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Our Experience Using the SCORE PRO Advance, New Low-Dose Fluoroscopic Image Processing, for Pancreaticobiliary Regions

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At the 55th Annual Meeting of the Japan Biliary Association (from October 3rd to 4th, 2019), Shimadzu conducted a luncheon seminar jointly with the association on October 3rd. With Masahiro Serikawa,Ph.D., Clinical Lecturer, Department of Gastroenterology and Metabolism, Graduate School of Biomedical & Health Sciences, Hiroshima University invited to chair the seminar, a presentation entitled "Our Experience Using the SCORE PRO Advance, New Low-Dose Fluoroscopic Image Processing, for Pancreaticobiliary Regions" was given by Yoshitaka Nakai, M.D., Deputy Director, Department of Gastroenterology, Digestive Disease Center, Kyoto Katsura Hospital. This article provides a summary of that presentation.

1. Introduction

Given the importance of interventional radiology (IVR) examinations such as endoscopic retrograde cholangiopancreatography (ERCP), endoscopic ultrasonography (EUS), or percutaneous transhepatic procedures to diagnose and treat patients with biliary tract or pancreatic disorders, X-ray R/F systems have become essential equipment for those examinations. However, to ensure the accuracy and safety of such examinations, the systems must provide high image quality and easy operability. Of course, because fluoroscopy systems emit radiation, users must be constantly mindful of radiation dose levels. On the other hand, survey results of medical staffs by Okuyama, et al. indicated that "Many medical staffs are inadequately aware of radiation exposure."[1)] Therefore, in an effort to increase interest in X-ray fluoroscopy examinations and proceed responsible diagnostic and treatment practices that minimize radiation dose levels to patients, I would like to report our experience with using the SCORE PRO Advance, new low-dose fluoroscopic image processing, based on basic knowledge about X-ray fluoroscopy examinations and our actual operations at our Digestive Disease Center.

2. Fundamentals of X-Ray Fluoroscopy Examinations

Some possible reasons for the low interest in X-rays even among many medical staffs could be that X-rays are not visible, their interest is focused on endoscopy or other procedures, and that harm from X-rays is not immediate.

Therefore, to gauge the physician interest level at our center, we asked each physician the following question. "How is the character for 'Hibaku' (X-ray radiation exposure) written (in Japanese)?" The correct answer is "被ばく". However, many answered "被爆" or "被曝". "被爆" means being bombed specifically by an atomic or hydrogen bomb. In contrast, "曝" of "被曝" is not among standard characters recommended for common use by the Japanese government. Therefore, it is officially written as "被ばく" using the phonetic symbols of "ばく" (baku) in regulatory guidelines, newspapers, and academic papers related to X-ray radiation. Occasionally, I notice it written "被曝" in papers about the digestive system, however. I hope learning this basic fact will serve as a first step toward having an interest in radiation exposure.

X-ray R/F systems essentially are an X-ray detecting system that can rapidly collect X-ray and output the images. By rapidly acquiring a series of X-ray images and connecting them together, the images can be made to appear as a video, which is analogous to flip-book animation. By acquiring about 30 images per second, the eyes are able to recognize the sequence of still images as a moving image. However, such fluoroscopic images are acquired using far lower radiation dose levels than that for normal radiography images, so the resulting fluoroscopic images appear grainy. Generally speaking, fluoroscopic image quality

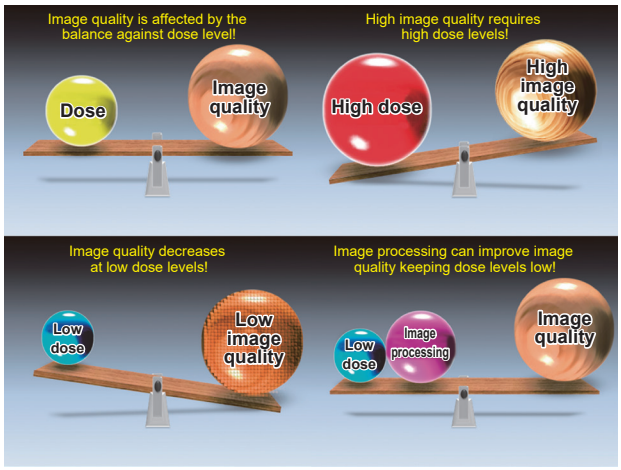


Fig.1 Balance between Fluoroscopic Image Quality and Dose Level

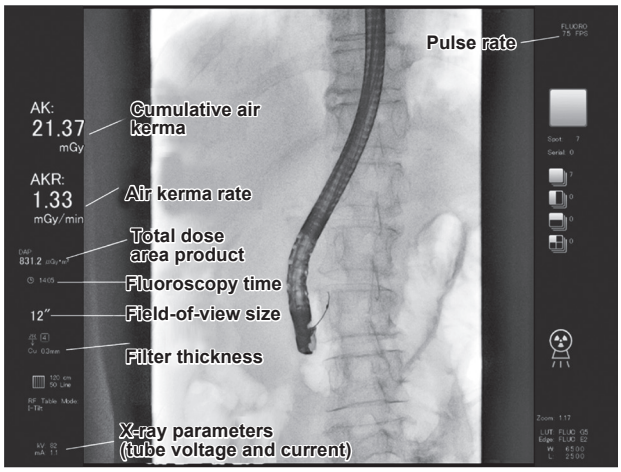


Fig.2 Fluoroscopy Parameters Displayed on the Fluoroscopy Monitor

improves as dose level is increased and image quality deteriorates as the dose is decreased **(Fig. 1)**. Advantages of higher image quality include improved visibility, less eye strain, and shorter examination times for the healthcare personnel and safer, more reliable, and more accurate examinations for patients. On the other hand, achieving higher image quality requires applying higher X-ray dose levels, which can cause radiation problems by the e direct or scattered X-rays.

Recently, Itoi, Kiso, et al. reported that “scattered radiation protective cloth for fluoroscopy systems is effective in reducing exposure to scattered radiation (about 80 to 90 % reduction of scattered X-rays).”.[2),3)] Consequently, many facilities, including our center, have started using such protective cloth. Results from verifying the effectiveness of the protective cloth to reduce scattered radiation exposure levels at our center indicated an 87.1 % reduction in exposure to the physician. However, considering that we know about the probabilistic effect where the higher the radiation dose level, the higher the risk of cancers, leukemia or other genetic effects, that reports indicate bodily effects cannot be ruled out even at low dose levels below 100 mSv[4)-6)], and that the protective cloth cannot be used in some situations, we must continue to strive to minimize exposure levels.

The X-ray dose rate at the patients undergoing interventional procedures for the pancreaticobiliary system is roughly 10 to 20 mGy/min. The guideline for radiation dose used for cardiovascular interventions specifies a maximum 2 Gy as the threshold value for deciding to stop the procedure.[7)] The 2006 Japanese Guideline for Medical Radiation Exposure specifies less than 25 mGy/min as a target value for reducing dose levels in radiological examinations and treatments.[8)] If an examination lasts a long time, the cumulative dose must be monitored at all times during the examination.

Recent fluoroscopy systems display various information on the fluoroscopy monitor screen **(Fig. 2)**, which means physicians and other medical staffs need to perform examinations responsibly with paying attention to not only the fluoroscopic images, but also those numerical values displayed.

3. X-Ray Fluoroscopy Examinations at the Digestive Disease Center

Our Digestive Disease Center treats pancreaticobiliary disorder cases mainly under the direction of three advising physicians and performs about 400 fluoroscopy examinations per year.

The use of X-ray fluoroscopy examinations can vary depending on the facility size, number of medical staffs, and what is involved in the examinations.

There are two basic system styles available for X-ray R/F systems in Japan: Over-tube table models and C-arm types. The over-tube models are configured with the tube positioned over the table and the detector installed under the table-top. Whereas C-arm models can position the tube under or over the table, whichever. The advantages and disadvantages of each configuration are summarized in **Table 1**. Selection between those two configurations depends on whether the system will be used exclusively for pancreaticobiliary procedures or also for gastrointestinal and other examinations/procedures. Because our center uses the system not only for pancreaticobiliary procedures, but also for gastrointestinal procedures, we selected a system with an over-tube configuration, due to its advantages of broad applicability, large table area, large space

Table 1 Advantages/Disadvantages of Over-tube vs C-Arm Models

Comparison between Over-tube models and C-Arm Models

	Over-tube table	C-Arm table
Broad Applicability	High	Low
Installation Space	Small	Large
Image Quality	Stable	Good
Observable Range	Narrow	Wide
Working Space	Large	Small
Scattered X-Ray Radiation	High	Low
Price	Reasonable	Expensive

between the table and tube that makes it easier to perform procedures, the space-saving size, and the sturdy and stable system structure.

We think using protective cloth to block scattered radiation can sufficiently mitigate the over-tube system's disadvantage of higher radiation dose to physicians, compared to under-tube models.

As for our staff operation including even for emergencies, we always work as a team of at least four professionals, consisting of a physician, assistant, nurse, and radiological technologist, to ensure examinations are performed safely and reliably. Sometimes, physicians can become so focused on operating the endoscope or watching the fluoroscopic image that they accidentally continue emitting fluoroscopic radiation. That can occur more, if the examination time becomes longer in the difficult procedure cases, or if the physician is not much experienced. To minimize such risks, our center assigns a dedicated radiological technologist to regular examinations. That technologist can adjust or switch the types of radiography modes indicated in **Table 2** with his experience to understand the intentions of the physician, and provide optimal image quality and X-ray dose levels. Furthermore, the technologist helps reduce exposure dose levels by switching fluoroscopy ON or OFF by his decision. In addition, he also contributes to early discovery of any adverse events by observing the overall examination from outside the examination room and pointing out any guidewire or device problems overlooked by the physician or assistant.

Our approach at the Digestive Disease Center is to assign a dedicated radiological technologist and share responsibilities, so that we can perform examinations safely, smoothly, and less stressfully, while also making every effort to minimize unnecessary radiation exposure.

Table 2 Adjustable functions that can affect Fluoroscopic Image Quality

Switching and Adjusting Radiography Modes

- ✓ High image quality (high dose mode) ↔ Low image quality (low-dose mode)
- ✓ Adjust pulse rate of pulsed fluoroscopy (15 ↔ 3.75 fps)
- ✓ Enlarge ⇔ reduce field-of-view size (17 ↔ 6 inches)
- ✓ Adjust the irradiation field using the collimator
- ✓ Adjust contrast or brightness
- ✓ Move image to region of interest
- ✓ Adjust observed area by oblique projection of X-ray

It is excellent at our Center to assign a dedicated radiological technologist and share responsibilities, so that we can perform examinations safely, smoothly, and less stressfully, while also making every effort to minimize unnecessary radiation exposure.

4. Our Experience Using SCORE PRO Advance

The Digestive Disease Center introduced a Shimadzu SONIALVISION G4 fluoroscopy system in October 2016 for endoscopic diagnosis and treatment. In September 2018, we started using the SONIALVISION G4 in combination with its Super Low Dose mode in the SUREengine FAST (digital image processing software which can reduces X-ray dose levels without decreasing pulse rate) for pancreaticobiliary endoscopy. Then recently, in July 2019, we introduced SCORE PRO Advance on a trial basis, which we evaluated at our center using phantoms **(Fig. 3)** and actual clinical use. That experience is described below.

SCORE PRO Advance is intended for maintaining image quality even at low dose levels, by (1) graininess improvement, (2) image lag reduction, and (3) improvement of device visibility through edge enhancement. Three modes are available for fluoroscopy —the high image quality mode (ERCP2), standard mode (ERCP (LD: Low dose) 2), and low-dose mode (ERCP (LD) 3) **(Table 3-a)**. In addition, the pulse rate can be changed to 15, 7.5, or 3.75 fps for pulsed fluoroscopy. **Fig. 4** shows the image quality obtained with each mode at 7.5 fps. Assuming the dose at 15 fps in the high image quality mode as

Fig.3 Evaluation of SCORE PRO Advance using a Phantom at our Digestive Disease Center

Table 3 a) SCORE PRO Advance Fluoroscopy Mode Settings

Procedure	Fluoroscopy Mode (Fluoroscopy dose)	Cu Filter Added (mm thick Cu)	Pulse Rate (Default Setting)
ERCP2 (High Quality Mode)	Pulse N	0.1	7.5fps
ERCP (LD) 2 (Standard Mode)	Pulse L2	0.3	7.5fps
ERCP (LD) 3 (Low-Dose Mode)	Pulse L3A	0.3	7.5fps

Table 3 b) Dose Reduction Ratio for Each SCORE PRO Advance Fluoroscopy Mode and Frame Rate Setting (1)

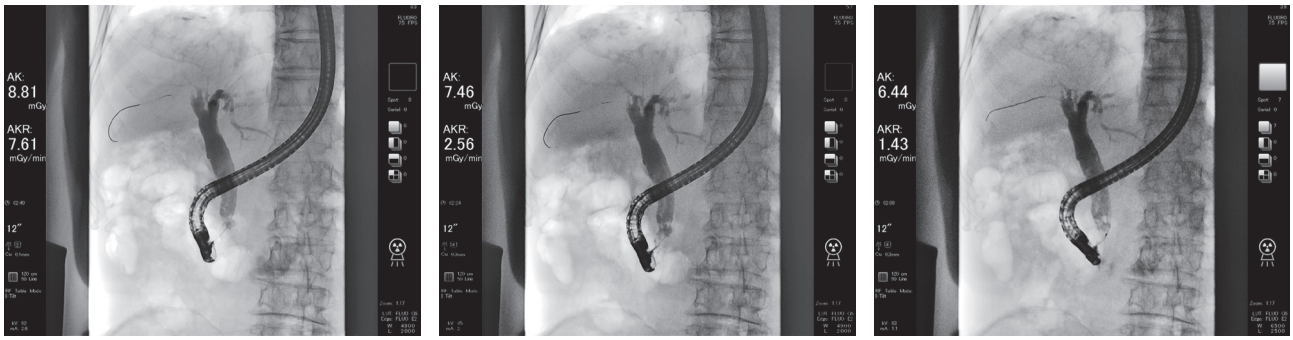
Procedure	15 fps	7.5 fps	3.75 fps
ERCP2 (High Quality Mode)	100%	50%	25%
ERCP (LD) 2 (Standard Mode)	40%	20%	10%
ERCP (LD) 3 (Low-Dose Mode)	23%	11.5%	5.75%

Table 3 c) Dose Reduction for Each SCORE PRO Advance Fluoroscopy Mode and Frame Rate Setting (2)

Procedure	15 fps	7.5 fps	3.75 fps
ERCP2 (High Quality Mode)	100%	50%	25%
ERCP (LD) 2 (Standard Mode)	40%	20%	10%
ERCP (LD) 3 (Low-Dose Mode)	23%	11.5%	5.75%

100%, the dose level can be reduced to 40 % or 20 % at 15 or 7.5 fps in the standard mode **(Table 3-b)**, or to 23 % or 11.5 % at 15 or 7.5 fps in the low-dose mode **(Table 3-c)**.

As a result of performing pancreaticobiliary examinations using SCORE PRO Advance and changing the mode appropriately for various cases, we discovered that the resolution level required for images differs depending on the type of each procedure **(Table 4)**. Using minimum image quality at 7.5 or 3.75 fps in the low-dose mode has minimal impact on procedures such as endoscope insertion or cannulation and 7.5 fps in the low-dose or standard mode provides adequate image quality even for placing plastic stents in biliary ducts or stents in pancreatic ducts. When selectively inserting a guidewire, removing a stone, or placing a metal stent in a biliary or pancreatic duct, it can be difficult to achieve adequate contrast between the biliary or pancreatic duct and the devices on the images. Such cases normally required high image quality, but we found the 7.5 fps setting in the high image quality mode was adequate for most cases. We also found that we could perform examinations more efficiently by first acquiring a radiography image and then referencing that on a second screen positioned next to the first(acquisition) screen. In cases that require more detailed image evaluation of lesion part, overall it is important to perform contrast fluoroscopy at low dose levels and then evaluate by radiography images acquired as appropriate rather than to perform contrast fluoroscopy at high dose levels for a long time.



ERCP2: High Quality Mode **ERCP (LD) 2: Standard Mode** **ERCP (LD) 3: Low-Dose Mode**

Fig.4 Comparison of Image Quality for Each Mode (Case of Choledocholithiasis)

Table 4 Resolution Required for Fluoroscopic Images in Various Procedures

Required resolution level differs for each procedure.

Metal stent placement	High
Stone removal	
Guidewire operations	
Plastic stent placement	
Contrast fluoroscopy	
Cannulation of biliary or pancreatic duct	
Scope insertion	Low

In addition, patient factors that can affect image quality include body thickness, quantity and position of intestinal gases, and respiration depth and count. The thicker the body or the more intestinal gases overlap with the region of interest, the less sharp images will be. Similarly, the greater the depth and number of breaths, the more image lag that will occur, which can cause inadequate recognition in the region of interest or of devices. Such cases require either switching to a high image quality mode or increasing the frame rate.

5. Summary

SCORE PRO Advance maintained adequate image quality necessary for normal pancreaticobiliary endoscopy procedures even at low radiation dose levels. It is especially recommended for facilities that intend to ensure pancreaticobiliary procedures are performed safely, reliably, and responsibly.

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