

# World Journal of *Clinical Cases*

*World J Clin Cases* 2018 December 26; 6(16): 1073-1222





**REVIEW**

- 1073 Biliary endoscopic sphincterotomy: Techniques and complications  
*Köksal AS, Eminler AT, Parlak E*

**MINIREVIEWS**

- 1087 Radiation exposure during image-guided endoscopic procedures: The next quality indicator for endoscopic retrograde cholangiopancreatography  
*Hayashi S, Takenaka M, Hosono M, Nishida T*

**ORIGINAL ARTICLE**

**Case Control Study**

- 1094 Feasibility of laparoscopic total gastrectomy in overweight patients: Implications of less impact of overweight on laparoscopic versus open approach  
*Nakagawa M, Kojima K, Inokuchi M, Kobayashi K, Tanioka T, Okuno K, Gokita K*

**Retrospective Study**

- 1101 Complications of newborn enterostomies  
*Wolf L, Gfroerer S, Fiegel H, Rolle U*
- 1111 Background factors influencing postgastrectomy syndromes after various types of gastrectomy  
*Kinami S, Takahashi M, Urushihara T, Ikeda M, Yoshida M, Uenosono Y, Oshio A, Suzukamo Y, Terashima M, Koderä Y, Nakada K*
- 1121 Safety of fecal microbiota transplantation in Chinese children: A single-center retrospective study  
*Zhang XY, Wang YZ, Li XL, Hu H, Liu HF, Li D, Xiao YM, Zhang T*

**Observational Study**

- 1128 Mandatory meningococcal vaccine, and other recommended immunisations: Uptake, barriers, and facilitators among health care workers and trainees at Hajj  
*Badahdah AM, Alfelali M, Alqahtani AS, Alsharif S, Barasheed O, Rashid H; the Hajj Research Team*

**Randomized Clinical Trial**

- 1136 Effect of clonidine on the cutaneous silent period during spinal anesthesia  
*Graf Zupcic S, Zupcic M, Duzel V, Šimurina T, Milošević M, Basic S, Vuletic V, Kapural L*



- 1146 Safety of applying midazolam-ketamine-propofol sedation combination under the supervision of endoscopy nurse with patient-controlled analgesia pump in colonoscopy

*Kayaaltı S, Kayaaltı Ö*

### CASE REPORT

- 1155 Renal aspergillosis in a liver transplant patient: A case report and review of literature

*Smolovic B, Vukcevic B, Muhovic D, Ratkovic M*

- 1160 Ureteral double J stent displaced into vena cava and management with laparoscopy: A case report and review of the literature

*Mao XW, Xu G, Xiao JQ, Wu HF*

- 1164 Combined silicosis and mixed dust pneumoconiosis with rapid progression: A case report and literature review

*Yoon HY, Kim Y, Park HS, Kang CW, Ryu YJ*

- 1169 Spontaneous cerebral abscess due to *Bacillus subtilis* in an immunocompetent male patient: A case report and review of literature

*Tsonis I, Karamani L, Xaplanteri P, Kolonitsiou F, Zampakis P, Gatzounis G, Marangos M, Assimakopoulos SF*

- 1175 Post-appendectomy pelvic abscess with extended-spectrum beta-lactamase producing *Escherichia coli*: A case report and review of literature

*Tse A, Cheluvappa R, Selvendran S*

- 1182 Gastric duplication cyst communicating to accessory pancreatic lobe: A case report and review of the literature

*Rousek M, Kachlik D, Nikov A, Pintova J, Ryska M*

- 1189 Oxygen insufflation *via* working channel in a fiberscope is a useful method: A case report and review of literature

*Lee D, Baik J, Yun G, Kim E*

- 1194 Primary sebaceous carcinoma of lacrimal gland: A case report and review of literature

*Park H, Choi SG*



- 1199** Uncommon cause of voiding dysfunction in a female patient-vaginal abscess: A case report  
*Yeh CC, Yang SSD, Huang SC, Wang YC*
- 1202** Schwannoma originating from the recurrent laryngeal nerve in a thyroid cancer patient: A case report and review of the literature  
*Xu XQ, Hong T, Zheng CJ*
- 1206** Posaconazole-associated severe hyperbilirubinemia in acute myeloid leukemia following chemotherapy: A case report  
*Song ZW, Pan YC, Huang ZC, Liu WX, Zhao RS, Jing HM, Dong F*
- 1210** Chondromyxoid fibroma of the temporal bone: A case report and review of the literature  
*Zheng YM, Wang HX, Dong C*
- 1217** Duodenal variceal bleeding secondary to idiopathic portal hypertension treated with transjugular intra-hepatic portosystemic shunt plus embolization: A case report  
*Xie BS, Zhong JW, Wang AJ, Zhang ZD, Zhu X, Guo GH*

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**INDEXING/ABSTRACTING**

*World Journal of Clinical Cases* (*WJCC*) is now indexed in PubMed, PubMed Central, Science Citation Index Expanded (also known as SciSearch®), and Journal Citation Reports/Science Edition. The 2018 Edition of Journal Citation Reports cites the 2017 impact factor for *WJCC* as 1.931 (5-year impact factor: N/A), ranking *WJCC* as 60 among 154 journals in Medicine, General and Internal (quartile in category Q2).

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**NAME OF JOURNAL**  
*World Journal of Clinical Cases*

**ISSN**  
ISSN 2307-8960 (online)

**LAUNCH DATE**  
April 16, 2013

**FREQUENCY**  
Semimonthly

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7901 Stoneridge Drive, Suite 501, Pleasanton, CA 94588, USA  
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Fax: +1-925-2238243  
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Baishideng Publishing Group Inc  
7901 Stoneridge Drive, Suite 501, Pleasanton, CA 94588, USA  
Telephone: +1-925-2238242  
Fax: +1-925-2238243  
E-mail: [bpgoffice@wjcn.net.com](mailto:bpgoffice@wjcn.net.com)  
Help Desk: <https://www.wjcn.net.com/helpdesk>  
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**PUBLICATION DATE**  
December 26, 2018

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## Radiation exposure during image-guided endoscopic procedures: The next quality indicator for endoscopic retrograde cholangiopancreatography

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**Author contributions:** Hayashi S wrote the initial draft of the manuscript; Takenaka M, Hosono M and Nishida T critically reviewed the manuscript.

**Conflict-of-interest statement:** The authors report no conflicts of interest. The authors alone are responsible for the content and writing of this paper.

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**Manuscript source:** Invited manuscript

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Received: September 25, 2018  
Peer-review started: September 25, 2018  
First decision: October 11, 2018  
Revised: October 23, 2018  
Accepted: October 31, 2018  
Article in press: November 1, 2018  
Published online: December 26, 2018

### Abstract

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most frequently used image-guided procedures in gastrointestinal endoscopy. Post-ERCP pancreatitis is an important concern, and prophylaxis, cannulation and other related technical procedures have been well documented by endoscopists. In addition, medical radiation exposure is of great concern in the general population because of its rapidly increasing frequency and its potential carcinogenic effects. International organizations and radiological societies have established diagnostic reference levels, which guide proper radiation use and serve as global standards for all procedures that use ionizing radiation. However, data on gastrointestinal fluoroscopic procedures are still lacking because the demand for these procedures has recently increased. In this review, we present the current status of quality indicators for ERCP and the methods for measuring radiation exposure in the clinical setting as the next quality indicator for ERCP. To reduce radiation exposure, knowledge of its adverse effects and the procedures for proper measurement and protection are essential. Additionally, further studies on the factors that affect radiation exposure, exposure management and diagnostic reference levels are necessary. Then, we can discuss how to manage medical radiation use in



these complex fluoroscopic procedures. This knowledge will help us to protect not only patients but also endoscopists and medical staff in the fluoroscopy unit.

**Key words:** Quality indicator; Fluoroscopic procedures; Endoscopic retrograde cholangiopancreatography; Diagnostic reference levels; Radiation exposure

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**Core tip:** Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most frequently performed image-guided procedures in gastrointestinal endoscopy. Among several quality measures of endoscopic procedures, including ERCP, radiation exposure is still not well documented. In the general population, medical radiation exposure is of great concern because of its rapid increase and potential carcinogenesis. International organizations have established diagnostic reference levels for proper use, which are now global standards. Therefore, radiation exposure represents the next quality indicator for ERCP. We must understand the adverse effects, the requirements for protection and other influencing factors. This knowledge will help us to protect patients, medical staff and endoscopists.

Hayashi S, Takenaka M, Hosono M, Nishida T. Radiation exposure during image-guided endoscopic procedures: The next quality indicator for endoscopic retrograde cholangiopancreatography. *World J Clin Cases* 2018; 6(16): 1087-1093  
URL: <https://www.wjgnet.com/2307-8960/full/v6/i16/1087.htm>  
DOI: <https://dx.doi.org/10.12998/wjcc.v6.i16.1087>

## INTRODUCTION

Endoscopic retrograde cholangiopancreatography (ERCP) is one of the most frequently used image-guided procedures in gastrointestinal endoscopy. Post-ERCP pancreatitis (PEP) is a major concern, and prophylaxis, cannulation and other related technical procedures have been well documented by endoscopists. Thus, many studies and guidelines have been reported for ERCP. Recently, the quality of endoscopic procedures has been a key focus in gastrointestinal endoscopy with the aim of promoting the best procedures. Generally, quality indicators for endoscopic procedures are assessed at three time points: preprocedure, intraprocedure and postprocedure<sup>[1]</sup>.

Radiation exposure during these procedures seems to be of less concern; such exposure is not well documented, and little data on this topic has been collected to date<sup>[2]</sup>. However, in the general population, medical radiation exposure is of great concern because of its rapidly increasing frequency and its potential carcinogenic effects, which can be evaluated based on the linear no-threshold model<sup>[3-6]</sup>. International organizations,

such as the International Commission on Radiological Protection (ICRP), the International Atomic Energy Agency, and the United Nations Scientific Committee on the Effects of Atomic Radiation and radiological societies have attempted to keep medical radiation exposure as low as reasonably achievable (ALARA) by establishing diagnostic reference levels (DRLs)<sup>[7,8]</sup>.

The concept of DRLs was first introduced by ICRP 73<sup>[9]</sup>, and ICRP 103 and ICRP 105 emphasized the important role of DRLs as a tool for optimizing patient protection during diagnostic procedures<sup>[8,10]</sup>. ICRP 135 recommends that all individuals who are involved in subjecting a patient to a medical exposure should be familiar with the DRL process as a tool for optimizing protection<sup>[11]</sup>. Currently, the DRL is the global standard for all procedures that use ionizing radiation. The DRL guidelines have been updated in each region by each radiological society. However, there is still not enough data available on radiation exposure for gastrointestinal fluoroscopic procedures, such as ERCP, interventional *endoscopic ultrasound*, small bowel endoscopy, and enteral stent placement, which are still being developed and have recently been used with increasing in frequency.

In this review, we present the current status of quality indicators for ERCP, including the affiliated fluoroscopic procedures, especially in terms of medical radiation and DRLs. Then, we discuss how to approach radiation exposure management for this image-guided procedure, which is inherently complex<sup>[12]</sup>.

## EXISTING QUALITY INDICATORS AND WHAT WE NEED TO KNOW NOW

ERCP is the major image-guided, high-risk procedure in gastrointestinal endoscopy, and its objective has changed from diagnostic to therapeutic purposes<sup>[13]</sup>. ERCP has various therapeutic applications, and although these applications are relatively less invasive than the previously employed surgical procedures, they are more invasive than the previous applications of ERCP<sup>[14]</sup>. Therefore, gastrointestinal societies have set guidelines for ERCP and tried to improve the quality of the procedure<sup>[1]</sup>. The American Society for Gastrointestinal Endoscopy (ASGE) refers to quality indicators in the following three categories: (1) indication, sedation and informed consent are preprocedure quality indicators; (2) cannulation, the procedure success rate, the radiation dose and fluoroscopy time are intraprocedure quality indicators; and (3) reporting and adverse events are postprocedure quality indicators<sup>[1]</sup>. Among these quality indicators, indication is one of the most important factors for avoiding unnecessary procedures. PEP is a major adverse event and can become life threatening<sup>[15-17]</sup>. Selective deep cannulation is an important component of successful ERCP and is also related to PEP<sup>[18]</sup>. There are, however, few statements about radiation exposure as a quality indicator.

**Table 1** Dose metrics and units for radiation exposure during endoscopic retrograde cholangiopancreatography or other image-guided procedures from each society and the associated diagnostic reference levels

Society	Year	Procedure	Numerical number	Metric	Unit
ESGE <sup>[2]</sup>	2012	ERCP	55-347	ESD	mGy
			3-333	KAP	Gy.cm <sup>2</sup>
ASGE <sup>[1]</sup>	2015	ERCP	Not listed	Radiation dose	mGy
				FT	
ASGE-DDW supplement <sup>[39]</sup>	2018	ERCP	Not listed	Dose RP	mGy
				DAP	μGy.m <sup>2</sup>
				Dose rate	mGy/min
Japan DRLs <sup>[32]</sup>	2015	IVR	20	Dose rate	mGy/min
EC DRLs <sup>[30]</sup>	2014	ERCP	30-45	DAP	Gy.cm <sup>2</sup>
UK NDRL <sup>[35]</sup>	2016	Biliary intervention	43	DAP	Gy.cm <sup>2</sup>
			14	FT	min
German DRL <sup>[31]</sup>	2013	ERCP	2500	DFP	μGy.m <sup>2</sup>
ARPANSA DRL survey <sup>[62]</sup>	ongoing	ERCP/IVR	Not listed	Reference dose	Gy
				DAP	Gy.cm <sup>2</sup>
				Frame rate	fr/sec
				Total frames	number
ACC/HRS/NASCI/SCAI/SCCT expert consensus <sup>[63]</sup>	2018	Cardiovascular intervention	Not listed	Air kerma	Gy
				KAP, DAP	Gy.cm <sup>2</sup>

ESD: Entrance skin dose; KAP: Kerma-area product; FT: Fluoroscopy time; Dose RP: Dose reference point; DAP: Dose-area product; DFP: Dosis-flächenprodukt (Dose-area product); ERCP: Endoscopic retrograde cholangiopancreatography; DRLs: Diagnostic reference levels; ESGE: European society of gastrointestinal endoscopy; ASGE: American society for gastrointestinal endoscopy.

Among the quality indicators for ERCP, the ASGE recommends that the fluoroscopy time and radiation dose be measured and emphasizes reducing patient exposure according to the ALARA principle, but no numerical levels are provided (Table 1). The European Society of Gastrointestinal Endoscopy (ESGE) provided specific numerical levels of radiation exposure for ERCP in its guidelines for radiation protection in digestive endoscopy in 2012; the recommended entrance skin dose (ESD) was 55-347 mGy, and the recommended kerma-area product (KAP) was 3-333 Gy.cm<sup>2</sup> based on six previous reports that included a total of 608 procedures<sup>[19-25]</sup>. The ESGE, however, has also commented that the available information regarding DRLs for ERCP is limited<sup>[2]</sup>.

Presently, although endoscopists can use the available guidelines for ERCP to assess the procedural indication, the ordinal PEP rate, the perforation rate and the cannulation rate as quality indicators<sup>[1]</sup>, most endoscopists cannot determine how much radiation exposure actually occurs during ERCP or determine the proper level of radiation exposure for a specific procedure. Thus, radiation exposure is an important quality indicator that requires further investigation due to the issues discussed in the following sections.

## INCREASING MEDICAL RADIATION AND ITS ADVERSE EVENTS

To understand medical radiation exposure, it is first necessary to understand the background and current status of medical radiation. Ionizing radiation has contributed to medical innovations since its discovery,

including methods such as X-ray, fluoroscopy, computed tomography (CT), scintigraphy and radiotherapy, and the use of these procedures has recently increased due to increasing demand. On the other hand, we have recognized the adverse effects of medical radiation, which have been reported since approximately 2000.

The National Council of Radiation Protection and Measurements reported that the annual medical radiation exposure in the United States general population had increased from 15% in the early 1980s to 48% in 2006<sup>[26]</sup>. Similarly, the United Nations Scientific Committee on the Effects of Atomic Radiation reported that medical radiation is increasing with the progression of medical care worldwide, and the number of medical units is growing, as represented by CT and other diagnostic procedures<sup>[7]</sup>. Consequently, we are concerned about the adverse effects of radiation related to increasing medical radiation exposure.

The adverse effects of radiation are mainly divided into two types: deterministic risks and stochastic risks. The former category incorporates the threshold dose, as represented by skin injury<sup>[27]</sup>. The Food and Drug Administration stated that the typical threshold for the absorbed radiation dose is 2 Gy<sup>[28]</sup>, and the ICRP recommends that the maximum cumulative absorbed dose for repeated procedures should be 1 Gy<sup>[29]</sup>. The latter risk category is related to the amount of total radiation exposure (linear no-threshold model), as represented by the cancer risk<sup>[6]</sup>. A total radiation exposure of 1 Sv is estimated to carry a 5% lifetime risk of cancer<sup>[12]</sup>. We should minimize both risks by understanding the threshold, the limit dose and the cumulative dose used for each patient.



## UNDERSTANDING THE DRL AND MANAGING RADIATION EXPOSURE DURING ERCP

To understand the radiation dose actually used and determine whether the dose is high in each procedure, we must set a reference level. This concept is precisely encompassed by DRLs, which serve as the current quality indicators for ERCP. The concept of DRLs was introduced by ICRP 73<sup>[9]</sup> in 1996, and concrete numerical levels were set by ICRP 103 in 2007<sup>[8]</sup>. Currently, DRLs are the global standards for all procedures that use ionizing radiation, and DRLs have been determined for almost all diagnostic procedures. Every procedure utilizing X-ray, CT or scintigraphy has been updated in each region<sup>[30-35]</sup>.

Detailed DRLs have been established for therapeutic image-guided procedures, such as percutaneous coronary intervention and interventional radiology, but not for endoscopic procedures, including ERCP (Table 1). Generally, DRLs are set by the 75th percentile value and are determined from a large amount of radiation dose data for each procedure<sup>[11]</sup>. However, therapeutic interventions have objectives and outcomes that differ from those of diagnostic procedures.

Procedural variations, including variations in procedure time, fluoroscopy time and radiation dose, can result in a wide range of values<sup>[36]</sup>, and a single DRL has not yet been established for ERCP because each DRL is designated for an individual CT location, such as the head, spine, chest or abdomen. Therefore, a sufficient amount of data and an applicable, simple classification scheme are necessary to set the DRL for ERCP.

## IMAGE-GUIDED PROCEDURES: HOW SHOULD THEIR COMPLEXITY BE APPROACHED?

An applicable classification scheme for the wide range of established DRLs seems to be necessary. In German DRLs, the angio-therapy classification divides aneurism treatment into three locations: the thoracic artery, the infrarenal artery and the suprarenal abdominal aorta. Similarly, percutaneous transluminal angioplasties are divided into three locations: the pelvis, the thigh with the knee and the lower leg with the foot<sup>[31]</sup>. Hence, simply dividing the procedure into three or four classifications may be preferable for ERCP<sup>[37]</sup>. We also previously reported a simple classification based on disease site (common bile duct stones, proximal malignant biliary obstruction, distal malignant biliary obstruction and other). Consequently, different classifications result in clearly divided outcomes and may be helpful for accurately determining DRLs<sup>[36]</sup>.

Image-guided procedures such as ERCP present another problem in determining DRLs. ERCP inherently requires fluoroscopy and characteristically includes

both standard radiography and cineradiography, which utilizes rapidly changing levels of radiation exposure. The moment-to-moment dynamic outcomes are generally explained by the following four fundamental factors: (1) magnification; (2) frame rate; (3) focus area and (4) moving field of view. These four factors automatically change the output from moment to moment. The flexibility of fluoroscopy makes it difficult to predict the final exposure level from the initial settings, in contrast to roentgenography or CT. Consequently, there are many difficulties in this field, and the ICRP has characterized image-guided procedures by their complexity<sup>[12]</sup>. We must be aware of the inherent nature of ERCP when evaluating the data and establishing appropriate DRLs.

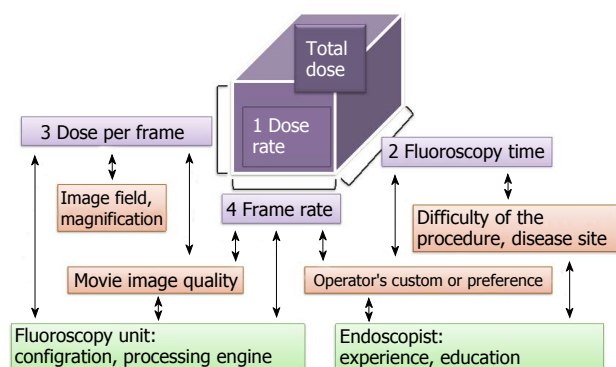
## MEASURES OF RADIATION EXPOSURE FOR FLUOROSCOPIC PROCEDURES

Dose metrics and units for radiation exposure in medical imaging modalities such as radiography, CT and fluoroscopy have been systematically defined by international organizations<sup>[11,38]</sup> and are used globally in the management of patient radiation doses. Among these metrics, those used in fluoroscopy are more diverse because of the wide variety of clinical applications; in addition, dose metrics and units have not been clearly specified for some fluoroscopic procedures. Consequently, various DRLs and guidelines use varying dose metrics and units, which results in confusion for endoscopists (Table 1). Moreover, there are many definitions of the relevant measures, which present difficulty for endoscopists who are not familiar with these definitions.

The ESGE refers to ESD in mGy and KAP in Gy.cm<sup>2</sup>, while the ASGE refers only to radiation dose and fluoroscopy time without providing numerical levels<sup>[1,2]</sup>. Faigel<sup>[39]</sup> and his colleagues<sup>[40]</sup> reported fluoroscopy time, dose-area product (DAP) in  $\mu\text{Gy.m}^2$  and dose reference point (dose RP) in mGy. Among the radiological societies, only the European Commission reported the radiation dose of ERCP as DAP in Gy.cm<sup>2[30]</sup>, and the German DRL was provided as the Dosis-flächen-produkt (DFP, or dose-area product) in  $\mu\text{Gy.m}^2[31]$ . In the field of interventional radiology, the Japanese DRL provides the dose rate in mGy/min<sup>[32]</sup>, the UK National DRL is presented as the DAP in Gy.cm<sup>2</sup> and the American College of Cardiology expert consensus uses air kerma in Gy and DAP with KAP in Gy.cm<sup>2[41]</sup>. Therefore, establishing a uniform measurement among the medical societies might be the first step in establishing DRLs, which represent the next quality indicators for ERCP.

## FACTORS INFLUENCING THE RADIATION DOSE

The total radiation dose (ESD, air kerma or dose RP) is approximated by the integrated value of fluoroscopy



**Figure 1** A model of the approximate calculation for total radiation dose during fluoroscopy and the relationships among the influencing factors. Total Dose = 1Dose Rate  $\times$  2Fluoroscopy Time; 1Dose Rate = 3Dose/Frame  $\times$  4Frame Rate. Here, total dose indicates the air kerma, entrance skin dose or radiation dose. Dose-area product/kerma-area product is not applied. Technically, the total dose must be added from standard radiography and cineradiography.

time, dose per frame and frame rate, as shown in Figure 1. Several factors affecting the radiation dose during image-guided procedures have been reported. For example, high-volume endoscopists can achieve lower radiation exposure<sup>[42-45]</sup>. In addition, brief educational program for endoscopists or a flashing warning light in the fluoroscopy unit can be effective for reducing radiation exposure<sup>[46,47]</sup> because fluoroscopy time is related to radiation exposure<sup>[40,48]</sup>. With regard to the fluoroscopy unit, pulsation, static fluoroscopy, C-arm, low pulse rate and the distance between the monitor and the endoscope can help to reduce the total radiation dose<sup>[19,49-54]</sup>.

Recently, some image-enhancing technologies, centre volume and local DRL guidelines have also been shown to influence the total radiation dose delivered to patients<sup>[36,55-58]</sup>. The simplest and most effective ways to reduce the total radiation dose are: (1) using a low frame rate; (2) using low magnification and (3) employing a short fluoroscopy time. A lower frame rate can reduce the dose per second, which impairs the image quality, resulting in a jumpy image or an afterimage. Similarly, lower magnification reduces the dose per frame but also results in lower spatial resolution. These two factors must be considered according to the ALARA principle. A better processing engine, such as a graphics processing unit, can help this problem. Finally, fluoroscopy time is strongly associated with the procedure time and the difficulty of the procedure<sup>[59,60]</sup>. Fluoroscopy time is often managed by the operators according to their preferences, but communicating the need for caution or providing education to operators can improve the fluoroscopy time and radiation exposure<sup>[46,47,61]</sup>.

## PERSPECTIVES

We need to set DRLs for all fluoroscopic procedures in the gastrointestinal field, including ERCP, interventional endoscopic ultrasound, balloon-assisted enteroscopy, enteral stenting and ileus tubing. Consequently,

endoscopists will know how much radiation to use and whether the delivered radiation level is higher or lower than the reference level. Then, we will be able to discuss how to manage medical radiation in fluoroscopic procedures. Developing DRLs will help us to protect not only patients but also medical staff and endoscopists in the fluoroscopy unit.

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