

Newly developed endoscopic detachable snare ligation therapy for colonic diverticular hemorrhage: a multicenter phase II trial (with videos)

Daisuke Akutsu, MD,¹ Toshiaki Narasaka, MD, PhD,² Katsumasa Kobayashi, MD,³ Kenji Matsuda, MD,⁴ Mariko Wakayama, MD, PhD,⁵ Yoshinori Hiroshima, MD,⁶ Shinji Endo, MD, PhD,⁷ Takashi Mamiya, MD, PhD,⁸ Takahisa Watahiki, MD,⁹ Kazuto Ikezawa, MD, PhD,¹⁰ Hiroyasu Ishida, MD, PhD,¹¹ Mitsuaki Hirose, MD, PhD,¹² Yuji Mizokami, MD, PhD,² Ichinosuke Hyodo, MD, PhD¹

Ibaraki, Tokyo, Chiba, Japan

Background and Aims: We previously reported preliminary safety results for a new method, endoscopic detachable snare ligation (EDSL), for diverticular hemorrhage. This method does not need endoscope removal to attach a ligation device after detection of the bleeding site. The aim of the present study was to evaluate the efficacy and safety of EDSL in a larger patient population.

Methods: This prospective study was conducted in 12 institutions. Patients suspected of having diverticular hemorrhage without serious systemic disease were enrolled. The primary endpoint was early (within 30 days) recurrent bleeding rate in patients treated with EDSL. The secondary endpoints were overall early recurrent bleeding rate in patients with definite diverticular bleeding and adverse events in patients treated with EDSL.

Results: From June 2015 to March 2017, bleeding diverticula were detected in 123 of 205 enrolled patients (60%), of whom 101 (82%) were treated with EDSL. Most patients (20/22) in whom EDSL was not successful were treated with clipping. The early recurrent bleeding rate was 7.9% (95% confidence interval, 2.6%-13.2%; 8/101) in patients who could be treated with EDSL. The median total endoscopic and EDSL procedure time was 40 minutes (interquartile range, 15-71) and 4 minutes (interquartile range, 1-7), respectively. Two mild adverse events, colonic diverticulitis and temporary abdominal pain, were observed.

Conclusion: EDSL was confirmed to be useful and safe for treatment of colonic diverticular hemorrhage. (Clinical trial registration number: UMIN 000001858.) (Gastrointest Endosc 2018; ■:1-8.)

Abbreviations: EBL, endoscopic band ligation; EDSL, endoscopic detachable snare ligation; IQR, interquartile range; SRH, stigmata of recent hemorrhage.

DISCLOSURE: All authors disclosed no financial relationships relevant to this publication. Research support for this study was provided by the nonprofit organization Tsukuba Cancer Clinical Trial Group.

Copyright © 2018 by the American Society for Gastrointestinal Endoscopy 0016-5107/\$36.00

<https://doi.org/10.1016/j.gie.2018.04.2337>

Received September 13, 2017. Accepted April 10, 2018.

Current affiliations: Department of Gastroenterology, University of Tsukuba, 1-1-1, Tennodai, Tsukuba, Ibaraki, Japan (1), Division of Endoscopic Center, University of Tsukuba Hospital, 2-1-1, Amakubo, Tsukuba, Ibaraki, Japan (2), Department of Gastroenterology, Tokyo Metropolitan Bokutoh Hospital, 4-23-15, Kotobashi, Sumida-ku, Tokyo, Japan (3), Department of Gastroenterology, Tsukuba Gakuen Hospital, 2573-1, Kamiyokoba, Tsukuba, Ibaraki, Japan (4), Department of

Gastroenterology, Koyama Memorial Hospital, 5-1-2, Kuriya, Kashima, Ibaraki, Japan (5), Department of Gastroenterology, Hitachinaka General Hospital, 20-1, Ishikawa, Hitachinaka, Ibaraki, Japan (6), Department of Gastroenterology, Shinmatsudo Central General Hospital, 1-380, Shinmatsudo, Matsudo, Chiba, Japan (7), Department of Gastroenterology, Ryugasaki Saiseikai Hospital, 1-1, Nakasato, Ryugasaki, Ibaraki, Japan (8), Department of Gastroenterology, Hitachi General Hospital, 2-1-1, Johnan, Hitachi, Ibaraki, Japan (9), Department of Gastroenterology, Tsukuba Memorial Hospital, 1187-299, Kaname, Tsukuba, Ibaraki, Japan (10), Department of Gastroenterology, Mito Medical Center, 280, Sakuranosato, Ibarakimachi, Ibaraki, Japan (11), Department of Gastroenterology, Kasumigaura Medical Center, 2-7-14, Shimotakatsu, Tsuchiura, Ibaraki, Japan (12).

Reprint requests: Daisuke Akutsu, MD, Department of Gastroenterology, University of Tsukuba, 1-1-1, Tennodai, Tsukuba, Ibaraki 305-8576, Japan. Tel: +81-29-853-3218; Fax: +81-29-853-3218. E-mail: dakutsu11@yahoo.co.jp.

Diverticular hemorrhage accounts for 20% to 42% of cases of lower GI bleeding.¹⁻⁴ The incidence of diverticular hemorrhage has been increasing with the growing use of antithrombotic drugs in elderly patients.^{5,6} In general, diverticular hemorrhage shows a better clinical course than upper GI, and the bleeding stops spontaneously in 70% to 80% of patients.⁷ However, some patients require hemostasis through endoscopic, surgical, or interventional radiologic treatment. Colonoscopy can detect the major stigmata of recent hemorrhage (SRH), such as active bleeding, visible vessels, and adherent clots, and minor SRH, such as flat spots in patients with colonic diverticula; the recurrent bleeding rate in these patients is reported to be relatively high (over 60%) with medication treatment alone.⁹

After identification of SRH, the current usual treatment for diverticular bleeding is endoscopic hemostasis,^{8,9} with clipping, endoscopic band ligation (EBL), injection therapy, or thermal contact. EBL has been used more frequently than clipping, because the early recurrent bleeding rate with EBL is lower than that with clipping.¹⁰ EBL is effective in patients with bleeding from the diverticular dome and in those with massive hemorrhage, who are difficult to treat with endoscopic clipping. However, EBL is inconvenient because removal and reinsertion of the colonoscope is required to place the band ligation device on the scope tip^{11,12} and is more expensive than endoscopic clipping.

To address these issues, we have developed a novel endoscopic hemostatic method, endoscopic detachable snare ligation (EDSL). We performed a pilot study and reported the preliminary safety results of EDSL.¹³ The ligation snare can be inserted through the forceps port, and endoscope removal is not needed in this procedure. In the present study, we evaluated the efficacy and safety of EDSL in a larger population of patients with diverticular bleeding.

METHODS

Patients

This is a prospective, multicenter interventional trial to evaluate the efficacy and safety of EDSL. Patients who fulfilled the following inclusion criteria were enrolled: presence of bloody stools and suspected diverticular bleeding, patients who were able to undergo colonoscopy safely, age ≥ 20 years, and written informed consent to participate in this study. Exclusion criteria were as follows: (1) serious heart failure (New York Heart Association class III or higher), chronic renal failure on dialysis, liver cirrhosis with Child-Pugh classification C, or respiratory failure ($\text{SpO}_2 < 90\%$ in room air); (2) sepsis; (3) high-dose steroid use (prednisolone dosage > 10 mg/day); and (4) bleeding tendency (platelets $< 5 \times 10^4/\mu\text{L}$, prothrombin time-international normalized ratio > 3.0 , activated partial thromboplastin time > 50 seconds, disseminated intravas-

cular coagulation, or other severe coagulopathy). In the present study, we evaluated the safety and efficacy of our new method objectively as a clinical trial. We believe patients with severe comorbidities are generally excluded in clinical trials for new drugs or procedures to ensure adequate safety and appropriate evaluation. Especially regarding the regular use of prednisone, because there was a report of perforation with EBL hemostasis, the use of prednisone was set as exclusion criteria.

Colonoscopy examination

All patients received standard supportive medical care for lower GI bleeding, including hemodynamic monitoring and fluid resuscitation. Packed red blood cells were transfused to improve anemia when necessary, and bowel preparation with polyethylene glycol solution and/or glycerin enema was performed before colonoscopy at the discretion of each endoscopist. In some cases of urgent colonoscopy, we performed colonoscopy without an oral bowel preparation using a water-jet system (PCF-Q260AZI or CF-H290I; Olympus Optical Co, Ltd, Tokyo, Japan) for vigorous irrigation and a transparent hood (MAJ663; Olympus) to improve visualization. Bowel preparation is also recommended before colonoscopies in Japan. However, in cases of urgent colonoscopies, we often perform colonoscopy using a water-jet scope with a cap because active bleeding should be stopped as soon as possible. The definite bleeding site was identified by suctioning diverticular mucosa into the cup of the hood. Definite colonic diverticular hemorrhage was defined as a diverticulum with major SRH (active bleeding, a nonbleeding, visible ruptured vessel, or an adherent clot despite vigorous irrigation) and minor SRH (a flat spot in a diverticulum).

Study design

The primary endpoint was the early recurrent bleeding rate from the treated diverticulum in patients who were treated with EDSL. Early recurrent bleeding was defined as lower GI bleeding within 30 days of hemostasis. The secondary endpoints were overall early recurrent bleeding rate in patients who had definite diverticular bleeding, total procedure time, EDSL procedure time, and adverse events in patients who were treated with EDSL. Total procedure time was defined as the total time from insertion of the scope to the end of colonoscopy. EDSL procedure time was defined as the time from insertion of the snare through the scope to detachment of the ligated snare and cutting of extra wire. Adverse events of endoscopic hemostasis were followed for 1 month after treatment.

This multicenter phase II study was conducted in 12 institutions and was supported by the nonprofit organization Tsukuba Cancer Clinical Trial Group. This study was performed in accordance with the Declaration of Helsinki and the Japanese Clinical Research Guidelines and was approved by the ethics committee of each participating

Download English Version:

<https://daneshyari.com/en/article/8727836>

Download Persian Version:

<https://daneshyari.com/article/8727836>

[Daneshyari.com](https://daneshyari.com)