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ORIGINAL ARTICLE

# Post-polypectomy bleeding in hot-snare polypectomy of colonic polyps under continued warfarin or short interruption of direct oral anticoagulants

Yuichi Shimodate[1] · Masayuki Ueno[1] · Tomohiko Sunami[1] · Hiroshi Takayama[1] · Rio Takezawa[1] · Akira Doi[1] · Naoyuki Nishimura[1] · Hirokazu Mouri[1] · Kazuhiro Matsueda[1] · Hiroshi Yamamoto[1] · Motowo Mizuno[1]

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## Abstract

**Background** Newly published guidelines of the Japanese Gastroenterological Endoscopy Society (JGES) suggest to consider endoscopic procedures with high risk of bleeding without stopping warfarin and with stopping direct oral anticoagulants (DOACs) only on the day of the procedure. In this study, we aimed to test the validity of these recommendations.

**Patients and methods** We retrospectively reviewed medical records of 344 patients with anticoagulant therapy who underwent hot-snare polypectomy between January 2012 and October 2018. Patients ($n = 132$) with interruption of anticoagulants (3–7 days for warfarin and 2–3 days for DOACs before the procedure) and without heparin-bridging were excluded. Among the remaining 212 patients, the incidence of post-polypectomy bleeding was compared between the following 2 patient groups: patients who had interruption of anticoagulants with heparin-bridging (HB group, $n = 139$) and patients treated according to the new JGES guideline (FG group, $n = 73$).

**Results** The rate of post-polypectomy bleeding (PPB) in FG group (9.6%) was not significantly different from that in HB group (12.9%, $p = 0.5$). In subgroup analysis, the incidence of bleeding in patients with warfarin (12.2%) and with DOAC (6.3%) in FG group was not significantly different from corresponding figures in HB group (14.2%, 0%). In multivariate analysis, number of resected polyps was associated with PPB, but the administration of anticoagulants according to the new guidelines was not a significant risk factor for PPB ($p = .98$).

**Conclusions** Our study affirms the recommendations of JGES for the management of anticoagulants in patients who undergo colonic polypectomy regarding post-polypectomy bleeding.

**Keywords** Direct oral anticoagulants · Heparin bridging therapy · Post-polypectomy bleeding · Colorectal polyp · Polypectomy

## Introduction

The number of patients who undergo hot-snare polypectomy or endoscopic mucosal resection of colorectal polyps while receiving anticoagulant therapy—warfarin or direct oral anticoagulants (DOACs)—for cardiovascular/neurovascular conditions is increasing. Protocols for safe management of the anticoagulants in these patients have been difficult to establish because of the conflicting risks of procedure-related bleeding and thromboembolic events. Guidelines of the American Society for Gastrointestinal Endoscopy, published in 2009 [1], and the Japanese Gastroenterological Endoscopy Society (JGES), published in 2012 [2], recommend heparin-bridging therapy with discontinuation of warfarin or DOACs for the procedure. However, a recently reported randomized controlled study [3] demonstrated that forgoing bridging was non-inferior to perioperative bridging with low-molecular weight heparin for the prevention of arterial thromboembolism and had a decreased risk of major bleeding. Thus, the newly published JGSE guideline (2017 appendix) [4] suggests to consider the endoscopic procedures without stopping warfarin when the prothrombin time-international normalized ratio (PT-INR) is in its therapeutic range, and with stopping DOACs only on the day of the procedure (recommendation grade 2; suggestion), but evidence to support this

✉ Yuichi Shimodate
ys13544@kchnet.or.jp

[1] Department of Gastroenterology and Hepatology, Kurashiki Central Hospital, 1-1-1, Miwa, Kurashiki, Okayama 710-8602, Japan

recommendation is lacking. Thus, we aimed to evaluate the rate of post-polypectomy bleeding and clarify risk factors for bleeding with polypectomies performed according to the new JGES guidelines in patients receiving anticoagulant therapy.

## Patients and methods

### Patients and outcomes

Hot-snare polypectomy for colorectal polyps was performed in 344 patients receiving anticoagulant therapy between January 2012 and October 2018 in Kurashiki Central Hospital. All patients had been consulted to cardiologists or neurologists with regard to their thromboembolic risk caused by interruption of antithrombotic drugs. Among them, 132 patients were advised to have a low thromboembolic risk with interruption of anticoagulants according to the 2012 JGES guideline [2], i.e., interruption 3–7 days before the procedure for warfarin and 2–3 days for DOACs without heparin-bridging. Excluding these patients, we retrospectively reviewed the medical records of the remaining 212 patients (571 colorectal polyps) and determined the incidence of post-polypectomy bleeding within 2 weeks after polypectomy (primary outcome), intra-procedural bleeding, and thromboembolism-related events within at least 2 weeks until 4 weeks after polypectomy (secondary outcome). Post-polypectomy bleeding was defined as hematochezia requiring emergent colonoscopy within 2 weeks after polypectomy, and intra-procedure bleeding was defined as spurting bleeding or prolonged oozing requiring endoscopic hemostasis during the procedure. The incidence of bleeding was compared between the following two patient groups according to the management of their anticoagulants: heparin-bridging (HB) group, patients with interruption of anticoagulants and replacement with heparin-bridging ($n = 139$), and following the new JGES guideline (FG) group, patients treated according to the guideline of JGES 2017 appendix ($n = 73$). After the publication of this new recommendation in July 2017, most patients were treated according to this guideline. Thus, the patients in group HB were mostly those who underwent polypectomy before the publication in 2017.

Anticoagulants were prescribed in each group according to these regimens: In HB group, warfarin was discontinued 3–7 days before polypectomy, and DOAC was discontinued 2–3 days before the procedure; then, continuous intravenous infusion of unfractionated heparin, 200 U/kg/day, was started, with the dose adjusted to achieve activated partial thromboplastin time 1.5–2.0-fold the upper limit or greater than 40 s. In FG group, warfarin was continued during and after polypectomy, with PT-INR maintained within the therapeutic range, or warfarin was temporarily replaced by DOACs, which were continued until 1 day before the procedure and discontinued on the morning of the procedure, according to the new JGES guidelines (2017, appendix) [4]. In all the patient groups, anticoagulants were resumed on the morning of the next day after the procedure unless signs of bleeding were observed. In HB group, heparin-bridging was continued until the PT-INR reached the therapeutic range after resumption of warfarin.

We also investigated possible risk factors associated with post-polypectomy bleeding. The location of polyps was categorized into right hemi-colon (cecum, ascending colon, and transverse colon), left hemi-colon (descending colon, sigmoid colon, and rectum), and bilateral (both right and left hemi-colon). Maximum polyp size was categorized as $< 10$ mm and $\geq 10$ mm diameter.

### Procedure

Colorectal polyps were observed with magnifying narrow-band imaging endoscopy and, when appropriate, with chromoendoscopy. The polyps were removed with a hot-snare polypectomy technique for pedunculated polyps or endoscopic mucosal resection for flat or protruded lesions. Devices used were as follows: captivator snare (13-mm small oval type, Boston Scientific, Marlborough, MA, USA) for polyps $< 15$ mm and double-loop snare (Dualoop, Medico's Hirata, Inc., Tokyo, Japan) or spiral snare (SD-230U-20, Olympus, Tokyo, Japan) for polyps $> 15$ mm. Prophylactic closure with clipping was carried out whenever possible, and a detachable snare was applied to large pedunculated polyps before resection. Two weeks after polypectomy, patients visited our outpatient clinic, when they were informed about the histopathology of the resected lesions and were interviewed about post-polypectomy adverse events, including bleeding. A median of follow-up period was 4 weeks (range, 2–4 weeks).

### Statistical analysis

A 2-sided 95% confidence interval of the incidence of post-polypectomy bleeding in each group was calculated. Characteristics of patients were compared by using the Fisher's exact test. Risk factors for post-polypectomy bleeding were analyzed with a multivariate logistic regression, in which variables with $p$ value less than 0.1 in the univariate analysis and variables related to antithrombotic drugs were included. Continuous variables were compared with the Mann-Whitney $U$ test. For the statistical analysis, we used EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria).

The study was approved by the institutional review board of the Kurashiki Central Hospital. Written informed consent for the procedures was obtained from all patients before they

**Table 1** Indications for taking anticoagulants

| | HB ($n = 139$) | FG ($n = 73$) | $p$ value |
|---|---|---|---|
| Non-valvular atrial fibrillation, $n$ (%) | 79 (57%) | 59 (81%) | < .001 |
| Valvular atrial fibrillation, $n$ (%) | 7 (5.0%) | 0 (0%) | .1 |
| Deep vein thrombosis, $n$ (%) | 11 (7.9%) | 5 (6.8%) | 1 |
| Pulmonary vein thrombosis, $n$ (%) | 10 (7.2%) | 0 (0%) | .02 |
| Post valve replacement, $n$ (%) | 15 (11%) | 0 (0%) | .002 |
| Post cerebral infarction, $n$ (%) | 2 (1.4%) | 3 (4.1%) | .34 |
| Old myocardial infarction, $n$ (%) | 6 (4.3%) | 4 (5.5%) | .74 |
| Dilated cardiomyopathy, $n$ (%) | 1 (0.7%) | 0 (0%) | 1 |
| Post vascular prosthesis implantation, $n$ (%) | 1 (0.7%) | 1 (1.4%) | 1 |
| Arteriosclerosis obliterans, $n$ (%) | 7 (5.0%) | 1 (1.4%) | .27 |

*HB* heparin bridging, *FG* following new Japanese guideline

underwent the procedure, and informed consent for participating in this study was obtained, with the opportunity to opt out.

## Results

### Characteristics of patients and polyps

Indications for anticoagulation therapy of the study patients are presented in Table 1. The most common indication in each group was atrial fibrillation. Characteristics of patients and polyps are presented in Table 2. Statistically significant differences among the groups were the following: (1) a higher proportion of patients was taking warfarin in HB group (91%) than in FG group (48%) ($p < .001$), (2) a higher proportion of patients was taking thienopyridine derivatives in HB group (13%) than in FG group (0%) ($p < .001$), (3) a higher proportion of patients was taking aspirin/non-steroidal antiinflammatory drugs (NSAIDs) in HB group (32%) than in FG group (18%) ($p = .02$), and (4) chronic heart failure was more prevalent in HB group patients (31%) than in FG group patients (15%) ($p = .01$). There was no statistically significant difference in several other variables: age, sex, and location, number, and maximum size of resected polyps among the groups.

### Outcomes

Post-polypectomy bleeding occurred in 25 of the 212 patients (11.8%). All bleeding episodes were managed successfully with endoscopic hemostasis. The rates of post-polypectomy bleeding according to the management of anticoagulants used are presented in Table 3 and Fig. 1. The rate of post-polypectomy bleeding in FG group (9.6%, 95% confidence interval, 3.9–18.8%) was not significantly different from that in HB group (12.9%, 7.9–19.7%) ($p = 0.5$) (Fig. 1).

**Table 2** Characteristics of patients and polyps

| | HB ($n = 139$) | FG ($n = 73$) | $p$ value |
|---|---|---|---|
| Warfarin, n (%)/DOAC | 127 (91%)/12 | 35 (48%)/38 | < .001 |
| Age ≥ 70 | 93 (67%) | 50 (68%) | .89 |
| Male | 102 (73%) | 57 (78%) | .51 |
| Thienopyridine derivative user | 18 (13%) | 0 (0%) | < .001 |
| Aspirin/NSAID user | 45 (32%) | 13 (18%) | .02 |
| Hypertension | 102 (73%) | 55 (75%) | .87 |
| Hyperlipidemia | 54 (39%) | 29 (40%) | 1 |
| Chronic heart failure | 43 (31%) | 11 (15%) | .01 |
| Cerebrovascular disease | 27 (19%) | 11 (15%) | .46 |
| Liver cirrhosis | 2 (1.4%) | 2 (2.7%) | .61 |
| Diabetes mellitus, $n$ (%) | 44 (32%) | 27 (37%) | .45 |
| Hemodialysis, $n$ (%) | 8 (5.8%) | 1 (1.4%) | .17 |
| Location of polyps (bilateral/right/left) | 58/40/41 | 36/14/20 | .56 |
| Number of polyps (≥ 3 polyps) | 59 (42%) | 40 (55%) | .11 |
| Maximum tumor size (≥ 10 mm) | 73 (53%) | 36 (49%) | .67 |

*DOAC* direct oral anticoagulant, *HB* heparin bridging, *FG* following new Japanese guideline

**Table 3** Post-polypectomy bleeding according to anticoagulants used

| | HB ($n = 139$) | FG ($n = 73$) | $p$ value |
|---|---|---|---|
| Warfarin/DOAC user, $n$ | 127/12 | 41/32 | |
| PPB per patient, $n$ (%, 95% CI) | 18/139 (12.9%, 7.9–19.7%) | 7/73 (9.6%, 3.9–18.8%) | 0.5 |
| PPB per warfarin user, $n$ (%, 95% CI) | 18/127 (14.2%, 8.6–21.5%) | 5/41 (12.2%, 4.1–26.2%) | 1.0 |
| PPB per DOAC user, $n$ (%, 95% CI) | 0/12 (0%, 0–22.1%) | 2/32 (6.3%, 0.8–20.8%) | 1.0 |

*CI* confidence interval, *PPB* post-polypectomy bleeding, *DOAC* direct oral anticoagulants, *HB* heparin bridging, *FG* following new Japanese guideline

The incidence of post-polypectomy bleeding in each group according to detailed management of their anticoagulants is presented in Fig. 2. In HB group, bleeding was observed in 18 (14.2%) of 127 patients with heparin-bridge for warfarin and in none of 12 patients with heparin-bridge for DOACs. In FG group, warfarin was not interrupted in 35 patients, and their PT-INR values on the day of polypectomy were within the therapeutic range (median PT-INR, 1.72); post-polypectomy bleeding occurred in 4 of these 35 patients (11.4%). In 6 patients, DOACs were temporarily substituted for warfarin, and the DOACs were stopped on the morning of the procedure; bleeding was observed in 1 patient (16.7%). In the remaining 32 patients of FG group receiving DOACs, the drugs were continued until the day before the procedure and discontinued on the morning of the procedure; bleeding occurred in 2 patients (6.3%).

Among patients receiving warfarin, the incidence of post-polypectomy bleeding in FG group (5/41, 12.2%; without cessation or switched to DOAC) was not significantly different from that in HB group with heparin-bridge (14.2%) ($p = 1.0$) (Table 3) (Fig. 3). In patients taking DOACs, the incidence was 6.3% in FG group and 0% in HB group; there was no significant difference among the groups (Table 3) (Fig. 4). In total, 50 patients were taking DOACs (rivaroxaban, $n = 19$; apixaban, $n = 15$; edoxaban, $n = 9$; and dabigatran, $n = 7$); post-polypectomy bleeding was observed in 3 (6%) patients among them. The incidence of post-polypectomy bleeding with each kind of DOACs, irrespective of the way the drug was prescribed, was 0% (0/19) with rivaroxaban, 6.7% (1/15) with apixaban, 11.1% (1/9) with edoxaban, and 14.3% (1/7) with dabigatran, an insignificant difference among the drugs ($p = .285$).

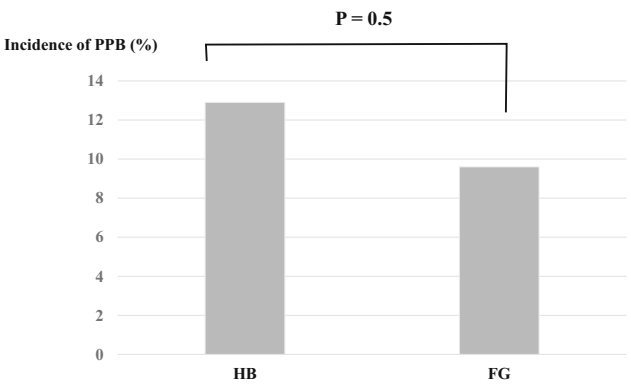


**Fig. 1** The incidence of post-polypectomy bleeding among the anticoagulant groups

Other outcomes of interest are summarized in Table 4. The day of onset of post-polypectomy bleeding was not significantly different among the groups ($p = .69$). Bleeding during the procedure and occurrence of bleeding after endoscopic hemostasis was observed only in HB group (3 patients taking warfarin, 2.2%, for each pattern of bleeding). No perforation occurred in any patient. Thromboembolism occurred in 1 patient, in HB group (0.7%), in whom transient ischemic attack was diagnosed at 14 days after polypectomy; the patient recovered without any neurologic symptoms. No mortality was observed in this study. The median days of hospital stay in FG group N (2 days) was significantly shorter than that in HB group (14 days) ($p < .001$) (Table 4).

### Risk factors for post-polypectomy bleeding

As illustrated in Table 5, multivariate analysis identified number of resected polyps (odds ratio, 2.8; 95% confidential interval, 1.1–7.2; $p = .03$) as a significant and independent risk factor of post-polypectomy bleeding, but management of anticoagulants according to the JGES new guidelines (FG group) was not a significant risk factor (1.0, 0.3–2.9, $p = .98$).

## Discussion

In this retrospective, case-controlled study of 212 patients receiving anticoagulant therapy who underwent hot-snare polypectomy or endoscopic mucosal resection for colonic polyps, the incidence of post-polypectomy bleeding in those managed according to the new guidelines of the JGES (uninterrupted warfarin if PT-INR is within the therapeutic range or short interruption of DOACs) was not significantly different from the incidence with traditional longer interruption of anticoagulants with heparin-bridging. The multivariate analysis also revealed that management of anticoagulants according to the new guidelines was not a significant risk factor for post-polypectomy bleeding. These findings support the validity of managing anticoagulants according to the new JGES guidelines, which is focused on reduction of thromboembolic

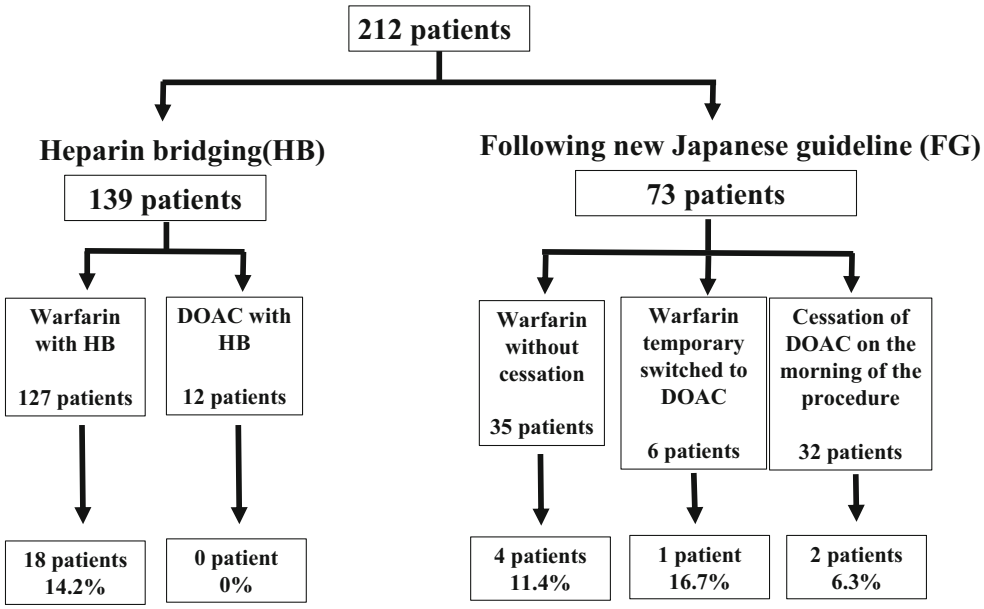


**Fig. 2** The incidence of post-polypectomy bleeding among the anticoagulant groups according to management of anticoagulants used. HB heparin-bridging, DOAC direct oral anticoagulant

events in patients taking anticoagulants, for hot-snare polypectomy of colonic polyps in terms of post-polypectomy bleeding. Cold polypectomy was demonstrated as a safe procedure for removal of small colorectal polyps among patients continuing anticoagulation therapy [5]; thus, patients who underwent cold polypectomy were not included in this study.

Before DOACs were commonly used, warfarin was the first-choice drug for anticoagulant therapy, and interruption of warfarin with heparin-bridging for 3 to 7 days before polypectomy was recommended for endoscopic procedures with bleeding risk. The new JGES guidelines [4], however, condone doing the procedures without interruption of warfarin if the PT-INR is within the therapeutic range. In this study, forgoing heparin bridging, i.e., continuation if warfarin during polypectomy, did not significantly increase the incidence of post-polypectomy bleeding (FG group; 12.2%) compared with that in patients whose warfarin treatment was interrupted with heparin-bridging (HB group; 14.2%) ($p = 1.0$). The figure of 12.2% was like the incidence (14%) that others have reported of post-polypectomy bleeding among patients who underwent the procedure without stopping warfarin [6]. Others have reported that forgoing heparin-bridging has decreased the risk of perioperative major bleeding without increasing the risk of arterial thromboembolism [3, 7–10]. Heparin bridging is a complicated and expensive addition to polypectomy protocols, requiring detailed instruction of patients and monitoring of activated partial thromboplastin time, and with significantly longer hospital stay, as shown in this study. In contrast, the new guidelines require only confirmation that the PT-INR is within the therapeutic range on the day of the procedure. Thus, not stopping warfarin for routine colorectal polypectomy circumvents the drawbacks of heparin bridging without evident increase in the risk of post-polypectomy bleeding.

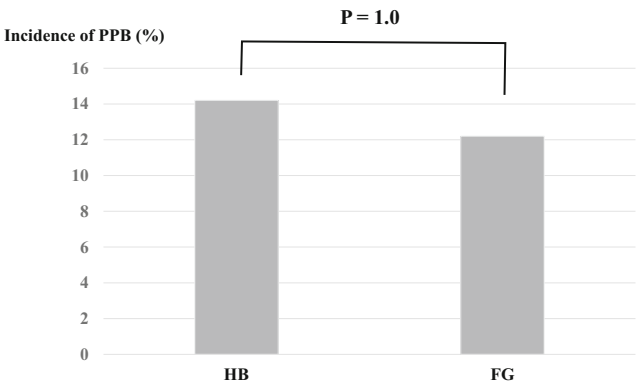


**Fig. 3** The incidence of post-polypectomy bleeding among anticoagulant groups in patients taking warfarin

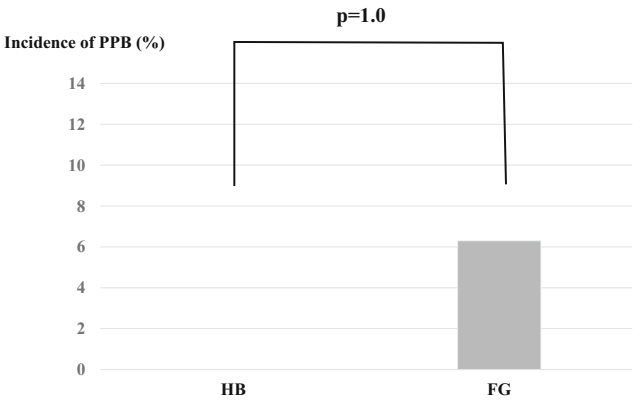


**Fig. 4** Incidence of post-polypectomy bleeding among anticoagulant groups in patients taking DOAC

**Table 4** Other outcomes of interest

| | HB ($n = 139$) | FG ($n = 73$) | $p$ value |
|---|---|---|---|
| Onset of PPB (day), median (range) | 3 (1–7) | 2 (1–4) | .69 |
| Recurrence of bleeding after endoscopic hemostasis, $n$ (%) | 3 (2.2%) | 0 (0%) | .53 |
| Incidence of bleeding during procedure, $n$ (%) | 3 (2.2%) | 0 (0%) | 1 |
| Perforation, $n$ (%) | 0 (0%) | 0 (0%) | 1 |
| Incidence of thromboembolic events, n (%) | 1 (0.7%) | 0 (0%) | 1 |
| Hospital stay (day), median (range) | 14 (2–33) | 2 (0–6) | < .001 |

*PPB* post-polypectomy bleeding, *HB* heparin bridging, *FG* following new Japanese guideline

**Table 5** Univariate and multivariate analysis for risk factors of post-polypectomy bleeding

| | | Univariate | | Multivariate | |
|---|---|---|---|---|---|
| | | Odds ratio (95% CI) | $p$ value | Odds ratio (95% CI) | $p$ value |
| Age | < 70 | Ref | | Ref | |
| | ≥ 70 | 4.0 (1.1–21.5) | .02 | 3.3 (0.9–11.9) | .06 |
| Sex | Female | Ref | | | |
| | Male | 1.1 (0.4–3.4) | 1 | | |
| Anticoagulant groups | HB | Ref | | Ref | |
| | FG | 0.7 (0.2–1.9) | .51 | 1.0 (0.3–2.9) | .98 |
| Anticoagulant | DOACs | Ref | | Ref | |
| | Warfarin | 2.4 (0.7–13.4) | .21 | 3.0 (0.7–12.5) | .14 |
| Aspirin/NSAID user | No | Ref | | Ref | |
| | Yes | 1.9 (0.7–4.9) | .15 | 1.8 (0.7–4.6) | .20 |
| Thienopyridine derivative user | No | Ref | | Ref | |
| | Yes | 0.4 (0.01–2.9) | .70 | 0.4 (0.1–3.4) | .41 |
| Hypertension | No | Ref | | | |
| | Yes | 0.6 (0.2–1.6) | .23 | | |
| Hyperlipidemia | No | Ref | | | |
| | Yes | 0.7 (0.2–1.8) | .52 | | |
| Chronic heart failure | No | Ref | | | |
| | Yes | 0.7 (0.2–2.1) | .63 | | |
| Cerebrovascular disease | No | Ref | | | |
| | Yes | 1.2 (0.3–3.5) | .78 | | |
| Liver cirrhosis | No | Ref | | | |
| | Yes | 2.5 (0.05–33.1) | .40 | | |
| Diabetes mellitus | No | Ref | | | |
| | Yes | 2.0 (0.8–5.1) | .12 | | |
| Hemodialysis | No | Ref | | | |
| | Yes | 0.9 (0.02–7.5) | 1 | | |
| Location of polyps | Bilateral | Ref | | | |
| | Right hemi-colon | 0.5 (0.1–1.5) | .23 | | . |
| | Left hemi-colon | 0.3 (0.1–1.1) | .08 | | |
| Number of polyps resected | < 3 | Ref | | Ref | |
| | ≥ 3 | 2.7 (1.0–7.6) | .03 | 2.8 (1.1–7.2) | .03 |
| Maximum tumor size | < 10 mm | Ref | | | |
| | ≥ 10 mm | 1.2 (0.5–3.2) | .67 | | |

*CI* confidence interval, *ref* reference, *PPB* post-polypectomy bleeding, *NSAIDs* non-steroidal antiinflammatory drugs, *HB* heparin bridging, *FG* following new Japanese guideline

With regard to patients receiving DOACs, we found that the incidence of post-polypectomy bleeding with short interruption of DOACs, only on the day of the procedure and resumption of the drug the next day, was higher than the incidence associated with interruption of the drug for 2 to 3 days before the procedure with heparin-bridging (6.3% vs. 0%), but the difference was not statistically significant. In the British Society of Gastroenterology (BSG)/European Society of Gastrointestinal Endoscopy (ESGE) guidelines [11], interruption of DOACs 2 to 3 days before and resumption of the drug 2 days after endoscopy in high-risk procedures, such as snare polypectomy and endoscopic mucosal resection, is suggested. In a recent prospective cohort study, Radaelli et al. [12] reported a trend for a higher rate of delayed bleeding with earlier resumption of DOACs (14.4%) than that recommended resumption by the BSG/ESGE guidelines (6.6%)($p = .27$). In our study with resumption of DOAC, the next day, such trend was not observed. The rate of 6.3% of post-polypectomy bleeding in our study seemed comparable to the rate (6.6%) with resumption of the drug according to the BSG/ESGE guidelines. Radaelli et al. reported also a trend for higher incidence rate of intraprocedural bleeding with shorter interruption of DOACs (25%) than that with recommended interval of interruption before procedures (10.3%)($p = .07$). In our study, shorter interruption of DOACs on the day of procedure did not increase the risk of intraprocedural bleeding (0%). The protocol in our study, where prophylactic closure with clipping was carried out whenever possible and a detachable snare was applied to large pedunculated polyps before resection, could be relevant to these variable results. More research may be needed to determine appropriate prescribing of DOACs for endoscopic procedures with high-risk of bleeding.

Limitations of our study are the following: First, the study was retrospective and single-center; thus, it may contain hidden biases and be non-representative of larger populations. Second, a thromboembolic event was observed only in 1 patient, in HB group. Because the risk of thromboembolic event is an infrequent post-polypectomy complication [13, 14], the number of subjects in this study may not have been large enough to permit accurate assessment of the possible effect of interruption of anticoagulants on this complication; large-scale or population-based studies should be conducted to further assess this issue.

In conclusion, this study found that the risk of bleeding after hot-snare polypectomy of colonic polyps in patients being treated with anticoagulants was not increased with periprocedural management of the anticoagulants according to new JGES guidelines (continuation of warfarin with PT-INR in the therapeutic range or 1-day interruption of DOACs), compared with that of heparin-bridge anticoagulation. Although the effects of new guidelines on the risk of thromboembolic effects have not been fully evaluated, prescribing of anticoagulants according to the guidelines appears to be acceptably safe in terms of the bleeding and may even be preferable to previous practices, given the complexities and expense of heparin-bridge anticoagulation.

## Compliance with ethical standards

The study was approved by the institutional review board of the Kurashiki Central Hospital. Written informed consent for the procedures was obtained from all patients before they underwent the procedure, and informed consent for participating in this study was obtained, with the opportunity to opt out.

**Conflict of interest** The authors declare that they have no conflict of interest.

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