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Efficacy of a novel hemostatic adhesive powder in patients with refractory upper gastrointestinal bleeding: Pilot study

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Introduction:

A new hemostatic adhesive powder (Nexpowder, NEXTBIOMEDICAL CO., LTD., Incheon, South Korea) has been developed to prevent the high re-bleeding rate and circumvent the technical challenges faced during application of current available hemostatic powders and conventional hemostatic treatment. The current study aimed to assess the efficacy of Nexpowder as a salvage therapy for the treatment of refractory upper gastrointestinal bleeding (UGIB).

Aims & Methods:

A total of 17 consecutive patients who had failed to achieve hemostasis with conventional endoscopic procedures and had undergone Nexpowder for endoscopic hemostasis in refractory UGIB were prospectively enrolled in the study. We evaluated the success rate of initial hemostasis and rate of re-bleeding within 30 days.

Fig 1. Compositions of Nexpowder

- Powder consists of oxidized dextran and succinic acid modified amino acid.
- Powder forms the highly adhesive gel after contacting the water.
- Adhesive gel provides mechanical barrier
- Gel persists for 24h and degraded within 3 days.

Fig 2. Flow diagram of enrolled patients

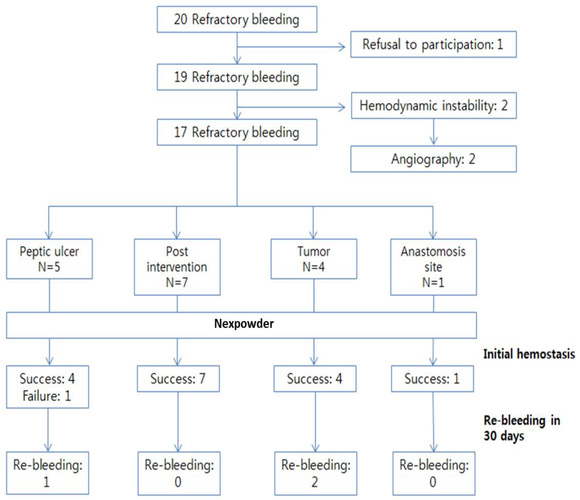


Table 1. Characteristics of patients and bleeding

Total patients, n	17
Age (years), median (range)	76 (41-82)
Gender (male/female)	13/4
The reasons for bleeding, n (%)	
Peptic ulcer	5 (29.4)
Post-intervention bleeding	7 (41.2)
Tumor bleeding	4 (23.5)
Other	1 (0.6)
Location of the bleed, n (%)	
Stomach	
Fundus and cardia	1 (5.9)
Body	8 (47.1)
Antrum	4 (23.5)
Duodenum	3 (17.6)
Anastomosis site bleeding	1 (5.9)
Comorbidity, n (%)	
Hypertension	9 (52.9)
Coronary artery disease	3 (17.6)
Congestive heart failure	3 (17.6)
Diabetes mellitus	2 (11.7)
Chronic kidney disease	2 (11.7)
Liver cirrhosis	1 (5.9)
Anticoagulation, n (%)	5 (29.4)
Warfarin	4 (23.5)
Aspirin and Clopidogrel	1 (5.9)
The prior endoscopic treatment, n (%)	
Injection and thermal treatment	13 (76.6)
Injection, thermal and clipping	4 (23.5)
Forrest classification, n (%)	
Ia	2 (11.7)
Ib	15 (88.3)

Results:

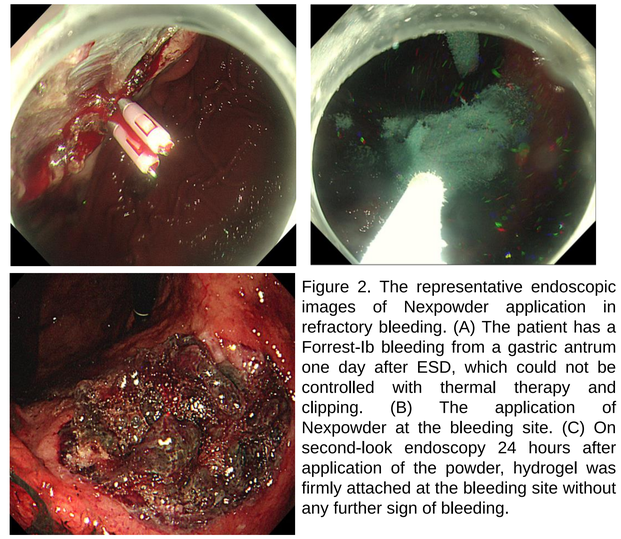
Nexpowder was used as a salvage therapy for refractory bleeding and successfully applied at bleeding sites in all patients. Successful initial hemostasis was achieved by Nexpowder in 16/17 patients (94.1 %, Table 2), and failed in only 1 patient. The patient with failure of initial hemostasis had a spurting arterial bleed at the duodenum, which could not be controlled even by combination of additional Nexpowder application, coagulation and injection therapies. The bleeding was finally controlled by interventional angiography.

In the second-look endoscopy 24 hours after the procedure, hydrogel from Nexpowder was still found attached at the bleeding site in 11/16 successful cases (68.8%).

Re-bleeding within 7 days occurred in 3 patients; 2 patients had re-bleeds quite early (within 48 hours) and was the result of tumor bleeding. Both were successfully treated with combination of Nexpowder application and thermal therapy. The remaining 1 patient was afflicted with liver cirrhosis and had a re-bleed at 7 days due to a peptic ulcer. Other than this, no other re-bleeding was occurred within 30 days. There was no occurrence of any adverse event related with the powder in

Table 2. Clinical outcome of Nexpowder in refractory bleeding

Total Patients, n	17
Success of initial hemostasis, n (%)	16 (94.1)
Overall re-bleeding at day 7, n (%)	3 (17.6)
Spurting hemorrhage (Forrest type Ia), n	2
Success of Initial hemostasis, n (%)	1 (50)
Re-bleeding, n (%)	0 (0)
Tumor bleeding, n	4
Success of Initial hemostasis, n (%)	4 (100)
Re-bleeding, n (%)	2 (50)



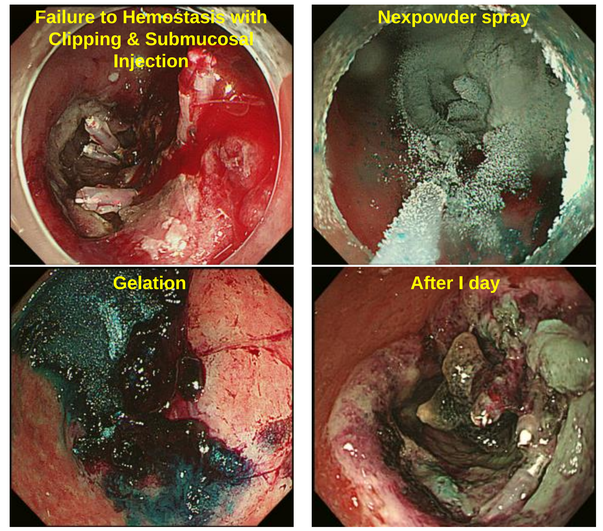


Figure 2. The representative endoscopic images of Nexpowder application in refractory bleeding. (A) The patient has a Forrest-Ib bleeding from a gastric antrum one day after ESD, which could not be controlled with thermal therapy and clipping. (B) The application of Nexpowder at the bleeding site. (C) On second-look endoscopy 24 hours after application of the powder, hydrogel was firmly attached at the bleeding site without any further sign of bleeding.

Conclusions:

This study demonstrates the effectiveness of Nexpowder as a salvage therapy in the treatment of refractory UGIB. The inclusion of these patients in future trials is recommended to increase the generalizability of the results.