

A PROSPECTIVE RANDOMIZED CONTROLLED MULTICENTER TRIAL OF HIGHLY MUCOADHESIVE POWDER FOR HEMOSTASIS IN THE BLEEDING OF PEPTIC ULCER AND POST-ENDOSCOPIC RESECTION

Su Jin Hong¹, Byoung Wook Bang², Kye Sook Kwon², Hyung Kil Kim², Jae Jin Hwang¹, Jong Ho Moon¹, Eunhye Lee³, Yong Woon Shin²

¹Digestive Disease Center and Research Institute, Department of Internal Medicine, SoonChunHyang University School of Medicine, Bucheon, Korea;

² Division of Gastroenterology, Department of Internal Medicine, Inha University School of Medicine, Incheon, Korea; ³ Utah-Inha DDS & Advanced Therapeutics Research Center, Incheon, Korea

INTRODUCTION

- ✓ Endoscopic hemostasis is represented by epinephrine injection, electrosurgical coagulation, and mechanical clipping
- ✓ Effective hemostasis can be challenging due to the location of and severity of bleeding
- ✓ UI-EWD (Next Biomedical, Incheon, South Korea)
 - A highly adhesive powder and new spraying device to prevent catheter clogging
 - For endoscopic use
- ✓ The hemostatic effects of UI-EWD
 - UI-EWD powder immediately forms a hydrogel when contacting the water
 - The hydrogel shows high adhesiveness and persistency on ulcer base

AIMS

- To confirm 1) success rate of hemostasis using UI-EWD powder, 2) re-bleeding rate on second-look endoscopy at 3 days after the procedure, 3) persistent rate of UI-EWD on ulcer base at follow-up endoscopy, 4) clogging rate of spraying catheter during applying UI-EWD

PATIENTS

- ✓ Study design (ClinicalTrials.gov No. NCT02978391)
 - Study period: May 2015 - November 2016
 - A prospective randomized controlled trial, two medical centers
- ✓ Inclusion criteria
 - Adults over 20 years
 - Active bleeding or nonbleeding visible vessels of peptic ulcer (Forrest Ib-IIb)
 - Bleeding after EMR/ESD
- ✓ Exclusion criteria
 - Advanced gastric malignant tumor
 - Uncorrected coagulopathy (platelet < 50,000/μl or INR>2)
 - Continuous anticoagulant or aspirin
 - Pregnant and lactating

METHODS

- ✓ UI-EWD and the new spraying device

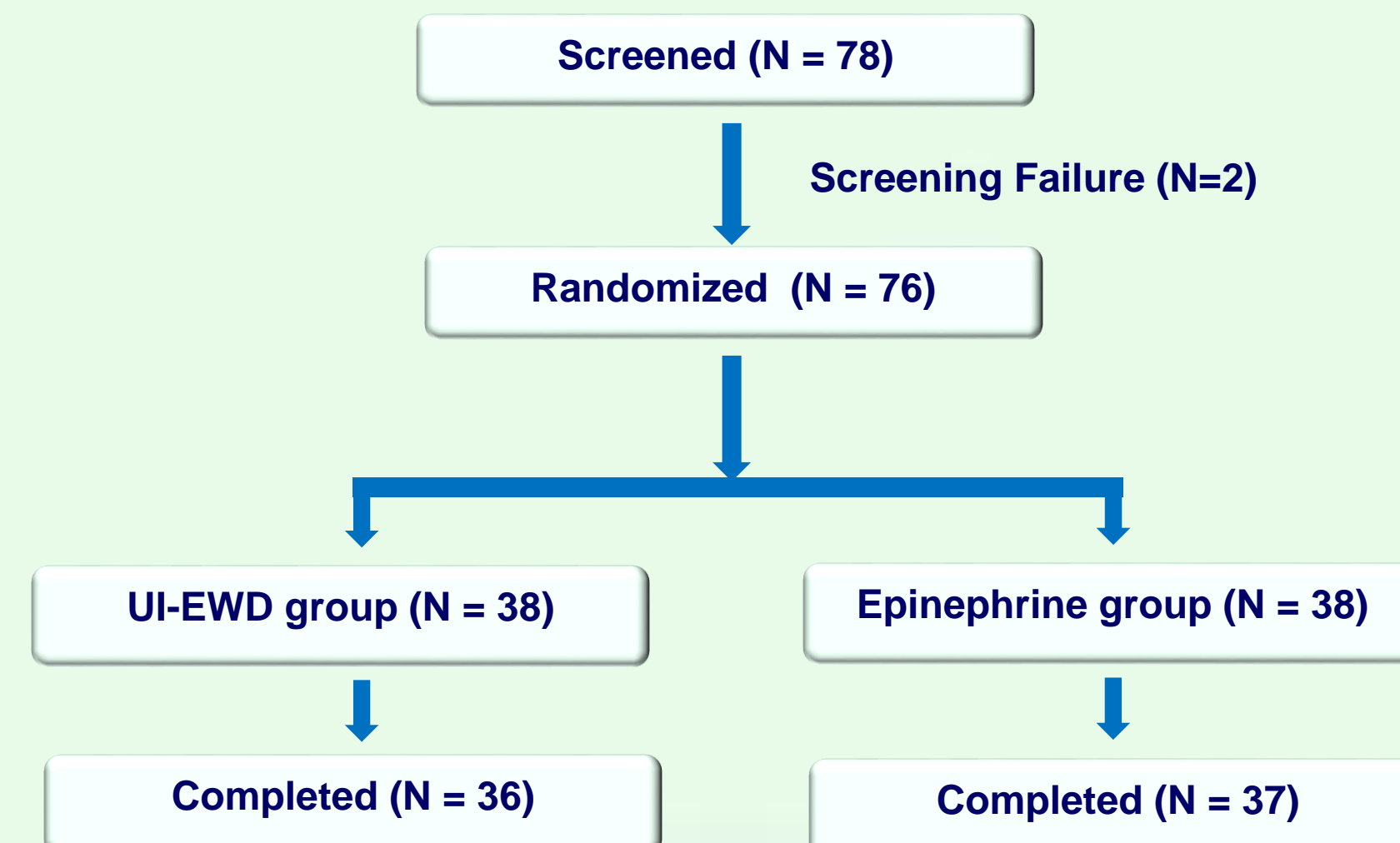


- ✓ The procedure

- Control group – epinephrine was diluted into 1:10,000 and injected into the submucosal tissue up to 10 mL
- UI-EWD group – UI-EWD powder was applied up to 6 gm
- ✓ The initial hemostatic success was defined as when the bleeding disappeared within 10 minutes after endoscopic treatment.
- ✓ A second-look endoscopy was performed in one and three days after the procedure.

RESULTS

RESULTS 1. Flow Chart of the Study Participants



RESULTS 2. Baseline Characteristics of Enrolled Patients

		UI - EWD	Epinephrine	Total
Sex	Male [N (%)]	26 (70.27)	27 (71.05)	53 (70.67)
	Female [N (%)]	11 (29.73)	11 (28.95)	22 (29.33)
	P-value			0.9407 ^{ff}
Age	Mean ± SD	65.57 ± 10.23	62.39 ± 10.10	63.96 ± 10.22
	P-value			0.1334 [§]

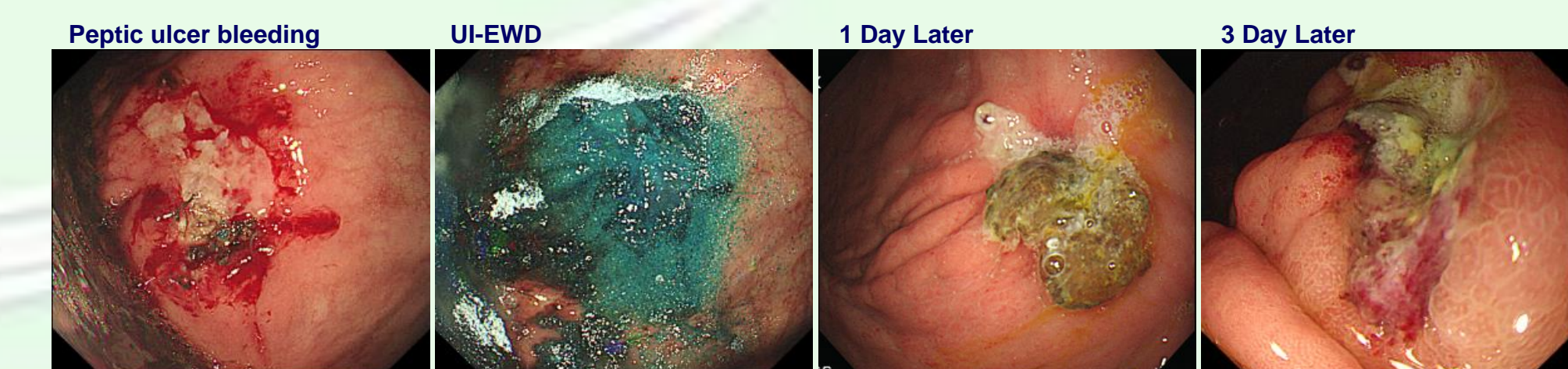
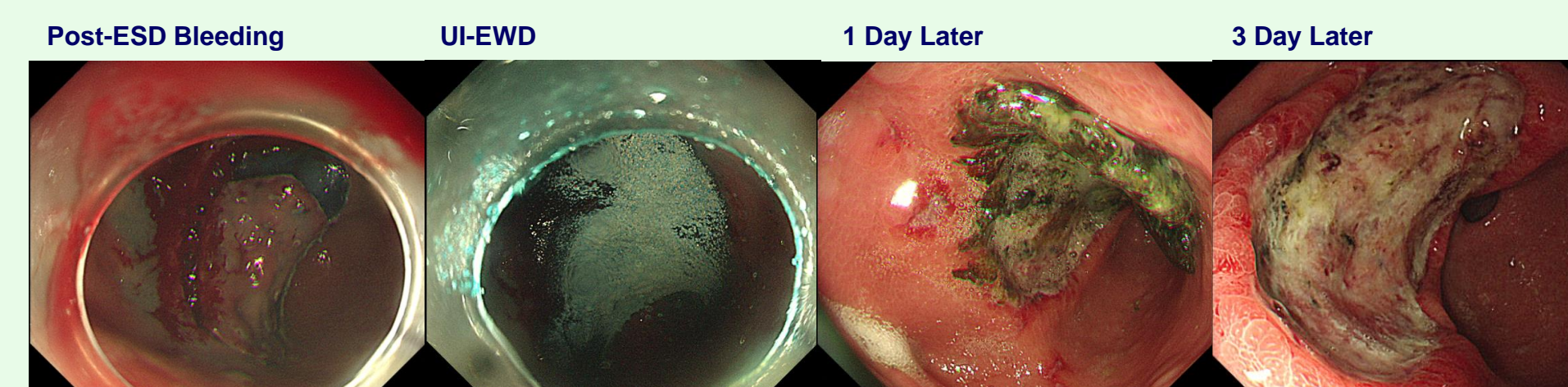
[†]: Independent two-sample t-test, [§]: Wilcoxon rank sum test, ^{ff}: Chi-square test.

RESULTS 3. Causes of Bleeding and Endoscopic Findings

		UI - EWD	Epinephrine	Total
Causes of Bleeding	EMR	3 (7.90)	3 (7.90)	6 (7.90)
	ESD	33 (86.84)	35 (92.10)	68 (89.47)
	Peptic ulcer	2 (5.26)	0 (0.00)	2 (2.63)
	P-value			0.3143 [§]
Endoscopic Findings (Forrest Classification)	Class I _b	29 (76.32)	27 (71.05)	56 (73.68)
	Class II _a	7 (18.42)	10 (26.32)	17 (22.37)
	Class II _b	2 (5.26)	1 (2.63)	3 (3.95)
	P-value			0.6819 [§]

[§]: Fisher's exact test

RESULTS 4. A Case of UI-EWD Group



RESULTS 5. Comparison of Clinical Outcomes

	UI - EWD	Epinephrine	P - value
Initial hemostatic success	97.2 % (35/36)	78.4% (29/37)	0.031
Re-bleeding rate within 3 days	5.6 % (2/36)	13.8 % (4/29)	0.096
Persistent rate of UI-EWD	63.6% (1 day after) 38.9% (3 days after)	-	
Clogging rate of spraying catheter	5.6 % (2/36)	-	

CONCLUSIONS

The endoscopic application of UI-EWD is more effective for the acute ulcer bleeding than epinephrine injection. The hemostatic action of UI-EWD appears to be from high mucoadhesiveness and hydrogel persistence. In addition, a newly developed delivery system shows low rate of catheter clogging and targeted spraying properties onto ulcer base.