

## Case Control Study

## Clinical impact of endoscopy position detecting unit (UPD-3) for a non-sedated colonoscopy

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### Abstract

**AIM:** To evaluate whether an endoscopy position detecting unit (UPD-3) can improve cecal intubation rates, cecal intubation times and visual analog scale (VAS) pain scores, regardless of the colonoscopist's level of experience.

**METHODS:** A total of 260 patients (170 men and 90 women) who underwent a colonoscopy were divided into the UPD-3-guided group or the conventional group (no UPD-3 guidance). Colonoscopies were performed by experts (experience of more than 1000 colonoscopies) or trainees (experience of less than 100 colonoscopies). Cecal intubation rates, cecal intubation times, insertion methods (straight insertion: shortening the colonic fold through the bending technique; roping insertion: right turn shortening technique) and patient discomfort were assessed. Patient discomfort during the endoscope insertion was scored by the VAS that was divided into 6 degrees of pain.

**RESULTS:** The cecum intubation rates, cecal intubation times, number of cecal intubations that were performed in < 15 min and insertion methods were not significantly different between the conventional group and the UPD-3-guided group. The number of patients who experienced pain during the insertion was markedly less in the UPD-3-guided group than in the conventional group. Univariate and multivariate analysis showed that the following factors were associated with lower VAS pain scores during endoscope insertion: insertion method (straight insertion) and UPD-3 guidance in the trainee group. For the experts group, univariate analysis showed that only the insertion method (straight insertion) was associated with lower VAS pain scores.

**CONCLUSION:** Although UPD-3 guidance did not shorten intubation times, it resulted in less patient pain

during endoscope insertion compared with conventional endoscopy for the procedures performed by trainees.

**Key words:** Colonoscopy; Training; Endoscopy position detecting unit

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**Core tip:** Non-sedated colonoscopy may be an uncomfortable or painful examination. It is very important for the colonoscopist to understand the shape of the endoscope during its insertion to successfully accomplish cecal intubation with minimal pain. ScopeGuide endoscopy position detecting unit (UPD-3) is designed to provide real-time three-dimensional images of the shape and configuration of the colonoscope inside the body. This study was conducted to evaluate the clinical impact of UPD-3, regardless of the level of experience of the colonoscopist. According to this study, ScopeGuide UPD-3 is useful for reducing patient abdominal discomfort during colonoscopies performed by trainees.

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## INTRODUCTION

Colorectal cancer is one of the major malignant cancers in Western countries and its incidence is rapidly increasing in other countries, including Japan. Colonoscopy has been considered the standard screening method for colorectal neoplasms<sup>[1,2]</sup>. However, expertise is required to correctly perform colonoscopy. Accumulation of a considerable amount of experience is necessary to be able to perform cecal intubation in a short time without causing pain to the non-sedated patient<sup>[3-7]</sup>. Previous studies have reported that trainees should perform more than 150 colonoscopy examinations to become technically competent in diagnostic colonoscopy<sup>[8]</sup>. Complete examination by colonoscopy may be difficult technically because of the shape of the endoscope, which may form a loop during insertion into the sigmoid or transverse colon. Furthermore, this looping and resultant stretching of the colon is a major source of pain for patients during colonoscopy and contributes to unsuccessful cecal intubation. Recent studies have reported low success rates of cecal intubations performed by inexperienced colonoscopists<sup>[4,9]</sup> and have pointed out the risk of complications due to the increasing number of

colonoscopies being performed<sup>[4,10]</sup>. Several factors, such as female sex and old age, have been associated with the difficulty of cecal intubation<sup>[9,11-20]</sup>, which may particularly apply to inexperienced colonoscopists. However, the resources for total colonoscopy, *i.e.*, the number of expert colonoscopists, are limited.

Patient comfort during and after colonoscopy is an important factor in determining patients' compliance with the procedures for the screening and surveillance of colorectal cancer. A number of techniques and endoscopes have been reported to reduce patient abdominal discomfort during difficult colonoscopies, such as the use of a pediatric colonoscope<sup>[21]</sup>, double balloon endoscope<sup>[22]</sup> and attachment of a transparent hood to the tip of the endoscope<sup>[23,24]</sup>. Sedation during colonoscopy is commonly performed in many clinics and hospitals to reduce the discomfort of insertion but there is growing recognition of the benefits of non-sedated colonoscopy. The patient who receives a non-sedated colonoscopy does not have to be in the hospital after examination for a long time and it costs less than sedated colonoscopy.

There have been few reports<sup>[25-27]</sup> on the effect of using an Endoscope Position Detecting Unit (UPD) during colonoscopy on the level of pain in non-sedated patients. The aim of this study was to evaluate whether UPD-3 can improve cecal intubation rates, cecal intubation times and Visual Analog Scale (VAS) pain scores, regardless of the level of experience of the colonoscopist.

## MATERIALS AND METHODS

### Patients

All patients were informed of the risks and benefits of colonoscopy and all patients provided written informed consent to undergo a colonoscopy. Between February 2012 and June 2012, a total of 260 patients (170 men and 90 women) who underwent a colonoscopy were divided into the UPD-3-guided group or the conventional group (no UPD-3 guidance). All colonoscopies were performed in four rooms. Conventional colonoscopies were performed in three rooms and UPD-3 guided colonoscopies were performed in one room in parallel. Finally, the number of patients was paired between the 2 groups and retrospective analyses were performed (Figure 1). Procedures were performed by 7 colonoscopists who were divided into 2 groups according to their colonoscopy experience: the expert colonoscopists (EC) group, which included colonoscopists with more than 10 years of experience involving more than 1000 procedures (MF, KY and MN), and the trainee colonoscopists (TC) group, with less than 3 years of colonoscopy practice involving less than 100 procedures (SA, YK, MA and MH). If an examining colonoscopist from the TC group failed to pass the endoscope through the sigmoid-descending colon junction within 15 min and a patient complained

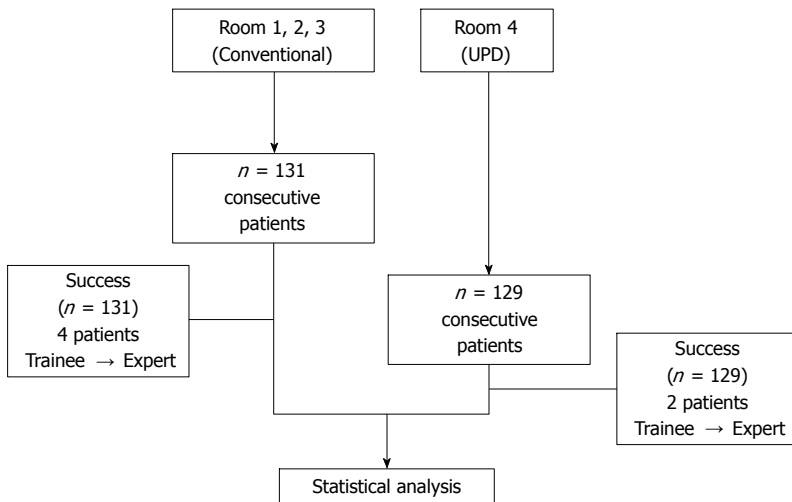


Figure 1 Inclusion schema of study. UPD: Position detecting unit.

of severe pain, a colonoscopist from the EC group replaced the initial examiner before midazolam was administered and the insertion was continued to the cecum.

We examined the association between patient discomfort during endoscope insertion and sex (male/female), age (< 65 years old/> 64 years old), UPD-3 use, experience of the colonoscopist (expert/trainee), insertion method (straight insertion: shortening the colonic fold by the bending technique; roping insertion: right turn shortening technique), past experience of abdominal surgery and use of antispasmodics. Patients recorded their pain level during insertion of the endoscope until it reached the cecum base. Another member of the medical staff, who did not know how the procedures were performed, interviewed the patients immediately after completion of their colonoscopies. Patients' pain and discomfort during endoscope insertion was scored by the VAS that was divided into 6 degrees (from 0 to 5). The VAS scores 0 and 1 were defined as painless and 2 to 5 were defined as painful. We then compared the various clinical characteristics and results of colonoscopy between the conventional and UPD-3-guided group and further investigated the factors affecting VAS pain scores during endoscope insertion by all colonoscopists, as well in the TC group only and in the EC group only. The study protocol was prepared in accordance with the Helsinki Declaration of 1975, as revised in 2008. Written informed consent to participate in the study was given by all subjects.

### Colonoscopy

The indications for colonoscopy examination were the standard clinical criteria as follows: colorectal cancer screening, surveillance for polyps, a positive fecal occult blood test, abdominal symptoms or anemia. Exclusion factors included severe heart or lung disease, prior colorectal resection, inflammatory bowel

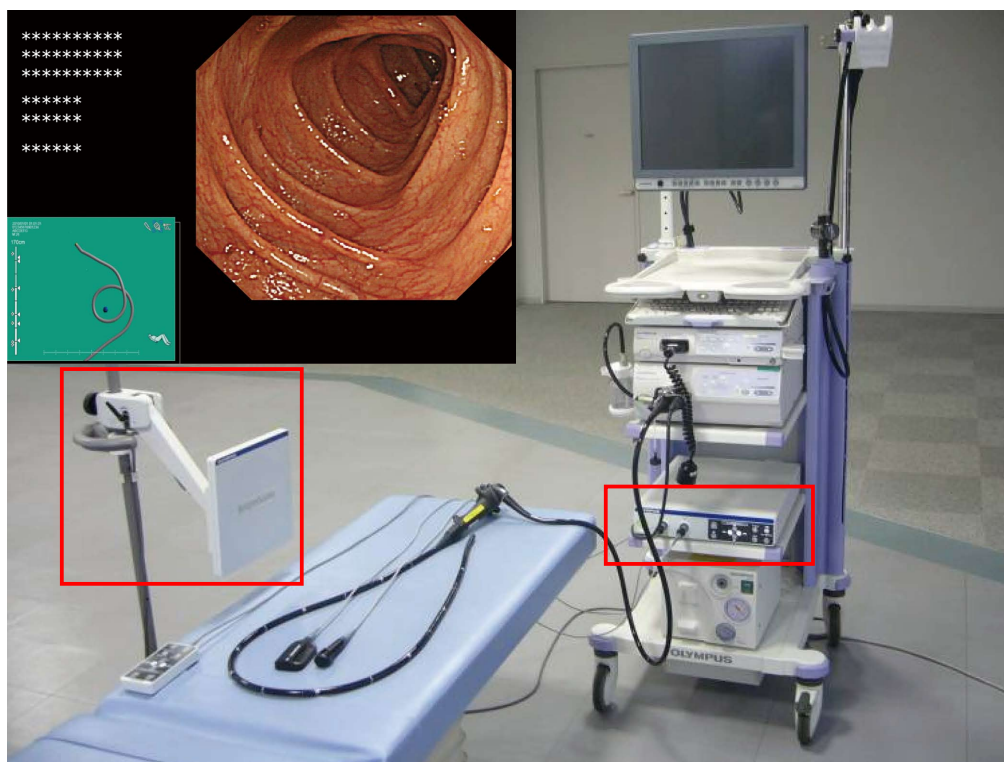
disease, severe hematochezia, age younger than 18 years and prior experience of repeated colonoscopies for therapeutic procedures, including polypectomy.

Patients underwent bowel preparation, taking sennoside on the day before their examination and 2 liters of polyethylene glycol solution in the morning of their colonoscopy. Scopolamine butylbromide (20 mg) was administered intramuscularly to suppress bowel movement, whereas patients with cardiac disease or benign prostatic hypertrophy or glaucoma received glucagon (1 IU) intramuscularly. Sedatives were administered to patients based on the examining colonoscopist's judgment or when requested by the patient due to abdominal pain or distension, and these cases were excluded from the study. Examinations were performed using a CF-Q260DI colonoscope (Olympus Co., Tokyo, Japan) with a distal tip diameter of 12.4 mm in the UPD-3 guided group. Examinations were performed using either a CF-Q260AI colonoscope (Olympus Co.) with a distal tip diameter of 12.2 mm or a CF-H260AI colonoscope (Olympus Co.) with a distal tip diameter of 13.2 mm in the conventional group. Carbon dioxide insufflation was available for all procedures.

### Endoscopy position detecting unit

It is very important for the colonoscopist to understand the shape of the endoscope during its insertion to successfully accomplish cecal intubation with minimal pain. Traditionally, an X-ray image of the area of interest in the patient was obtained with the endoscope insertion unit inserted to check the insertion state, such as the insertion position and the orientation of the insertion unit in the body cavity. However, such X-ray imaging is not completely harmless to the body and is restricted to the area of irradiation and is thus not always suitable as a detection method for the insertion state of the endoscope insertion unit.

A magnetic imaging system of colonoscope (Unit



**Figure 2** Position detecting unit system. The new Scope Guide receiver dish is compact and thin. Faster frame rate for enhanced image quality with picture in picture.

of Position Detection: UPD, Olympus Optical Co., Ltd.) provides a new facility for viewing real-time three-dimensional (3D) images of the shape and configuration of the colonoscope inside the body, without exposing patients or medical staff to radiation. Electromagnetic coils incorporated along the length of the colonoscope's insertion tube generate a pulsed low-intensity magnetic field that is picked up by the receiver dish. The magnetic pulses are used to calculate the precise position and orientation of the colonoscope. A new, improved UPD-3 model generates 3D images faster than ever. When used in conjunction with a monitor with picture-in-picture functionality, the ScopeGuide image is viewed alongside the endoscopic image (Figure 2).

### Statistical analysis

Continuous variables were expressed as the mean  $\pm$  SD. Categorical variables were expressed as frequencies and percentages. Differences between the 2 groups of patients (conventional group vs UPD-3-guided group) were detected using an independent *t*-test or Mann-Whitney *U* test for continuous data, and the  $\chi^2$  test or the Fisher's exact test for categorical data, as appropriate. Univariate and multivariate linear regression models were used to identify factors affecting VAS pain scores during endoscope insertion. Multivariate linear regression with stepwise selection was applied; variables that did not improve the model fit at  $P < 0.05$  were discarded. A  $P$ -value  $< 0.05$

was considered to indicate a statistically significant difference between groups. All statistical evaluations were performed using SPSS version 15.0 J software (SPSS Japan Inc., Tokyo, Japan).

## RESULTS

A total of 260 patients (170 men and 90 women) underwent colonoscopy during the study period. The mean age of the patients was 62.5 years (range 23-89;  $> 65$ : 133 patients;  $< 65$ : 127 patients). The patients were assigned to either the conventional group ( $n = 131$ ) or the UPD-3-guided group ( $n = 129$ ). One-hundred and sixty-six patients were examined by expert colonoscopists and 94 patients were examined by trainee colonoscopists. There were 20 post-abdominal operation cases (7.7%) and 239 cases using antispasmodics (91.9%). The baseline characteristics of the patients are summarized in Table 1.

The cecum-intubated proportions were the same in patients in the conventional group and those in the UPD-3-guided group (both 100%). In 6 cases (4 patients from the conventional group and 2 patients from the UPD-3-guided group), the trainee colonoscopist initially performing the procedure was replaced by an experienced colonoscopist due to technical difficulties resulting in intolerable pain for the patient.

The average cecal intubation time was  $13.2 \pm 4.1$  min in the conventional group and  $12.5 \pm 2.3$  min in the UPD-3-guided group. The time taken for the

**Table 1** Baseline characteristics of the patients *n* (%)

|  | Overall        | Conventional   | UPD            | <i>P</i> value |
|--|----------------|----------------|----------------|----------------|
| Patients                               | 260            | 131            | 129            | -              |
| Female                                 | 90 (34.6)      | 48 (36.6)      | 42 (32.6)      | 0.726          |
| Age (yr, mean $\pm$ SD)                | 62.5 $\pm$ 4.8 | 62.5 $\pm$ 5.3 | 62.9 $\pm$ 6.5 | 0.455          |
| Abdominal surgery                      | 20 (7.7)       | 9 (6.9)        | 11 (8.5)       | 0.334          |
| Examination by an expert colonoscopist | 166 (63.8)     | 83 (63.4)      | 83 (64.3)      | 0.768          |
| Antispasmodics use                     | 239 (91.9)     | 120 (91.6)     | 119 (92.2)     | 0.849          |

UPD: Position detecting unit.

**Table 2** Results of colonoscopy *n* (%)

|  | Overall        | Conventional   | UPD            | <i>P</i> value |
|--|----------------|----------------|----------------|----------------|
| Cecal intubation rate                      | 100%           | 100%           | 100%           | -              |
| Cecal intubation time (min, mean $\pm$ SD) | 12.9 $\pm$ 4.3 | 13.2 $\pm$ 4.1 | 12.5 $\pm$ 2.3 | 0.455          |
| Cecal intubation time (< 15 min)           | 182 (70.0)     | 92 (70.2)      | 90 (69.8)      | 0.935          |
| Straight insertion methods                 | 120 (46.1)     | 58 (44.3)      | 62 (48.1)      | 0.540          |
| Change of the colonoscopist                | 6 (2.3)        | 4 (3.1)        | 2 (1.6)        | 0.420          |
| Absence of pain                            | 143 (55.0)     | 64 (48.9)      | 79 (61.2)      | 0.045          |

UPD: Position detecting unit.

endoscope to reach the cecum was not significantly different between patients in the conventional group and those in the UPD-3-guided group. The number of cecal intubations that were performed in < 15 min, the insertion methods used and the VAS pain scores were comparable between the patients examined by a trainee colonoscopist and those examined by an expert colonoscopist. Moreover, there were no significant differences in these parameters between the conventional group and the UPD-3-guided group. The number of patients who experienced pain during the insertion was markedly less in the UPD-3-guided group than in the conventional endoscopy group (Table 2).

To investigate the factors affecting VAS pain scores during insertion of the colonoscope, we performed univariate and multivariate linear regression analyses (Table 3). Univariate analysis showed that the following factors were related to lower VAS pain scores during colonoscope insertion: straight insertion methods, UPD-3 guidance, examination by an expert colonoscopist and absence of abdominal surgery. After controlling for other covariates in the multivariate model, the same 4 factors were found to significantly affect VAS pain scores during colonoscope insertion. However, univariate analysis showed that only for the TC group, straight insertion methods and UPD-3 guidance were related to lower VAS pain scores during colonoscope insertion. After controlling for other covariates in the multivariate model, the same 2 factors were found to significantly affect VAS pain scores during colonoscope insertion (Table 4). For the

EC group, univariate and multivariate analysis showed that only the insertion method (straight insertion methods) was related to lower VAS pain scores during colonoscope insertion (Table 5).

## DISCUSSION

In the present study, there were no differences between the conventional endoscopy and UPD-3-guided groups in cecal intubation rates, mean cecal intubation time, number of cecal intubation procedures that were performed in < 15 min and insertion methods. The number of patients who experienced pain during the insertion was significantly lower in the UPD-3-guided group than in the conventional endoscopy group.

Based on the results of univariate and multivariate analyses for factors influencing VAS pain scores during colonoscope insertion, the straight insertion technique was found to be associated with less pain when experts performed the procedure. When trainees performed the procedure, however, UPD-3 guidance in combination with the straight insertion technique was found to be associated with less pain.

Because colonoscopy is generally regarded as an examination often involving pain, various approaches to reduce the pain have been reported. In Western countries, colonoscopy is frequently performed under sedation, based on a large number of reports supporting its safety and effectiveness<sup>[28,29]</sup>. In contrast, in Japan, colonoscopy is most commonly performed without sedation owing to its safety and effectiveness and it is frequently difficult to ensure sufficient numbers of recovery beds for patients undergoing endoscopy under sedation. Furthermore, in recent years, the use of an endoscope with a hood attached to its tip for colonoscopy without sedation has been reported to shorten the time required to intubate the cecum, thus reducing the amount of pain compared with conventional endoscopy (without a hood)<sup>[23,24]</sup>. On the other hand, some reports pointed out that colonoscopy with carbon dioxide insufflation is indispensable for treatment, such as for colorectal endoscopic submucosal dissection<sup>[30]</sup>, as it reduces the feeling of fullness after surgery. However, this does not alleviate the pain experienced during insertion<sup>[31]</sup>. For pain reduction, selecting an appropriate endoscope insertion technique is an important factor. At present, a method in which the endoscope is made to form a loop at the sigmoid colon and is withdrawn before intubating the cecum is considered a common technique on a worldwide basis. However, in the case of loop formation, the length of the endoscope may be insufficient, leading to difficulties in inserting it into the cecum and completing the examination procedure. One of the most important points regarding examination techniques such as colonoscopy is the education of trainees. Longer procedure times and

**Table 3 Univariate and multivariate analysis of the factors affecting visual analog scale pain scores for colonoscope insertion**

| Factors                                | Pain |        | Univariate analysis | Multivariate analysis |     |          |
|--|------|--------|---------------------|-----------------------|-----|----------|
|  |      |        | P value             | P value               | OR  | 95%CI    |
| Insertion methods (straight vs roping) | No   | 88/55  | < 0.001             | < 0.001               | 4.1 | 2.3-7.3  |
|  | Yes  | 32/85  |                     |                       |     |          |
| UPD vs Conventional                    | No   | 79/64  | 0.045               | 0.041                 | 1.8 | 1.1-3.2  |
|  | Yes  | 50/67  |                     |                       |     |          |
| Expert vs Trainee                      | No   | 111/32 | < 0.001             | < 0.001               | 4.2 | 2.3-7.6  |
|  | Yes  | 55/62  |                     |                       |     |          |
| Abdominal surgery (+ vs -)             | No   | 5/138  | 0.005               | 0.006                 | 4.7 | 1.5-15.0 |
|  | Yes  | 15/102 |                     |                       |     |          |
| Gender (Male vs Female)                | No   | 98/45  | 0.238               | 0.231                 | 1.4 | 0.8-2.6  |
|  | Yes  | 72/45  |                     |                       |     |          |
| Antispasmodic (+ vs -)                 | No   | 132/11 | 0.801               |                       |     |          |
|  | Yes  | 107/10 |                     |                       |     |          |
| Age (≥ 65 vs < 64)                     | No   | 72/71  | 0.774               |                       |     |          |
|  | Yes  | 61/56  |                     |                       |     |          |

UPD: Position detecting unit.

**Table 4 Univariate and multivariate analysis of factors affecting visual analog scale pain scores for colonoscope insertion by trainees**

| Factors                                | Pain |       | Univariate analysis | Multivariate analysis |     |          |
|--|------|-------|---------------------|-----------------------|-----|----------|
|  |      |       | P value             | P value               | OR  | 95%CI    |
| Insertion methods (straight vs roping) | No   | 22/10 | < 0.001             | < 0.001               | 6.8 | 2.6-18.2 |
|  | Yes  | 14/48 |                     |                       |     |          |
| UPD vs conventional                    | No   | 21/11 | 0.020               | 0.043                 | 2.7 | 1.1-7.2  |
|  | Yes  | 25/37 |                     |                       |     |          |
| Abdominal surgery (+ vs -)             | No   | 1/31  | 0.252               | 0.429                 | 2.6 | 0.2-28.8 |
|  | Yes  | 6/56  |                     |                       |     |          |
| Antispasmodic (+ vs -)                 | No   | 30/2  | 0.773               |                       |     |          |
|  | Yes  | 59/3  |                     |                       |     |          |
| Age (≥ 65 vs < 64)                     | No   | 16/16 | 0.767               |                       |     |          |
|  | Yes  | 33/29 |                     |                       |     |          |
| Gender (Male vs Female)                | No   | 21/11 | 0.961               |                       |     |          |
|  | Yes  | 41/21 |                     |                       |     |          |

UPD: Position detecting unit.

**Table 5 Univariate and multivariate analysis of factors affecting visual analog scale pain scores for colonoscope insertion by experts**

| Factors                                | Pain |       | Univariate analysis | Multivariate analysis |     |         |
|--|------|-------|---------------------|-----------------------|-----|---------|
|  |      |       | P value             | P value               | OR  | 95%CI   |
| Insertion methods (straight vs roping) | No   | 66/45 | 0.001               | 0.002                 | 3.0 | 1.5-5.9 |
|  | Yes  | 18/37 |                     |                       |     |         |
| Gender (Male vs Female)                | No   | 77/34 | 0.098               | 0.486                 | 1.3 | 0.6-2.8 |
|  | Yes  | 31/24 |                     |                       |     |         |
| UPD vs Conventional                    | No   | 58/53 | 0.410               |                       |     |         |
|  | Yes  | 25/30 |                     |                       |     |         |
| Abdominal surgery (+ vs -)             | No   | 4/107 | 0.422               |                       |     |         |
|  | Yes  | 9/46  |                     |                       |     |         |
| Antispasmodic (+ vs -)                 | No   | 102/9 | 0.343               |                       |     |         |
|  | Yes  | 48/7  |                     |                       |     |         |
| Age (≥ 65 vs < 64)                     | No   | 84/27 | 0.958               |                       |     |         |
|  | Yes  | 28/27 |                     |                       |     |         |

UPD: Position detecting unit.

increased abdominal pain and discomfort are caused by both the patient's condition and the colonoscopist's skills and experience<sup>[8-32]</sup>. However, training methods for colonoscope insertion using UPD-3 have not yet

been established.

Unlike conventional colonoscopy under fluoroscopy, the UPD-3 apparatus used in the present study does not involve the risk of radiation exposure and allows

colonoscopists to view the 3D shape of the endoscope similarly to X-ray imaging. It is also very compact and provides clear images without a time delay following actual endoscope handling. In the present study, the use of a UPD-3 by experts was not a pain-reducing factor, whereas its use in combination with the straight insertion technique by trainees resulted in reduced pain.

One limitation of this study is that because it is a case study rather than a randomized control study, the data obtained from this study may be biased in several respects and therefore it may be necessary to conduct prospective comparative studies in the future.

Considering the increasing incidence of colon cancer, reducing the pain involved in colonoscopy is crucial for the promotion of fecal occult blood tests, as well as for increasing the rate of patients undergoing colonoscopy. At the same time, training for those in charge of the examination procedures in educational institutions, such as university hospitals, is also an important issue. As an initial approach, it may be possible to reduce the pain involved in colonoscope insertion by providing trainees with the opportunity to master the straight insertion technique combined with a UPD-3.

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## COMMENTS

### Background

Achievement of a high success rate for cecal intubation with minimal patient discomfort depends on the shape of the inserted endoscope during the examination, which in turn is affected by the colonoscopist's level of experience.

### Research frontiers

This retrospective study was conducted to evaluate the clinical impact of an endoscopy position detecting unit (UPD-3), regardless of the level of experience of the colonoscopist.

### Innovations and breakthroughs

Although UPD-3 guidance did not shorten intubation times, it resulted in less patient pain during endoscope insertion compared with conventional endoscopy for the procedures performed by trainees.

### Applications

As an initial approach, it may be possible to reduce the pain involved in colonoscope insertion by providing trainees with the opportunity to master the straight insertion technique combined with a UPD-3.

### Peer-review

This article seems to have some novelties and the concept of study is interesting. The results are interesting and suggest that UPD-3 guidance did not shorten intubation times but it resulted in less patient pain during endoscope insertion compared with conventional endoscopy for the procedures performed by trainees.

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