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Cutting Edge of ERCP
—Experience Using the SONIALVISION G4 and Reducing Scattered Radiation Dose Levels

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On October 4th, Shimadzu and the Japanese Society of Radiological Technology joinly held a luncheon seminar at the 46th Autumn Scientific Congress of (from October 4 to 6, 2018). Hiroshi Hirano, R.T. (Director, Clinical Technology Department, Marunouchi Hospital) chaired the seminar, and Yoshitaka Nakai, M.D. (Deputy Director, Department of Gastroenterology, Digestive Disease Center, Kyoto Katsura Hospital) gave a presentation entitled "Cutting Edge of ERCP." This article provides an overview of that presentation.

1. Introduction

As you know, ERCP is an acronym for Endoscopic Retrograde CholangioPancreatography. ERCP has a long history, and in 1968, Dr. William S. McCune of the United States was the first to successfully produced a contrast image of the pancreatic duct[1]. This is the origin of ERCP, the year of 2018 is the 50th anniversary since ERCP was developed. In 1969, the year after the first successful pancreatography, Oi[2], Takagi[3], et al succeeded in the first pancreatography in Japan. Later, as additional techniques and devices related to ERCP were developed, the method became an essential examination method for diagnoses and procedures for disorders of the biliary tract and pancreas. However, even though ERCP has a long history as an examination method, diagnostic ERCP involves a risk of accidental postoperative pancreatitis. Consequently, ERCP is often substituted in recent years with MRCP or endoscopic ultrasonography (EUS), which can now be used to diagnose many disorders.

This article reports on our current status of ERCP at our facility, cooperation with radiological technologists, measures to reduce scattered radiation dose, and our experience using a Shimadzu SONIALVISION G4 Multi-purpose Digital X-ray R/F system.

2. Current Status of ERCP at the Digestive Disease Center

Our hospital, which is located in the Nishikyo Ward of Kyoto City and is a facility with 585 licensed beds, mainly provides acute care and regional cancer treatment center for the western part of Kyoto City, Kameoka City, and the Otokuni region **(Fig. 1)**. The Digestive Disease Center is divided into departments for internal medicine and surgery, and the internal medicine department is further divided into departments for gastrointestinal, hepatic, biliopancreatic, and chemotherapy. The Digestive Disease Center is also designated as an instructional facility for the Japanese Society of Gastroenterology, Japan Gastroenterological Endoscopy Society, and the Japan Biliary Association. The biliopancreatic department performs procedures related to biliary and pancreatic systems, including outpatient and inpatient ERCP and endoscopic ultrasonography examinations under the supervision of three advising physicians.

Fig.1 Hospital Information

Though the need for diagnostic ERCP is declining due to the introduction of MRCP and endoscopic ultrasonography, the number of ERCP examinations at our center is almost flat **(Fig. 2)**. That is probably due to the aging of the population and an increase in emergency patients and biliary tract cancer patients after the hospital strengthened emergency medical care capabilities and cancer treatment partnerships. It seems to be in the similar tendency nationally, because the aging will advance further in future.

During the period from January to December 2016, our facility treated 326 ERCP cases (with an average age of 74.2). Out of those, 44 % involved disorders related to stones in the biliary tract and 40 % involved malignancies, including pancreatic and biliary tract cancers **(Fig. 3)**. In the case of biliary tract stones, common bile duct stones are mainly treated with endoscopic sphincterotomy (EST) and endoscopic stone removal and the cholangial drainage is performed for acute cholangitis. For malignancies, pancreatic juice aspiration cytological examination for early diagnosis of pancreatic cancer, a definitive diagnosis or a disease range diagnosis for biliary tract cancers, or a stent implantation for obstructive jaundice are treated. In addition, we remove pancreatic stones or implant stents in the pancreatic duct for chronic pancreatitis. We also handle acute cholangitis cases that require emergency drainage 24-hour a day. In fact, in our center in 2016, the proportion occupied by emergency ERCP cases was 17.5% of the whole. The number of these cases is expected to increase nationwide as the number of patients with biliary tract stones increases due to aging.

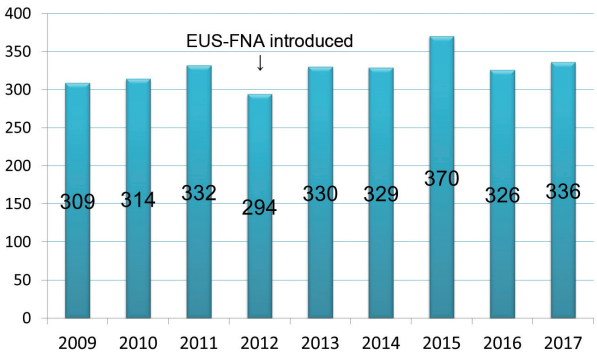


Fig.2 Total ERCP Cases at the Digestive Disease Center by Year
Number of ERCP examinations did not decrease even after advancements in MRCP or introduction of EUS-FNA.

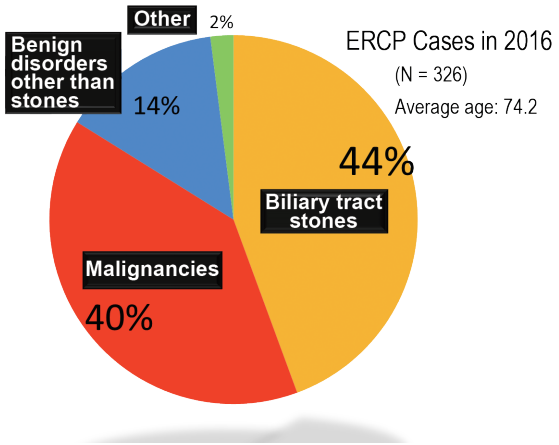


Fig.3 ERCP Cases in our facility in 2016 by Disorder Type

3. Cooperation Between Radiological Technologists and Endoscopists

Even in the emergency, ERCP is carried out in the system of over four medical professionals of a physician, assistant, nurse, and radiological technologist in our facility. Currently, at almost all facilities, the physician is the person that actually operates the X-ray R/F system, even at high-volume facilities in the Kyoto-Shiga region. Normally we always assign an appointed radiological technologist to every ERCP procedure, and the merit is explained as follows. During examinations, since the physician focuses on operating the endoscope, watching the fluoroscopy monitors, and monitoring vital signs, the more difficult the examination is, and the more inexperienced the physician tends to narrow his field of vision. It is easy to imagine that the field of view becomes narrow further more when the operation of the X-ray R/F system is added. It is considered that it inevitably leads to increase of fluoroscopic dose and scattered radiation exposure dose and overlooking of the accident diseases. For that reason, our facility assigns an appointed radiological technologist. Their role is not only to manage the X-ray R/F system but also to accurately depict fluoroscopic images and imaging positions required by physicians by sharing examination procedures before examination. Therefore, the switching of the fluoroscopy on/off and the switching of the fluoroscopy mode can be performed at an appropriate timing, to avoid unnecessary fluoroscopy by the operator and to reduce radiation dose levels. They also use fluoroscopic images during and immediately after the examination to confirm location of the device or lesion in a wide field of view and contingencies such as "free air" or leakage of contrast material. Technologists are also in charge of managing spot and dynamic images (fluoroscopic and endoscopic) and managing fluoroscopy exposure times. We believe that cooperation between the physician and an appointed radiological technologist is important for achieving safe, smooth, and less stressful examinations.

4. Measures to Reduce Scattered Radiation Dose Levels

If multiple ERCP examinations are required in the same case, the same physician, assistant, and nurse are assigned. Therefore, it is extremely important of countermeasures against radiation exposure of patients and the scattered radiation exposure of the medical personnel. Measures at our facility include (1) enhancement of lead X-ray protective gear, (2) reconsidering the X-ray parameter settings for X-ray R/F system, and (3) assigning appointed radiological technologists, as previously mentioned. Initial countermeasures in 2008 was only a protective apron, but later a neck guard and protective glasses were prepared. Then in 2015, protective cloth barriers (protection on four sides equivalent to 0.25 mmpb of lead, manufactured by Hoshina Co., Ltd.) were introduced over the X-ray R/F system to block scattered radiation **(Fig. 4)**. The scattered radiation protective cloth involves is used by directly covering the X-ray tube with a mesh-like cover, and suspending the lead protective cloth on the four sides with fastener tape. It is said to reduce scattered radiation levels by about 80 to 90 %.[4)]

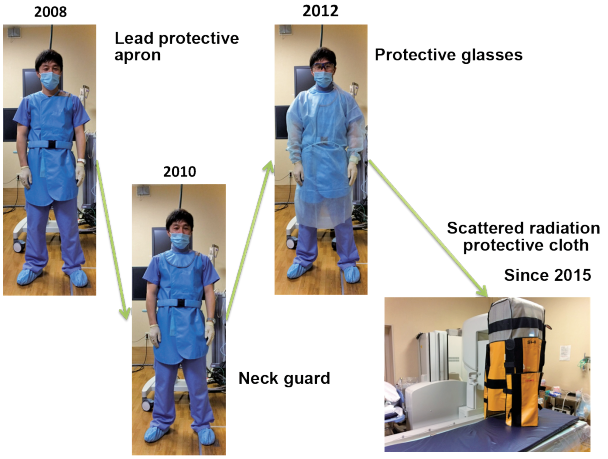
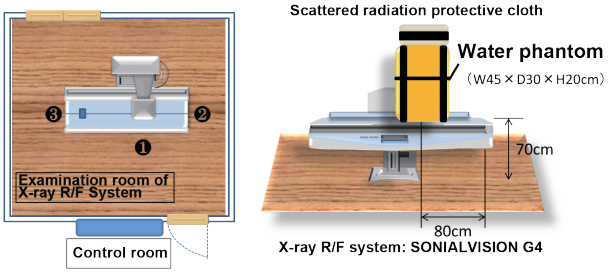


Fig.4 Enhancements of Lead X-Ray Protective Gear



Irradiation field: 12 × 12 inches
Measurement points: ❶ Physician, ❷ Assistant 1, and ❸ Assistant 2, about 80 cm above the floor
Remarks: Assumes ERCP use (tabletop height = 70 cm, center of X-rays = 80 cm from tabletop edge, toward ❷ (Assistant 1))
Measuring device: X-ray dosimeter (survey meter model: 451B-DE-SI-RYR, S/N: 1501)

Fig.5 Measurement of Air Dose Level in R/F Room

The measurement parameters and methods used to measure the effectiveness of the scattered radiation protective cloth installed at our facility is shown in **Fig. 5**. It reduced scattered radiation dose levels at the position of the physician by 87.1 %, at the position of assistant (2) at the head end by 66.6 %, and at the position of assistant (3) at the feet end by 62.0 % **(Table 1)**. It is particularly effective for the physician position, probably due to the higher scattered radiation levels near the X-ray tube.

We also examined the scattered radiation reduction levels for a variety of fluoroscopy parameters. Changes in scattered radiation levels were measured after changing filter thickness from 0.1 to 0.3 mm Cu and the pulse rate from 15 to 7.5 fps in X-ray R/F X-ray parameters. Decreasing the pulse rate reduced the scattered radiation dose level by up to 48.2 %, increasing the filter thickness reduced it by up to 55.3 %, and combination of decreasing the pulse rate and increasing the filter thickness reduced it by up to 76.0 % **(Table 2)**.

The condition of desirable fluoroscopy image required in ERCP are “good visibility” of endoscopy guide wires and devices, “excellent trackability” for the fluctuation of the respiration and the movement of the guide

Table 1 Effectiveness of Scattered Radiation Protective Cloth in Protecting against Scattered Radiation Dose
X-ray parameters: 93 kV/9.2 mA, 15 fps pulse, 0.1 mm Cu filter

Scattered Radiation Protective Cloth	Measurement Value (μSv/h)		
	❶	❷	❸
Without	5600	900	290
With	720	300	110
Reduction (%)	**87.1**	**66.6**	**62.0**

❶ Physician, ❷ Assistant 1, ❸ Assistant 2

Table 2 Reduction of Scattered Radiation Dose By Pulse Rate and Filter Thickness

X-Ray Parameters (kV/mA)	Pulse (fps)	Filter (mm Cu)	Measurement Value (μSv/h)			
			❶	Reduction	❷	❸
Pulse 15 N 93 / 5.2	**15**	**0.1**	5600 (720)	–	900 (300)	290 (110)
Pulse 7.5 N 93 / 2.6	**7.5**	**0.1**	2900 (310)	**48.2%**	420 (156)	148 (56)
Pulse 15 L2 90 / 4.2	**15**	**0.3**	2500 (300)	**55.3%**	400 (155)	135 (54)
Pulse 7.5 L2 90 / 2.1	**7.5**	**0.3**	1340 (162)	**76.0%**	210 (76)	69 (30)

❶ Physician, ❷ Assistant 1, ❸ Assistant 2, measurement values with scattered radiation protective cloth indicated in parentheses

wires, and “high resolution” biliary and pancreatic duct images for diagnostics **(Fig. 6)**. It is important to select the optimum fluoroscopic conditions based on examination contents and the purpose at the time in order to secure the quality of the examination and to reduce the exposure to scattered radiation.

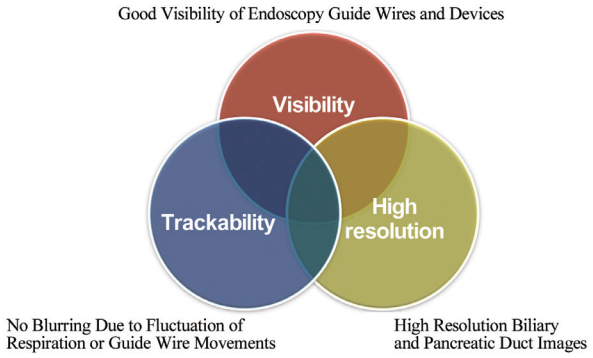


Fig.6 Desirable Fluoroscopy Image Required in ERCP

5. Experience Using the SONIALVISION G4

In our facility, Shimadzu SHIMAVISION POWER PRO system had been used as a X-ray R/F system for endoscopic diagnostic imaging and procedure, but Shimadzu SONIALVISION G4 system was newly introduced in October 2016. Our impressions from using the system were that (1) image quality and visibility were significantly improved, (2) two 19-inch LCD monitors installed in the examination room enabled to compare the fluoroscopy and radiography images and enable to ensure sufficient working space for examinations by the space saving design **(Fig. 7a)**, and (3) the process of recording, saving, and processing images was simplified. Though it is easy to forget the benefit of the good image quality, when it gets used to new X-ray R/F system, the difference in image quality is clear at a glance, when comparing it to the previous system. It also results in less eye fatigue after examinations and shorter examination times.

In the previous system, DVD recorders were required for both endoscopic and fluoroscopic images, respectively, and that caused various problems, such as recording errors, DVD media storage space requirements, and the time consuming for checking videos. Since SONIALVISION G4 is linked with the desktop computer located inside the control room, the endoscopic images and fluoroscopic images are displayed on the same sub-monitor screen using a picture-in-picture display mode **(Fig. 7b)**. Consequently, we can now record both endoscopy images and fluoroscopy images with the same time axis with a single click. That has eliminated recording errors and made it easy to check video images or process images immediately after examinations. That is not only helpful for checking procedures, but also for teaching and advising. Also, switching from using DVD media to using an external hard drive for recording video images has enabled to store large amount of images in a small space.

Meanwhile, when reducing fluoroscopic exposure with the previous X-ray R/F system tended to rely on a reduced pulse rate, or on a recursive filters which improve the graininess under low dose. That left problems in trackability for quick movements of guide wires or devices and in visibility of fluoroscopy images, due to image lag. The SONIALVISION G4 is equipped with SUREengine FAST (high-speed fluoroscopy image processing), which can reduce the radiation dose levels by image processing without decreasing the pulse rate. Since September 2018, the Super Low Dose mode has been installed in this system to further the reduce fluoroscopic exposure. The experience of it is described below.

Fig.7(a) 19-Inch LCD Monitors
Enables comparison of images

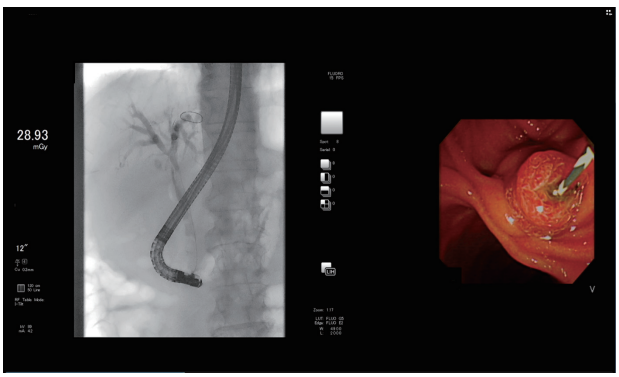


Fig.7(b) Picture-in-Picture System (Shimadzu System Development Corporation)
This simplified the process of recording, saving, and processing images.
The ability to record fluoroscopy and endoscopy images on the same time axis makes it easy to understand positional relation with lesions.
Replaying the images immediately after examinations is helpful for checking procedures and for use in training or advising.

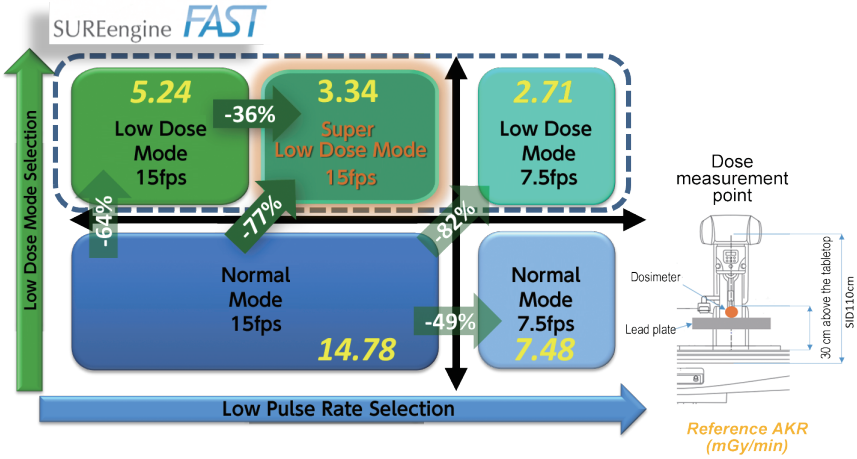


Fig.8 Comparison of Radiation Dose (AKR) for Each Fluoroscopy Mode

At our facility, we found that the Super Low Dose mode can reduce radiation dose by 77 % **(Fig. 8)** compared to the Normal mode (for pulsed fluoroscopy at 15 fps) given the same pulse rate. In terms of image quality, it also significantly improved trackability compared to pulsed fluoroscopy at 7.5 fps, which eliminated any image problems during normal guide wire operations or plastic stent placement in biliary ducts, for example. In addition, to improve visibility for metal stents in the biliary duct, baskets for removing stones, microliths, and so on, fluoroscopy parameters are adjusted according to the situation, as mentioned above. In the future, further image quality improvement is expected, while low radiation dose levels is maintained in calculus treatment or implanting metal stents.

6. Summary

ERCP, which has a 50-year history, will continue to be an essential examination method for early diagnosis of cancers in the biliary tract or pancreas and for emergency drainage during acute cholangitis. In order to carry out ERCP examinations of safely, smoothly, and less stressfully, the cooperation with a radiological technologist is necessary.

To reduce scattered radiation exopsure, we think it is important to enhancement of the use of lead protective gear and to optimize fluoroscopic condition for the X-ray R/F system. The introduction of SONIALVISION G4 system at our facility is improving the quality of examinations, and we expect Shimadzu to continue developing technologies to further reduce radiation dose levels and improve image quality with good visibility in the future as well.

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3) Takagi,K., et al. Retrograde pancreatography and cholangiography by fiber duodenoscope. Gastroenterology.59;445-452,1970
4) Minami T,et al. Occupational Radiation Exposure during Endoscopic Retrograde Cholangiopancreatography and Usefulness of Radiation Protective Curtains. Gastroenterology Research and Practice.13:1-5,2014