Detectability of colorectal neoplastic lesions using a novel endoscopic system with blue laser imaging: a multicenter randomized controlled trial CME

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Background and Aims: Most studies have not reported an improvement in the detection of adenomas with the use of image-enhanced colonoscopy methods, possibly because of the darkness of the images. To overcome this limitation, a new-generation endoscopic system has been developed. This system has 2 blue-laser imaging (BLI) observation modes. The BLI observation was set to BLI-bright mode to detect lesions. We aimed to evaluate the efficacy of BLI in detecting lesions.

Methods: This study was designed as a randomized controlled trial with participants from 8 institutions. We enrolled patients aged ≥40 years. The participants were randomly assigned to 2 groups: observation by using white-light imaging (WLI) with a conventional xenon light source (WLI group) or observation by using BLI-bright mode with a laser light source (BLI group). All of the detected lesions were resected or had a biopsy taken for histopathologic analysis. The primary outcome was the mean number of adenomas per patient (MAP) that were detected per procedure.

Results: The WLI and BLI groups consisted of 474 and 489 patients, respectively. The MAP was significantly higher in the BLI group than in the WLI group (mean ± standard deviation [SD] WLI 1.01 ± 1.36, BLI 1.27 ± 1.73; $P = .008$). Adenoma detection rate in the BLI group was not significantly higher than in the WLI group. Observation times differed significantly, with BLI (9.48 minutes) being longer than WLI (8.42; $P < .001$). The mean (± SD) number of polyps per patient was significantly higher in the BLI group compared with the WLI group (WLI 1.43 ± 1.64, BLI 1.84 ± 2.09; $P = .001$).

Conclusions: A newly developed system that uses BLI improves the detection of adenomatous lesions compared with WLI. (Clinical trial registration number: UMIN 000014555.) (Gastrointest Endosc 2017;86:386-94.)

Abbreviations: ADR, adenoma detection rate; BLI, blue-laser imaging; FICE, flexible spectral imaging color enhancement; HP, hyperplastic polyp; MAP, mean number of adenomas per patient; NBI, narrow-band imaging; SSA/P, sessile serrated adenoma/polyp; WLI, white-light imaging.

DISCLOSURE: *All authors disclosed no financial relationships relevant to this publication.*

See CME section; p. 398.

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2017.01.017

Received August 18, 2016. Accepted January 19, 2017.

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Screening colonoscopy is considered the criterion standard for the early detection and removal of colorectal neoplastic lesions; however, the adenoma miss rate of 10% to 30% during colonoscopy under white-light imaging (WLI) is a persistent problem.[1-3]

Recently, novel colonoscopic technologies, such as wide-angle colonoscopy,[4-6] Third Eye colonoscopy,[7-9] balloon colonoscopy,[10] and cap-assisted colonoscopy[11,12] have been developed to improve detection of adenomas and found to be useful. However, all of these technologies require a special machine, colonoscope, or attachment. Similarly, some researchers have investigated improvements in the adenoma detection rate (ADR) by image-enhanced colonoscopy, such as narrow-band imaging (NBI),[13-19] and flexible spectral imaging color enhancement (FICE).[20,21] An image can be obtained easily by using image-enhanced colonoscopy because it enables endoscopic imaging with a 1-touch electric button. Unfortunately, most studies have not indicated an improvement in the adenoma miss rate with the use of image-enhanced colonoscopy, possibly because the images appear darker than those obtained with WLI. To overcome this limitation, a novel endoscopic system (LASEREO; Fujifilm Co, Tokyo, Japan) that uses a semiconductor laser light source was developed.[22-27] This system has a unique illumination feature that uses 2 lasers with different wavelengths.

The white light–mode laser excites phosphors to create white light illumination (mean ± standard deviation [SD] wavelength = 450 ± 10 nm). The BLI-mode laser has high-contrast signals that can obtain information on surface vascular and other structures (mean ± SD wavelength = 410 ± 10 nm). By changing the intensity ratio of the 2 types of lasers, WLI, blue-laser imaging (BLI), and BLI-bright observational modes can be selected by using combinations of image processing with illumination suitable for white light observation and narrow-band light observation. The BLI mode is considered useful for magnified observations and enables the acquisition of mucosal surface information regarding vascular and surface patterns.[26,27] However, the BLI-bright mode is brighter than the regular BLI mode and is thought to improve the detection of GI neoplastic lesions.[23]

In this study, we aimed to compare the detectability of colorectal lesions by using the novel endoscopic system of a laser light source with a conventional endoscopic system of the xenon lamp.

METHODS

Study design

This study was designed as a randomized controlled trial at 8 university and academic centers in Japan from July 1, 2014 to June 30, 2015. The study protocol was approved by the medical ethics committees at each center. This study was registered in the University Hospital Medical Network Clinical Trials Registry (UMIN 000014555).

Patients

We enrolled patients aged ≥40 years who had been referred for polypectomy, postsurgical cancer surveillance, polyp surveillance, or screening. The exclusion criteria included patients with inflammatory bowel disease, familial adenomatous polyposis, uncorrectable coagulopathy, and advanced colorectal cancer as well as those undergoing anticoagulant therapy. After randomization, patients with an incomplete total colonoscopy, multiple polyps that were unresectable in a single endoscopic examination, melanosis coli, insufficient bowel preparation, and advanced cancer that was detected during the examination were withdrawn. The study was performed in accordance with the ethical principles associated with the Declaration of Helsinki. All of the patients gave written informed consent for diagnosis and treatment before the procedures.

Randomization and masking

Random assignments were performed just before an examination in each case by using a computer-aided system at an independent data center, namely, the Medical Research Support Web site (Kyoto, Japan). Minimization was used to balance the selection of the primary examination according to the following 6 stratification variables: institution, sex, age (≥60 and <60 years), presence of a known lesion, presence of a surgical resection, and number of colonoscopies performed (≥5000 and <5000 cases). The participants were randomly assigned to 2 groups: observation by using WLI with a conventional xenon light source (WLI group) or observation by BLI-bright mode with a laser light source (BLI group). The endoscopist was blinded to the group assignment until immediately before the start of the colonoscopy.

Endoscopic procedure

For bowel preparation, 2 to 3 L of polyethylene glycol solution was administered on the morning of the colonoscopy. Scopolamine butylbromide (10 mg) or glucagon (0.5 mg) was administered in the absence of contraindications, and midazolam (0.03 mg/kg) and/or pethidine hydrochloride (35 mg) was used for conscious sedation only when a patient complained of discomfort or pain. In total, 46 endoscopists (11 experienced [≥5000 cases] and 35 inexperienced [<5000 cases]), participated in this study. All endoscopists had performed at least 10 cases in BLI observation for training before this trial. The endoscopists who participated in the study were blinded to the indication for the procedure and to the findings of the previous colonoscopy. A video endoscopic system (Advancia; Fujifilm Co, Tokyo, Japan) and high-definition colonoscopes (EC-590ZW3, EC-590ZP; Fujifilm Co, Tokyo, Japan) were used in the WLI group, whereas the video endoscopic system (LASEREO; Fujifilm Co) and high-