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Original Research Article

Can Non-expert Physicians Use the Japan Narrow-band Imaging Expert Team Classification to Diagnose Colonic Polyps Effectively?

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Abstract

Objectives: In 2014, the Japan narrow-band imaging expert team (JNET) proposed the first unified colorectal narrow-band imaging magnifying classification system, the JNET classification. The clinical usefulness of this system has been well established in JNET member institutions, but its suitability for use by "non-expert physicians" (physicians with no expertise in the use of JNET classification) remains unclear. This study aimed to examine the clinical usefulness of the JNET classification by "non-expert physicians".

Methods: We retrospectively analyzed 852 consecutive patients who underwent screening colonoscopy following a positive fecal occult blood test between January 2017 and May 2018. Endoscopic results from colon polyp diagnosis by physicians who started using the JNET classification (JNET group) were compared with those of physicians who did not (control group). Mann-Whitney U test and Fisher's exact test were used to compare continuous and categorical variables, respectively.

Results: The median patient age was 68 years, and the male-to-female ratio was 1:0.84. When no lesions were found, the median withdrawal time was significantly different between groups (JNET group: 12 min; control group: 15 min; $P < 0.01$). The number of resected adenomas per colonoscopy was significantly higher in the JNET group (1.7) than in the control group (1.2; $P < 0.01$). Among the resected lesions, 8.9% in the JNET group and 17% in the control group were non-neoplastic lesions that did not require resection ($P < 0.01$).

Conclusions: Colon polyp diagnosis using the JNET classification can reduce unnecessary resection during magnifying colonoscopy when conducted by "non-expert physicians".

Keywords

JNET classification, colonoscopy, colorectal adenoma

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Introduction

Colorectal cancer (CRC) is the third most commonly diagnosed cancer globally, accounting for about 1.3 million new cases and 700,000 estimated deaths, annually[1]. Polypectomy of all identified adenomatous polyps of the colon or rectum reduces the incidence and mortality rate of CRC[2]. To remove adenomatous polyps quickly and efficiently, the physician performing the colonoscopy needs to be skilled at distinguishing between adenomatous polyps and non-neoplastic polyps, which do not require resection.

The usefulness of narrow-band imaging (NBI) systems with magnification for differentiating between adenomatous and non-neoplastic polyps has been previously re-

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ported[3-12]. To establish a common diagnostic strategy for using magnifying NBI (M-NBI), a committee of 38 magnifying colonoscopy specialists in Japan, the Japan NBI Expert Team (JNET), was created in 2011. In 2014, JNET proposed the first unified colorectal M-NBI classification, the JNET classification[13]. Sumimoto et al. reported the usefulness of the JNET classification at an educational hospital representing a JNET member institution[12]. Iwai et al. reported that the proportion of non-neoplastic lesions among the resected diminutive polyps was 7.9% at a JNET participating tertiary cancer center[14]. It has been reported that the JNET classification is useful when implemented by experts in magnifying colonoscopy. However, for it to be considered clinically useful in routine settings, non-expert physicians must also be able to use it effectively; there are currently no reports concerning this issue.

Therefore, in this study, we aimed to clarify the advantages of introducing the JNET classification into colonoscopy examinations performed by physicians who are not experts in JNET classification. The study was performed in general hospitals that were not educational facilities and did not belong to the JNET network.

Methods

Participating physicians (JNET and control groups)

In our hospital (the Ise Red Cross Hospital, Mie, Japan), the qualitative diagnostic strategies for colonic polyps using colonoscopy are not unified. The use of the JNET classification for polyp diagnosis depends on the preference of individual physicians.

After 2 years of clinical training in our hospital, three trainees decided to become gastroenterologists. In the next 2 years, they learned the skills of colonoscope insertion; in the latter half of these 2 years, they learned about the JNET classification for colon polyp diagnosis. The training for scope insertion was supervised by experienced gastroenterologists (S.S., M.T., J.O., and A.K.), and study of the JNET classification was performed by S.S., who had not undergone special education or lectures pertaining to the JNET classification from magnifying colonoscopy experts; these 4 physicians referred to figures in an article by Sano et al. for learning the classification[13]. While learning JNET classification, the vessel pattern observed using NBI and the surface structure observed by NBI and indigo carmine spray were classified according to the JNET classification. In addition, these 4 physicians were required to compare the JNET classification and pathological findings, thereby increasing diagnostic accuracy. From January 2017, they decided to perform polyp diagnosis according to the JNET classification, using only NBI. At that time, three trainees inserted the colonoscope without supervision. In this retrospective study, these three trainees and S.S. were classified into the JNET group (those who started using the JNET classification since January 2017). Among the 10 physicians performing colonoscopies at our hospital, 4 in the JNET group started using the JNET classification for qualitative diagnosis of polyps, whereas 6 based their diagnoses on their own clinical experience; these 6 physicians were classified into the control group (those who determined the need for polyp removal based on their clinical experience using characteristics such as size, morphology, color, and location). The 4 physicians in the JNET group had, on average, fewer years of colonoscopy experience (3, 3, 3, and 9 years) than the 6 in the control group (16, 11, 9, 5, 4, and 3 years). We defined the JNET group physicians as "non-expert physicians" on the JNET classification because they had no experience in using the JNET classification until January 2017, i.e., the first day of this retrospective study period.

Endoscopic procedure and pathological evaluation

All procedures were performed using high-resolution magnifying colonoscopes (CF-H260AZI, CF-H290ZI, or PCF-H290ZI colonoscope, EVIS LUCERA ELITE System; Olympus, Tokyo, Japan). Polyp location, size, and morphology[15] were recorded by physicians in both groups. Locations were categorized as being on the right side of the colon (cecum, ascending, and transverse colon); on the left side of the colon (descending and sigmoid colon); or within the rectum, and were classified based on the Japanese Classification of Colorectal Carcinoma[16]. Pathological evaluations were performed according to the Vienna classification and the classifications of the Japanese Society for Cancer of the Colon and Rectum[16].

Endoscopic diagnosis and treatment strategy in the JNET group

In the JNET group, if any lesion was found during colonoscopy, the endoscopist immediately decided whether to remove it based on the real-time diagnosis, including findings from M-NBI endoscopy. The vessel and surface patterns were evaluated according to the JNET classification using M-NBI.

Type 1 JNET polyps larger than 6 mm in diameter and located on the right side of the colon were resected using cold snare polypectomy (CSP), endoscopic mucosal resection (EMR), or endoscopic submucosal dissection (ESD). These criteria were decided for the JNET group in order to not fail to remove SSA/P when introducing the JNET classification. JNET type 2A polyps were considered adenomatous and were treated with cold forceps polypectomy (CFP), EMR, or ESD. Because JNET type 2B polyps were likely to be high-grade adenomas or intra-mucosal cancers, they were treated with EMR or ESD, unless obvious massive submucosal invasion was found. When JNET type 3 was identi-

fied, the polyp was further evaluated using high magnification endoscopy with 0.05% crystal violet staining. JNET type 3 polyps with obvious massive submucosal invasion were surgically resected because of their likelihood of being deep submucosal invasive cancer.

Endoscopic diagnosis and treatment strategy in the control group

In the control group, if any lesion was found during colonoscopy, the endoscopist immediately decided whether to remove it based on the real-time diagnosis, and findings, such as size, morphology, color, and location. Physicians in the control group used the chromoendoscope or M-NBI without the JNET classification; however, there was no common diagnostic strategy.

In the control group, participants underwent CFP, CSP, EMR, or ESD according to polyp size. CFP was used for diminutive (1-5 mm) polyps, CSP was used for small (6-9 mm) polyps, and EMR and ESD were used for polyps >10 mm in size. When a deep depression or a coarse nodule was identified on the surface of a polyp, it was further evaluated using high magnification endoscopy with 0.05% crystal violet staining. Polyps with obvious massive submucosal invasion were surgically resected. If the endoscopist determined that a lesion should be removed by surgery, tattooing, and biopsy were performed at the time of the colonoscopy. As a common procedure for both groups, all participants underwent resection, even for diminutive adenomas. This decision was made by each individual endoscopist, with or without consideration of the JNET classification.

Non-neoplastic lesion resection rate

To evaluate the efficiency of colonoscopies, we compared the non-neoplastic lesion resection rate (NNR) for each physician. We defined NNR as the proportion of unnecessarily resected non-neoplastic polyps among the total number of resected polyps.

Study population

Patients who underwent screening colonoscopy after positive fecal occult blood tests for cancer screening, and lacked clinical symptoms (e.g., abdominal pain, diarrhea, and fresh blood in the stool), between January 2017 and May 2018 at the Ise Red Cross Hospital, Mie, Japan, were considered eligible for enrollment in this retrospective study. Baseline colonoscopy was defined as the first colonoscopy in life for patients who had no previous history of colonoscopy from their medical records. Exclusion criteria were as follows: (i) patients who underwent colonoscopy by a physician during scope insertion training; (ii) patients who could not have their entire colon observed because of obstruction due to advanced colon cancer; (iii) patients with ulcerative colitis; and (iv) patients who underwent colon resection. During the study period, 15 of the 852 patients underwent second colonoscopy 1 year after the first colonoscopy. They underwent resection of five or more adenomas during the first colonoscopy. European guidelines for quality assurance in colorectal cancer screening and diagnosis recommend that if more than five adenomatous polyps are removed, the next surveillance colonoscopy should be performed before 1 year[17]. Surveillance intervals after the removal of colorectal tumors have not been established in Japan; therefore, our hospital provides surveillance colonoscopy for patients who had more than five neoplastic polyps before a year. Therefore, in this retrospective study, the total number of colonoscopies was 867.

Statistical analyses

The Mann-Whitney U test and Fisher's exact test were used to compare continuous and categorical variables, respectively. Statistical significance was defined as $P < 0.05$. All data analyses were performed using R software (version 2.15.2, R Core Team, Foundation for Statistical Computing, Vienna, Austria).

Ethical considerations

Participants gave their written informed consent. The study protocol was approved by the research institute's committee on human research. The Institutional Review Board of the Ise Red Cross Hospital gave ethical approval for this study (Institutional code: 30-54).

Results

Patient characteristics and endoscopic examination results

A total of 852 consecutive patients (867 colonoscopies) who underwent screening colonoscopy after positive fecal occult blood tests for cancer screening were included in the final analysis in this study. Patient characteristics are shown in Table 1. The median age of patients was 68 (range: 24-90) years, and the male-to-female ratio was 1:0.84. The cecal intubation rate was 100% (867/867). The median cecal intubation and withdrawal times were 8 (range: 1-60) and 13 (range: 4-31) min, respectively. At least one adenoma was removed in 58% of patients (496/852), and this was limited to baseline colonoscopy in 59% of cases (386/655). Since we did not record all lesion data obtained during follow-up without resection, the precise adenoma detection rate could not be calculated; however, it was not less than 59% (386/655).

Endoscopic examination results (JNET group vs. control group)

Table 2 shows the endoscopic examination results of the two study groups. The 4 JNET group physicians had fewer

Table 1. Patient Characteristics and Results of Endoscopic Examination.

Characteristic	Value
No. of colonoscopies/no. of patients	867/852
Sex (male/female)	464/388
Median age, years (range)	68 (24-90)
CIR, % (n)	100 (867/867)
CIT, min, median (range)	8 (1-60)
Withdrawal time with no lesions, min, median (range)	13 (4-31)
Withdrawal time with lesions, min, median (range)	22 (4-65)
Patients with at least 1 adenoma removed, % (n)	58 (496/852)
Patients with at least 1 adenoma removed (limited to baseline CS), % (n)	59 (386/655)
Number of removed adenomas per CS, (n)	1.4 (1230/867)

CIR: cecal intubation rate; CIT: cecal intubation time; CS: colonoscopy

Table 2. Results of Endoscopic Examination.

Variable	JNET group 4 members	Control group 6 members	*P* value
Experience with CS, median years (range)	3 (3-9)	7 (3-16)	0.15**
No. of colonoscopies/no. of patients	384/379	483/473	NA
Sex (male/female)	216/163	248/225	0.18*
Median age, years (range)	68 (24-90)	69 (28-88)	0.79**
CIR, % (n)	100 (384/384)	100 (483/483)	NA
CIT, min, median (range)	7 (1-50)	8 (2-60)	<0.01**
Minimum withdrawal time with no lesions, median (range)	12 (5-30)	15 (4-31)	<0.01**
Minimum withdrawal time with lesions, median (range)	22 (5-65)	22 (4-65)	0.70**
Patients with at least 1 adenoma removed, % (n)	60 (228/379)	57 (268/473)	0.25*
Patients with at least 1 adenoma removed (limited to baseline CS), % (n)	60 (185/307)	58 (201/348)	0.52*
Number of removed adenomas per CS, (n)	1.7 (636/384)	1.2 (594/483)	<0.01*

CIR: cecal intubation rate; CIT: cecal intubation time; CS: colonoscopy; JNET: Japanese NBI Expert Team; NA: not available
* Fisher's exact test; ** Mann-Whitney U test

number of years of colonoscopy experience (3, 3, 3, and 9 years), than the 6 in the control group with more extensive number of years of experience in colonoscopy (16, 11, 9, 5, 4, and 3 years). The median cecal intubation time was 7 (range: 1-50) in the JNET group and 8 (range: 2-60) min in the control group ($P < 0.01$). The median withdrawal time with no lesions was significantly different between the two groups ($P < 0.01$) (JNET group: 12 min vs. control group: 15 min). However, the proportion of patients with at least one adenoma removed was not significantly different (60% in the JNET group vs. 57% in the control group; $P = 0.25$). The number of removed adenomas per colonoscopy was significantly higher in the JNET group (JNET group: 1.7 vs. control group: 1.2; $P < 0.01$).

Characteristics of removed polyps (JNET group vs. control group)

The histological diagnosis of all resected polyps was reviewed by an experienced gastrointestinal pathologist (TY). The characteristics of the polyps removed in each group are shown in Table 3. In the control group, four out of five deep submucosal invasive (SM-d) carcinomas that should have been resected by radical surgery were removed by ESD. Additionally, one submucosal superficial (SM-s) invasive carcinoma that should have been resected by ESD was instead resected by radical surgery. Among the resected lesions, the proportion of non-neoplastic lesions that did not require resection was 8.9% (64/722) in the JNET group and 17% (130/768) in the control group ($P < 0.01$). Physicians in the JNET group removed adenomatous polyps more efficiently within a shorter time and with fewer medical resources.

Non-neoplastic lesion resection rate according to physician

The NNRs for each physician are summarized in Table 4. The NNR was 8.9% (64/723) in the JNET group and 16.8% (130/774) in the control group ($P < 0.01$). One control group physician with 16 years of colonoscopy experience showed a higher NNR than one of the JNET group physi-

Table 3. Characteristics of Polyps Removed.

Variable	JNET group 4 members	Control group 6 members	*P*-value
SM-d carcinoma, n	2	5	NA
Removed by ESD, n	0	4	
SM-s carcinoma, n	1	3	
Removed by ESD, n	1	1	
Intramucosal carcinoma, % (n)	1.7 (12/722)	2.7 (21/768)	0.15*
Adenoma, % (n)	88 (636/722)	77 (594/768)	<0.01*
SSA/P, % (n)	0.7 (5/722)	2.1 (16/768)	0.04*
TSA, % (n)	0.7 (5/722)	0.9 (7/768)	0.86*
Non-neoplastic, % (n)	8.9 (64/722)	17 (130/768)	<0.01*

SM-d carcinoma: deep submucosal invasive carcinoma; SM-s carcinoma: superficial submucosal invasive carcinoma; ESD: endoscopic submucosal dissection; SSA/P: sessile serrated adenoma/polyp; TSA: traditional serrated adenoma; JNET: Japanese NBI Expert Team; NA: not available

* Fisher's exact test

Table 4. Non-neoplastic Lesion Resection Rate for Each Physician.

	Physician	JNET-1	JNET-2	JNET-3	JNET-4			Total
JNET group	Experience of CS, year	3	3	3	9			
	NNR,% (n)	12 (26/226)	9 (27/311)	7 (6/87)	5 (5/99)			8.9[a] (64/723)
	Physician	Control-1	Control-2	Control-3	Control-4	Control-5	Control-6	
Control group	Experience of CS, year	4	5	16	3	11	9	
	NNR,% (n)	25 (6/24)	20 (38/190)	17 (43/258)	16 (22/136)	16 (14/87)	9 (7/79)	16.8[b] (130/774)

CS: colonoscopy; NNR: non-neoplastic resection rate

a vs. b: $P < 0.01$ in the Fisher's exact test

cians with only 3 years of experience in colonoscopy. This tendency was confirmed among other physicians in the JNET and control groups.

Characteristics of removed polyps in the JNET group

The results of M-NBI diagnosis for 725 lesions using the JNET classification (performed by the JNET group) are summarized in Table 5. Histologically, 2, 3, and 15 type 1 lesions were identified as tubular adenomas, SSA/P, and non-neoplastic polyps, respectively. Moreover, 1, 12, 634, 2, 5, and 49 type 2A lesions were identified as superficial submucosal invasive carcinomas, intramucosal carcinomas, tubular adenomas, SSA/P, traditional serrated adenomas, and non-neoplastic polyps, respectively. There were no lesions with JNET classification type 2B; there were 2 type 3 cases.

Discussion

According to this study, the JNET classification in a general hospital setting (does not belong to the JNET network and was not an educational hospital), is useful for avoiding the unnecessary resection of non-neoplastic polyps. In other words, the JNET classification is a useful and applicable clinical tool. Physicians with a sufficiently high adenoma detection rate should also be aware that unnecessary polypectomy leads to increased risks for the patient. With the increasing use of antithrombotic drugs, endoscopic procedures at high-risk of bleeding can lead to death[18]. This study is the report that even non-expert physicians in the use of JNET classification can eliminate unnecessary resection without lowering the adenoma detection rate. In Table 2, the proportion of patients with at least one adenoma removed was not significantly different (60% in JNET group vs. 57% in the control group; $P = 0.25$). We have not verified the quality of the JNET classification. What we want to reveal here is that the adenoma detection rate of the JNET group did not decline. Even if unnecessary resection can be reduced, it would be useless if the adenoma detection rate decreases. In addition, to maintaining the quality of colonoscopy, the proportion of resected SSA/P should not differ between the two groups. In our cohort, the number of removed SSA/Ps per patient was not significantly different

Table 5. Characteristics of Removed Polyps in the JNET Group.

JNET classification	Size of lesion	n	Location	n	Pathology	n
Type 1	≤5 mm	6	Cecum-SF	16	Adenoma	2
	6-9 mm	7	SF-Sigmoid	3	SSA/P	3
	≥10 mm	7	Rectum	1	Non-neoplastic	15
Type 2A	≤5 mm	387	Cecum-SF	385	SM-s carcinoma	1
	6-9 mm	242	SF-Sigmoid	281	Intramucosal carcinoma	12
	≥10 mm	74	Rectum	37	Adenoma	634
					SSA/P	2
					TSA	5
					Non-neoplastic	49
Type 2B	(-)					
Type 3	≥10 mm	2	Sigmoid	2	SM-d carcinoma	2

SF: splenic flexure; SSA/P: sessile serrated adenoma/polyp; SM-d carcinoma: deep submucosal invasive carcinoma; SM-s carcinoma: superficial submucosal invasive carcinoma; TSA: traditional serrated adenoma; JNET: Japanese NBI Expert Team

(JNET group 0.013% (5/379) vs. the control group 0.034% (16/473); P=0.088).

For submucosal invasive cancer, there is a consensus in Japan that submucosal superficial (SM-s) carcinoma is appropriate for endoscopic resection, and that SM-d carcinoma should be surgically resected due to the possibility of lymph node metastasis. In this study, only 11 lesions with submucosal invasive cancer were included; therefore, definitive conclusions could not be made with respect to these cases. However, in the control group, four out of five SM-d carcinomas, which should have been resected by radical surgery, were removed by unnecessary ESD; and one SM-s carcinoma, which should have been resected by ESD, was resected by unnecessary radical surgery. Although this occurred in only a few cases, such incorrect choices of resection methods due to misdiagnosis of invasion depth were not observed in the JNET group.

Although the incidence of adverse events from EMR or CSP for colorectal polyps is not high, such events are still prevalent[19]. Colonoscopy quality indicator is primarily assigned according to the number of adenomas that are removed[20,21]. Avoiding unnecessary removal of non-neoplastic polyps while identifying and removing adenomas is important in patients, particularly when considering the recent increase in antithrombotic drug administration. Appropriate diagnosis of JNET type 1 lesions as hyperplastic polyps was found to be useful for avoiding unnecessary polypectomy. In contrast, it is concerning that the resection rate of adenomatous polyps decreased due to misidentification of JNET type 1 lesions by physicians. In our study, the proportion of patients with at least one adenoma removed was not significantly different between the two groups (JNET group, 60% vs. control group, 57%; P = 0.25), and the number of adenomas removed per colonoscopy was significantly higher in the JNET group (JNET group: 1.7 vs. control group: 1.2; $P < 0.01$). These results suggest that the JNET group detected more lesions in less time than the control group, but the causal relationship between this finding and the use of the JNET classification is not clear. The JNET classification is a useful classification only after polyps are found, but it cannot explain the statistically significant difference in the number of adenomas removed per colonoscopy. Notably, the JNET group was able to significantly reduce the removal of non-neoplastic polyps while removing a similar number of adenomas as the control group. In addition, both groups exceeded the target level set by the American Society for Gastrointestinal Endoscopy and Bowel Cancer screening program[20,21].

A total of 20 JNET type 1 lesions were resected due to the possibility of SSA/P. JNET type 1 lesions can be considered important for both efficient colonoscopy and for reducing the risk of unnecessary complications. Regarding JNET type 2A lesions, Sumimoto et al. reported that 1% (17/1888), 86% (1626/1888), and 12% (230/1888) of type 2A lesions were identified as hyperplastic/sessile serrated polyps, low-grade dysplasia, and high-grade dysplasia, respectively[12]. However, in this study, suspected JNET type 2A lesions that were identified by "non-expert physicians" consisted of 7.0% (49/703) non-neoplastic lesions, 90.0% (634/703) tubular adenomas, and 1.8% (13/703) carcinomas. The proportion of non-neoplastic lesions among suspected type 2 A lesions appears to be high when diagnosed by non-expert physicians. In addition, JNET type 2A lesions consist of various lesion types, including hyperplastic polyps, adenomas, intramucosal carcinomas, and invasive SM-s carcinomas. In contrast, the target lesions of interest for endoscopic treatment are adenomas, intramucosal carcinomas, and invasive SM-s carcinomas. Given that JNET 2A lesions cannot

be accurately detected, there are minimal clinical disadvantages to removing all neoplastic lesions.

Regarding the diagnostic performance for differentiating between neoplastic and non-neoplastic lesions, the JNET classification, when used by "non-expert physicians", showed diagnostic accuracy similar to that of previous studies[13,22]. Even when "non-expert physicians" used the JNET classification for diagnosis, the number of unnecessary polypectomies was reduced, but the diagnostic accuracy of JNET type 2A lesions was not as high as that for the control group[12]. One of the reasons for this was that an educational system for improving the understanding of the JNET classification has not been established for physicians.

On the other hand, as shown in Table 4, NNR was 8.9% (64/723) in the JNET group and 16.8% (130/774) in the control group, respectively ($P < 0.01$). On the other hand, NNR did not appear to be physician dependent ($P = 0.36$ across JNET and 0.45 across control group, respectively). So, we considered that the statistically significant difference in NNR was not caused by differences between specific individual physicians but was caused by introducing the JNET classification into one group. In addition, one control group physician with 16 years of colonoscopy experience showed a higher NNR than one of the JNET group physicians with only 3 years of experience in colonoscopy. This tendency was confirmed among other physicians in the JNET and control groups. It is likely that many endoscopists may be motivated to use the JNET classification, as it may help overcome some degree of inexperience.

The present study has several notable limitations. First, there were insufficient patient numbers to evaluate JNET type 2B and type 3 lesions. JNET classification is used to reduce unnecessary resection in clinical practice and to identify deep invasive carcinomas not eligible for endoscopic resection. This study only discussed one part of the usefulness of the JNET classification. Secondly, this was a retrospective study conducted at a single institution. Finally, we have no pathological data regarding the non-removed polyps, and will never know the number of adenomas that remained; we consider this to be one of the biggest limitations of this study. Future studies should be conducted at multiple centers, including a larger sample size, and with data on non-resected polyps. Despite the issue of unresected polyps, the introduction of the JNET classification to colonoscopy examinations performed by physicians who are not experts in this classification did not reduce the number of removed adenomas per patient. In conclusion, compared to that of experience-based diagnosis, colon polyp diagnosis performed by "non-expert physicians" using the JNET classification may reduce the rate of unnecessary resections of non-neoplastic lesions.

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Conflicts of Interest

There are no conflicts of interest.

Author Contributions

The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication. All other authors have contributed to data collection and interpretation, and critically reviewed the manuscript. All authors approved the final version of the manuscript, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Approval by Institutional Review Board (IRB)

The study protocol was approved by the research institute's committee on human research. The Institutional Review Board of the Ise Red Cross Hospital gave ethical approval for this study (Institutional code: 30-54).

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