radyasyona maruz kalma sınırının önerilen yıllık sınırı (20 mSv/yıl) aşmadığı gibi bunun çok altında olduğu tespit edildi. Bu nedenle göz vizörlerinin kullanılmaması önerilmektedir.

Anahtar Kelimeler: Endoskopik retrograd kolanjiyopankreatografi, radyasyon maruziyeti, floroskopi süresi

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