ORIGINAL PAPER

Evaluation of radiation exposure dose at double-balloon endoscopy for the patients with small bowel disease

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ABSTRACT

Double-balloon endoscopy (DBE) is useful for the diagnosis and treatment of small bowel diseases. Although fluoroscopy is used to confirm the position of endoscope at DBE, the endoscopist does not have the knowledge with regard to the radiation exposure dose. In this study, we evaluated the absorbed dose during DBE in patients with suspected or established small bowel diseases. This was a retrospective study in which the estimated fluoroscopic radiation absorbed doses loaded on the small bowel and skin were determined according to the data of the referential X-ray experiment with a human body phantom. The subjects were 415 DBEs preformed in total. The mean small bowel absorbed doses on antegrade and retrograde DBEs were 42.2 and 53.8 mGy, respectively, showing that the organ dose applied in retrograde DBE was significantly higher (*P*<0.0001). The mean skin absorbed doses of them were 79.2 and 101.0 mGy, respectively, showing that the dose was also significantly higher on retrograde DBE (*P*<0.0001). Of 27 cases who were applied endoscopic balloon dilation, the mean fluoroscopy time was 16.0 minutes, and mean small bowel and skin absorbed doses were 121.9 and 228.9 mGy, respectively. In conclusion, endoscopist should be careful for reducing the organ exposure dose at DBE, particularly for the lower abdominal region.

Key Words: double-balloon endoscopy, radiation exposure, endoscopic balloon dilation, small bowel disease

Abbreviations: Double-balloon enteroscopy (DBE), endoscopic balloon dilation (EBD), endoscopic mucosal resection (EMR), double-balloon endoscopic retrograde cholangiopancreatography (DBERCP), percutaneous coronary intervention (PCI)
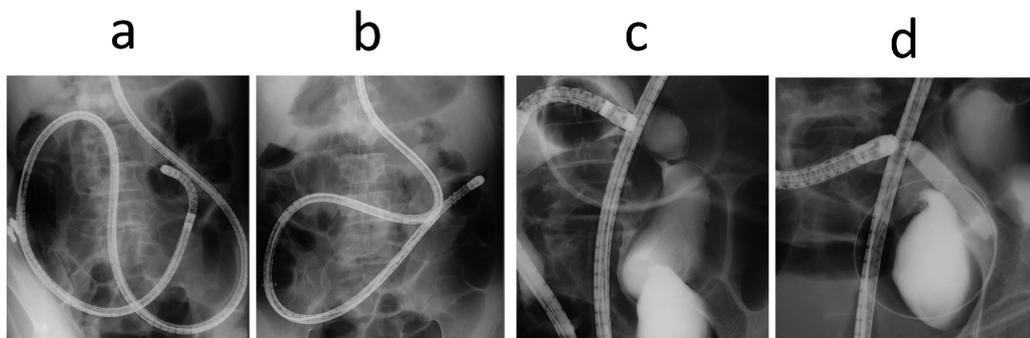
INTRODUCTION

Double-balloon enteroscopy (DBE) is the promising tool for the diagnosis and treatment of small bowel diseases,[1-3)] and DBE has provided the definite diagnosis for most small bowel

Fig. 1 Fluoroscopy in double-balloon endoscopy
a. Confirming the position
b. Shortening
c. Gastrografin contrast radiography
d. Endoscopic balloon dilation

diseases which previously could be treated by only surgical resection.[4, 5] However, generally, it takes a longer time to perform DBE than the other gastrointestinal endoscopic examinations. DBE is usually performed under fluoroscopy to confirm the position of the endoscope and the change of position during endoscope withdrawing, to perform additional gastrografin contrast radiography for the detecting lesions, and to treat the stenotic lesion using endoscopic balloon dilation (EBD) (Figure 1). The small bowel is the longest hollow organ, with a 5–7-m length. When it is hard to insert endoscope deeper during DBE, fluoroscopy often provides us new information for the deeper insertion. When the retrograde method is employed, the lower abdominal region is repeatedly exposed in cases with difficult insertion due to intrapelvic adhesion, which may influence the genital organs. During EBD under DBE, fluoroscopy is necessary to confirm whether or not the balloon has been fully inflated and appropriately dilated at the stenotic region. The treatment time and exposure level may increase when many lesions require dilation, or there is a bend in the stenosis because of the ulceration scar and difficult to fix the dilated balloon at the lesion area. Particularly, the influence of the lower abdominal exposure on the genital organs is of concern for Crohn's disease patients with stenosis in the ileum and patients with NSAIDs-induced membranous small bowel stenosis. However, there has been no concrete report on the exposure level in DBE. In this study, we retrospectively evaluated the radiation exposure dose during DBE, and investigated an appropriate radiation examination method including the skin exposure and influence on the genital organs.

SUBJECTS AND METHODS

This was a retrospective study in which the estimated fluoroscopic radiation and absorbed doses loaded on the small bowel and skin were determined based on the data of a referential X-ray experiment with a human body phantom. The subjects were 254 patients who underwent 415 DBEs in total at Nagoya University Hospital between May 2006 and July 2008. There were 161 male (268 examinations) and 93 female (147 examinations) patients. The mean age was 54±19 years old. DBE was performed to examine hemorrhage in 228 examinations, stenosis in 97, tumors in 61, abdominal symptoms in 19, and others in 10 (Table 1). Of all 415 examinations, antegrade and retrograde DBE were performed in 190 and 225, respectively. Antegrade DBE was performed for diagnosis and treatment in 125 and 65 of the 190 examinations,

Table 1 Patient backgrounds

Collected period	May 2006~July 2008
Patients	254
Number of examinations	415
The mean age	54±19 years old
Male/Female (examinations)	161 cases (268) / 93 cases (147)
Indications of DBE (examinations)	
bleeding	228
stenosis	97
tumor	61
abdominal symptom	19
others	10
(foreign body 3, parasite 3, malabsorption syndrome 4)	
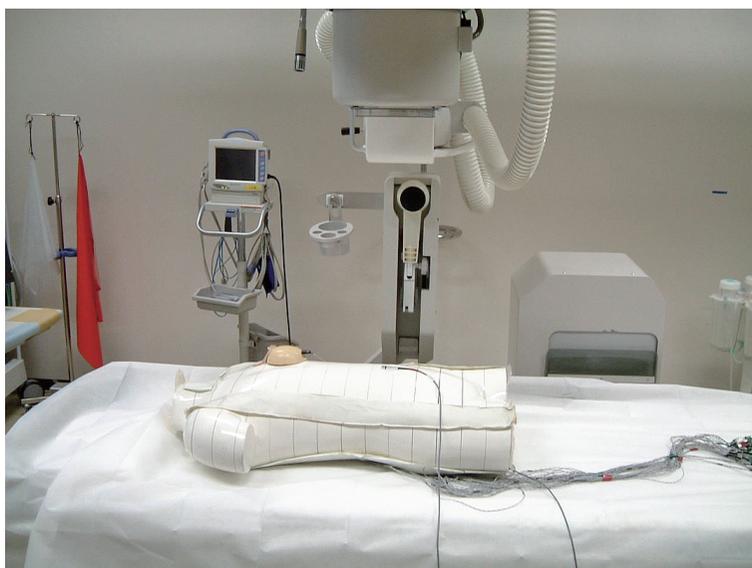
Fig. 2 Measurement of basic radiation exposure dose using human body phantom

respectively. Retrograde DBE was performed for diagnosis and treatment in 189 and 36 of the 225 examinations, respectively.

In DBE, a patient was given two types of X-ray exposures. One was the fluoroscopy in operating time and the other was plain X-photo to obtain the X-ray image of the lesion. The small bowel and skin absorbed doses of 10-second fluoroscopy were determined in the X-ray reference dose experiment using a human body phantom, and the absorbed doses per plain X-ray photo were also determined. For measuring the dose, an organ dose measurement system was used. Photodiode dosimeters (Hamamatsu Photonics, S2506-04) were embedded at the organ positions in a human body phantom (THRH1, Kyoto Kagaku), and the phantom was set in a supine position on the fluoroscope table used in the regular series of DBE (Figure 2). Fluoroscopy

was applied to the phantom similarly to that in actual DBE, followed by plain X-ray photo. The imaging equipment was DR-2000F, manufactured by HITACHI. The X-ray tube voltage and tube current were automatic. The distance of source image receptor was 110 cm. The fluoroscopy and X-ray photo direction were straight, which focused a point that both iliac horns and abdominal midline crossed. The dosimeter data were transmitted to a computer with the specific function and converted to the absorbed dose of each organ for detecting the referential value. Real absorbed doses loaded on the small bowel, skin, and genital organs were estimated using specific software in the computer according to fluoroscopy operating time, numbers of plain X-ray photo, and reference doses.

The primary endpoint was evaluation of the organ dose in DBE performed for diagnosis and treatment including the skin exposure and influence on the genital organs. The secondary endpoints were comparison of the small bowel and skin absorbed doses between antegrade and retrograde DBE and comparison of the small bowel absorbed dose among the treatment methods.

RESULTS

In the human body phantom X-ray experiment, the referential absorbed doses of 10-second fluoroscopy for the small bowel, skin, testis, and ovary were 1.208, 2.241, 0.053, and 0.971 mGy, respectively, showing that the dose for the ovary was about 0.23 mGy lower than that for the small bowel. The referential absorbed doses for the small bowel and skin per plain X-ray photo were 0.211 and 0.386 mGy, respectively.

The mean fluoroscopy time, small bowel and skin absorbed doses in diagnostic and therapeutic DBE were investigated. The mean fluoroscopy time in all antegrade DBE examinations was 5.5 minutes, and those for diagnosis and treatment were 4.7 and 7.2 minutes, respectively. The mean fluoroscopy time in all retrograde DBE examinations was 6.9 minutes, and those for diagnosis and treatment were 5.9 and 12.8 minutes, respectively.

The small bowel and skin absorbed doses were compared between antegrade and retrograde DBE. The mean small bowel absorbed doses in all examinations of antegrade and retrograde DBEs were 42.2 and 53.8 mGy, respectively, showing a significantly higher dose in retrograde DBE ($P<.0001$). The mean skin exposure doses were 79.2 and 101.0 mGy, showing a significantly higher dose in retrograde DBE as well ($P<.0001$).

The small bowel absorbed dose was then compared between antegrade and retrograde DBE by the objective to perform DBE (diagnosis and treatment) (Figure 3). The absorbed doses in diagnostic and therapeutic antegrade DBEs were 36.4 and 52.7 mGy, respectively, showing no significant difference, but those in retrograde DBE were 45.1 and 96.9 mGy, respectively, showing that the small bowel absorbed dose in retrograde DBE was significantly higher in therapeutic than diagnostic DBE ($P=0.0006$).

The skin absorbed dose was compared between antegrade and retrograde DBE by the objective (Figure 4). The skin absorbed doses in diagnostic and therapeutic antegrade DBEs were 68 and 99 mGy, respectively, showing no significant difference, whereas those in retrograde DBE were 85 and 182 mGy, respectively, showing a significantly higher dose in therapeutic retrograde DBE ($P=0.0006$).

Of treatments under DBE performed at our hospital, endoscopic hemostasis was the most frequently performed, followed by EBD, endoscopic mucosal resection (EMR), double-balloon endoscopic retrograde cholangiopancreatography (DBERCP) +EBD, foreign body removal, antiparasitic treatment, and DBERCP (Table 2). Of these procedures, the organ dose was high in DBERCP and foreign body removal, but these were rarely performed. Both the number of
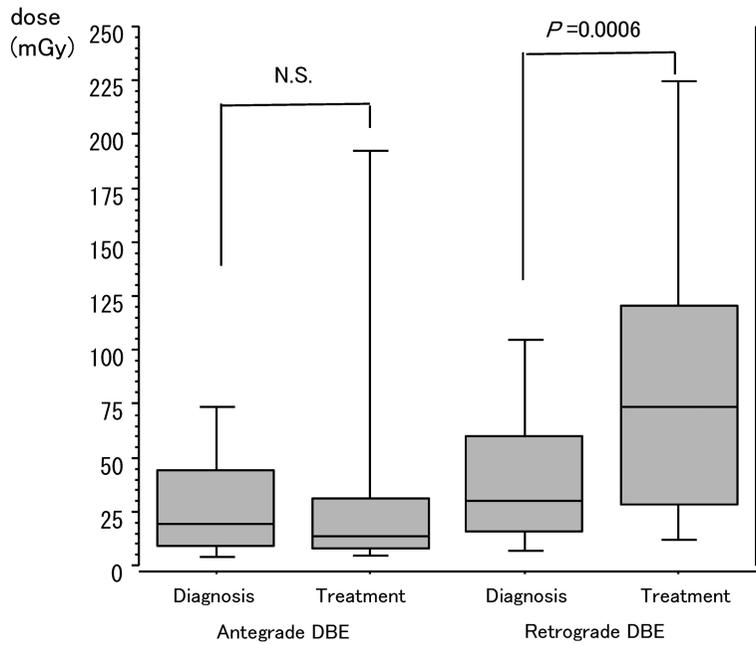
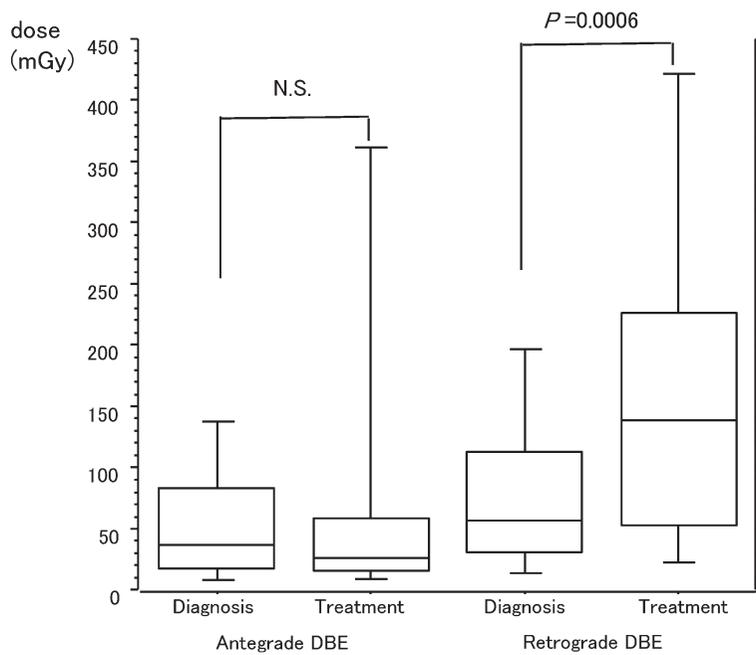**Fig. 3** Comparison of the small intestinal absorbed dose

Fig. 4 Comparison of the skin absorbed dose

examinations and organ dose were high in EBD. EBD was performed for 27 examinations: the mean fluoroscopy time was 16.02 minutes, and the mean small intestinal and skin absorbed doses were 121.9 and 228.9 mGy, respectively.

Since the organ dose was the highest in therapeutic retrograde DBE, as described above, endoscopic treatment under retrograde DBE was investigated in detail. It was performed for 35 examinations in total, and EBD, EMR, endoscopic hemostasis, and foreign body removal were performed for 21, 6, 5, and 3 examinations, respectively. EBD was the most frequently performed (Table 3), and the mean small bowel and skin absorbed doses per single EBD examination were 118.8±94.4 and 223.2±177.5 mGy, respectively. EBD was performed for Crohn's disease, accounting for 17 of the 21 examinations (81%), followed by small bowel ileus due to ischemic enteritis performed in 3, and NSAIDs-induced stenosis in 1. Crohn's disease patients are young

Table 2   Total treatment cases under DBE

Type of treatment	N	Mean fluoroscopy time (min)	Mean absorbed dose (mGy)	
			Small intestine	Skin
Hemostasis	42	1.96	14.9	27.98
EBD	27	16.02	121.94	228.97
EMR	18	2.2	16.76	31.47
DBERCP+EBD	4	38.16	285.32	536.07
Foreign body removal	3	29.39	216.58	407.13
Antiparasitic treatment	1	8.03	64.66	121.17
DBERCP	1	50.56	377.74	709.72

EBD: endoscopic balloon dilation, EMR: endoscopic mucosal resection
DBERCP: double-balloon endoscopic retrograde cholangiopancreatography

Table 3   Endoscopic treatment under retrograde DBE

Type of treatment	N	Mean fluoroscopy time (min)	Mean absorbed dose (mGy)	
			Small intestine	Skin
EBD	21	15.60±12.66	118.87±94.48	223.20±177.53
EMR	6	3.13±1.47	24.02±11.55	45.10±21.67
Hemostasis	5	2.76±1.80	20.89±13.62	39.24±25.59
Foreign body removal	3	29.39±15.40	216.58±113.22	407.13±212.86

EBD: endoscopic balloon dilation, EMR: endoscopic mucosal resection

Table 4   The gonads absorbed dose in therapeutic retrograde DBE (mGy)

	10-second fluoroscopy	per plain X-ray photo	EBD	EMR	endoscopic hemostasis	foreign body removal
testis	0.053	0.011	4.49	0.9	0.84	9.2
ovary	0.971	0.172	90.6	17.5	15.5	168.9

EBD: endoscopic balloon dilation, EMR: endoscopic mucosal resection

and EBD may be repeatedly performed, for which the influence on the gonads is of concern. Thus, the absorbed doses loaded on the testis and ovary were investigated. When converted to the absorbed dose per single EBD examination, the doses on the testis and ovary were 4.4 and 90.6 mGy, respectively (Table.4). The absorbed dose per single EBD was higher than EMR and endoscopic hemostasis, except for foreign body removal which was rarely performed.

DISCUSSION

Diagnostic radiological examinations are frequently performed in Japan compared to those in other countries, and this setting is related to the introduction of medical radiology equipment by the institutions. Particularly, the rate of installing CT scan equipment has been increasing every year. The number of devices per million people was 92.6 in 2002 in Japan, which is the highest in the world and markedly greater than the second highest number (34.1 in Australia).[6] The annual medical effective dose per Japanese is about 5.3 mSv, and CT and general diagnostic radiography account for about 2.3 and 1.4 mSv, respectively. It has been reported that the dose for barium enemas and CT colonography in Japan. The organ dose by barium enemas ranged from 9 to 26 mGy, and that by CT colonography was ranged from 30 to 44 mGy. For barium enemas, maximum skin doses were less than 100 mGy. In the lower digestive examination using fluoroscopy, the absorbed doses of DBE were higher than barium enemas and CT colonography, especially the cases of treatment.[7]

Upper gastrointestinal examination using radiologic system is performed as the health check-ups in Japan, and the absorbed dose in direct and indirect radiography and abdominal CT have been reported to be 100, 50, and 23 mGy, respectively.[7] The cumulative carcinogenesis risk due to diagnostic radiography is the highest in Japan among all countries, and it has been reported to be 3% or higher in persons aged 75 years old.[8]

In whole life, we are given amount of radiation exposure dose than we estimated. We investigated the radiation exposure level in DBE because it is assumed to be relatively high, in consideration of the examination route and the operating time of endoscopic treatment. The organ dose was high in endoscopic treatment under retrograde DBE. Since Crohn's disease patients are repeatedly treated with EBD from a young age, the organ dose increases compared to other DBE-applied patients in total. As fluoroscopy is frequently applied to the lower abdominal region in Crohn's disease patients, its influence on the genital organs should be considered. The testicular and ovarian absorbed doses per single EBD examination were 4.4 and 90. mGy, respectively. The threshold to avoid permanent sterility is 3,500–6,000 mGy for the testis (spermatogonia) and 2,500–3,000 mGy for the ovary (oocytes). Thus, single examination of EBD does not cause permanent sterility. The testicular and ovarian absorbed doses were lower than the small bowel absorbed dose. The mean exposure dose applied in retrograde DBE was 53.8 mGy and the mean skin absorbed dose per single EBD examination under retrograde DBE was 223.2 mGy. Based on the small bowel and skin absorbed doses, the gonadal absorbed dose was assumed to be low. However, when EBD is repeated within a short period, gene aberration and carcinogenesis risks may increase due to the stochastic influence, not definite influence, leading to sterility. Reportedly, the threshold to avoid temporary sterility in males is 100 mGy.

Regarding the influence of radiation on fetuses, the threshold to avoid abortion and fetal malformation in pregnant women is 100 mGy. If a female Crohn's disease patient in early pregnancy status who is unaware of her pregnancy, is treated with EBD, the patient will be exposed to about 100 mGy of radiation, which will reach the threshold. The pregnancy has to be confirmed before examination in fertile female patients. It was previously considered that

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exposure in the fetal period may induce pediatric cancer after birth,[9] but a later cohort study reported that exposure in the fetal period did not increase the risk of pediatric cancer.[10] The excess relative cancer risk of exposure at 10 years old is about 2–3 times higher than that at 40 years old. The cancer risk decreases by 17% with 10-year increments in the age at the time of exposure.[11] The cancer incidence rate ratio rises as the age at exposure decreases,[12] but the cancer risk in childhood involves not only radiation exposure but also the incorporation of chemical carcinogens from the surrounding environment, such as in food and water.[13]

To reduce the exposure dose in DBE, shortening of the fluoroscopy time is essential. It should be avoided that prolonged use of fluoroscopy on contrast imaging and deep insertion of DBE, and prolonged confirmation of the balloon shape in EBD. Newly less invasive fluoroscopy equipment can be introduced alternatively, and this is recommended in other fields,[14] but generally it is not simple to introduce because of budgetary problems.

The antegrade and retrograde routes were compared for organ dose. Route selection is important for DBE.[15] The organ dose was higher in the retrograde than antegrade route in both diagnostic and therapeutic DBE. The route was selected by the endoscopist based on the position of lesions and abdominal adhesion observed with the other types of imagings. The organ dose was significantly higher in therapeutic retrograde DBE, and the reason for this was as follows: Among treatments under DBE, both the number of examinations and organ dose were high in EBD, and 81% of EBD-treated cases were for Crohn's disease patients. Stenotic lesions frequently develop in the ileum in such diseases patients, and they had severe adhesion due to previous abdominal surgery for stenosis and fistula. The retrograde route is often selected because the lesion is present in the ileum, and the examination time prolongs because insertion is difficult due to adhesion. Therefore, the fluoroscopy is frequently applied to confirm balloon inflation in EBD, finally increasing the organ dose.

Comparison of the doses among radiological examinations in Crohn's disease patients has been reported, and minimizing the frequency of examination was recommended.[16]

The organ dose in EBD under DBE is not so high compared to the dose in other medical treatments under fluoroscopy. For example, it has been reported that the fluoroscopy time and radiation dose in percutaneous coronary intervention (PCI) were 12.9 minutes and 1.3 Gy, respectively.[17, 18] However, PCI-treated patients are middle-aged to elderly patients with coronary arterial stenosis and they are unlikely to be repeatedly treated in their lifetime. In contrast, Crohn's disease patients are repeatedly treated with EBD from a young age, increasing their exposure to radiation. Although the exposure dose per single EBD is low compared to that in PCI, it is requested to reduce the dose.

Radiation effect due to a high exposure dose in PCI has been reported.[19] In the study, a radiation-induced complication, erythema, developed in 6 of 400 subjects. Skin effect is generally caused when the exposure dose is 2 Gy or higher. Fortunately, no DBE-related radiation effect has developed in any patient at our hospital.

Although radiation exposure is unavoidable to some extent, EBD facilitates the avoidance of surgery, which is markedly beneficial for patients.[20] Radiation exposure is inevitable to safely perform EBD. Single examination of EBD does not cause sterility, but the skin and gonadal absorbed doses were higher than those in other treatments under DBE. Development of enteroscopy and radiology system are expected while making efforts to reduce the lower abdominal organ dose.

CONFLICT OF INTEREST

None declared.

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