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Research Article

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Compression Hemostasis in Refractory Esophageal Bleeding

A.Yu. Anisimov ✉, R.A. Ibragimov, G.Sh. Mansurova, R.K. Zalyalov

Department of Emergency Medical Care and Simulation Medicine, Center of Medicine and Pharmacy, Higher School of Medicine, Institute of Fundamental Medicine and Biology Kazan (Volga Region) Federal University
18, Kremlyovskaya Str., Kazan 420008, Russian Federation

✉ **Contacts:** Andrey Yu. Anisimov, Doctor of Medical Sciences, Professor, Corresponding Member RANS, Head of the Department of Emergency Medical Care and Simulation Medicine, Center of Medicine and Pharmacy, Higher School of Medicine, Institute of Fundamental Medicine and Biology, Kazan (Volga Region) Federal University. Email: aanisimovbsmp@yandex.ru

RELEVANCE Efficiency and safety of compression hemostasis with esophageal self-expanding nitinol stents Danis compared to the Sengstaken–Blakemore tube in the treatment program of refractory esophageal bleeding still remains a controversial issue.

AIM OF THE STUDY To conduct a comparative analysis of the effectiveness of Danis self-expanding compression hemostasis nitinol stent and the Sengstaken-Blakemore tube for variceal esophageal bleeding refractory to drug and endoscopic treatment.

MATERIAL AND METHODS The first comparison group included 44 patients, in whose complex treatment program tamponade with a Sengstaken-Blakemore tube was used to save lives. The second main group of the study consisted of 15 patients in whom compression hemostasis was performed using Danis self-expanding nitinol stent. Statistical processing was carried out using the Kolmogorov-Smirnov, Student, χ^2 and Fisher exact tests. Differences were considered statistically significant at $p \leq 0.05$.

RESULTS In the comparison group, complications occurred in 44 (100%), in the main group complications were observed in 8 patients (53.3%). Accordingly, reliable mechanical hemostasis was achieved in 33 (75.0%) and 13 clinical observations (86.7%); trophic changes in the esophageal mucosa were detected in 12 (27.2%) and 8 patients (53.3%). When assessing the function of external respiration, 5th and 2nd degrees of decrease in the ventilation capacity of the lungs, as well as 3rd and 1st degrees of decrease in the vital capacity of the lungs were established. The overall mortality was 56.8% in the comparison group and 26.7% in the main group.

CONCLUSION Self-expanding compression hemostasis nitinol stent Danis as a bridge to the choice of definitive therapy compared to tamponade with the Sengstaken–Blakemore tube is a promising alternative first-line treatment for patients with refractory esophageal bleeding. At the same time, it is necessary to conduct randomized controlled studies to confirm the safety and effectiveness of self-expanding nitinol stents.

Keywords: portal hypertension, refractory esophageal bleeding, compression hemostasis, self-expanding nitinol stent, tube

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Affiliations

Andrey Yu. Anisimov	Doctor of Medical Sciences, Professor, Corresponding Member RANS, Head of the Department of Emergency Medical Care and Simulation Medicine, Center of Medicine and Pharmacy, Higher School of Medicine, Institute of Fundamental Medicine and Biology, Kazan (Volga Region) Federal University; https://orcid.org/0000-0003-4156-434X, aanisimovbsmp@yandex.ru; 40%, idea and development of study design, participation in analysis of results, writing, editing, approval of the final version of the manuscript
Rinat A. Ibragimov	Associate Professor of the Department of Emergency Medical Care and Simulation Medicine, Center of Medicine and Pharmacy, Higher School of Medicine, Institute of Fundamental Medicine and Biology, Kazan (Volga Region) Federal University; https://orcid.org/0000-0003-0788-9845, rinatibr@mail.ru; 20%, selection and supervision of patients, collection and processing of data, participation in the analysis of results, text editing
Guzel Sh. Mansurova	Associate Professor of the Department of Emergency Medical Care and Simulation Medicine, Center of Medicine and Pharmacy, Higher School of Medicine, Institute of Fundamental Medicine and Biology, Kazan (Volga Region) Federal University; http://orcid.org/0000-0003-3780-5243, gsmansurova@kpfu.ru; 20%, collection and analysis of literature data, participation in the analysis of results, text editing
Ramil K. Zalyalov	Head of the Endoscopy Department of the Medical and Sanitary Unit of the Kazan (Volga Region) Federal University; http://orcid.org/0000-0001-7459-9878, romazzol@mail.ru; 10%, performing endoscopic procedures, data collection and technical processing

FEV – forced expiratory volume
pVC – proper vital capacity of the lungs
pFEV – proper forced expiratory volume
VC – vital capacity of the lungs

INTRODUCTION

In September 1877, at the St. Petersburg Imperial Medical-Surgical Academy, the young Russian doctor Nikolai Vladimirovich Eck ushered in the era of effective surgical treatment of patients with portal hypertension [1]. However, even today, 145 years after the experimental formation of the Eck fistula, mortality from variceal bleeding, despite the achievements of recent years, is about 10–20% within 6 weeks, depending on the degree of liver dysfunction [2–4].

Current recommendations for the treatment of variceal bleeding consist of a combination of hemodynamic stabilization with careful intravascular volume replacement, antibiotic prophylaxis, vasoactive drugs such as terlipressin, somatostatin or their analogues, and endoscopic treatment, preferably endoscopic ligation [5–6]. However, despite the use of modern "gold standards" of pharmacological and endoscopic therapy, in 15–20% of patients, primary massive bleeding excludes the possibility of endoscopic ligation, or the bleeding cannot be stopped, or it relapses within the next 5 days [7, 8]. Mortality in such patients reaches 30–50% in several series [9]. If the above first-line therapy fails in hemodynamically stable patients, endoscopic ligation may be attempted again. If this cannot be done in case of profuse bleeding and unstable hemodynamics, compression hemostasis is usually performed with balloon tamponade using a Sengstaken–Blakemore tube, which is effective in controlling bleeding, at least temporarily, in more than 80% of patients [5]. At the same time, balloon tamponade with a Sengstaken–Blakemore tube should be used only as a temporary "bridge" to combat massive bleeding, no more than 12–24 hours, during which a decision should be made on the choice of definitive therapy: surgical bypass, TIPS or liver transplantation [10]. The fact is that balloon tamponade is associated with a high risk of developing serious complications, especially in cases where the obturator probe is in place for a long time, more than 24 hours, or when it is inserted by untrained personnel [11].

Recent studies indicate that in case of refractory variceal esophageal bleeding, esophageal self-expanding nitinol stents can be a means of hemostasis that is just as effective and safer than balloon tamponade [2, 8, 11, 12]. However, despite recommendations based on evidence in accordance with the Oxford system, developed during a number of consensus meetings [13–15], this position in the treatment program for variceal bleeding remains not fully resolved.

Taking into account the above, **the aim of the study was a comparative analysis of the effectiveness of compression hemostasis with** the Danis self-expanding nitinol stent and the Sengstaken–Blakemore tube for variceal esophageal bleeding refractory to drug and endoscopic treatment.

MATERIAL AND METHODS

We analyzed the results of treatment of variceal bleeding from the esophagus, refractory to drug and endoscopic therapy in two relatively representative groups of patients. Inclusion criteria were bleeding that reappeared within 2 hours after the start of drug therapy and endoscopic ligation with latex Shooter rings of the endoscopic ligator of Cook Medical (USA, Denmark, Ireland) [14], or massive bleeding, the severity of which excluded endoscopic ligation, or the latter was technically unavailable at the time of bleeding. The first comparison group included 44 patients who used the Sengstaken–Blakemore tube. The second main group included 15 patients who used a self-expanding nitinol stent. There were 28 men (47.5%) and 31 women (52.5%). There were

12 (20.3%) patients aged from 15 to 39 years, 32 (54.2%) from 40 to 59 years, 15 patients (25.5%) from 60 years and older. All 59 patients had liver cirrhosis, including viral hepatitis B in 4 (6.8%), viral hepatitis C in 27 (45.8%), mixed hepatitis B and C" – in 5 (8.5%), alcoholic etiology – in 19 (32.2%), unspecified etiology – in 4 (6.7%). According to the Child–Pugh criteria, liver cirrhosis of class A was in 6 (10.2%), B – in 30 (50.8%), C – in 23 patients (39.0%). Fifty-two patients (88.1%) had a history of variceal bleeding, and 7 (11.9%) were hospitalized for their first episode of bleeding. Eleven patients (18.6%) had moderate blood loss, and 48 (81.4%) had severe blood loss.

Sengstaken–Blakemore obturator probe was 2.2 ± 1.2 (p = 0.075) days. To prevent trophic disorders, the esophageal balloon was released 2–4 hours after installation. If bleeding from esophageal varices continued, the esophageal balloon was reinflated. This procedure was repeated at intervals of 2–4 hours until hemostasis of the self-expanding nitinol stent was achieved—6.4±1.4 days (p =0.063).

Sengstaken–Blakemore obturator probe is a multi-lumen rubber tube with inflatable esophageal (100 cm^3) and gastric (150 cm^3) balloons (Fig. 1) [16].

Fig. 1. External view of the Sengstaken–Blakemore tube with inflated esophageal and gastric balloons

A self-expanding nitinol stent is a hollow metal frame made of nitinol wire coated with a silicone film [17]. The diameter of the expanded stent is 25 mm, the neck diameter is 30 mm, and the length of the stent is 135 cm (Fig. 2). After installation, the distal end of the stent should be located 1–2 cm below the esophagogastric junction, and the proximal end below the upper esophageal sphincter (Fig. 3).

Fig. 2. Expanded nitinol stent

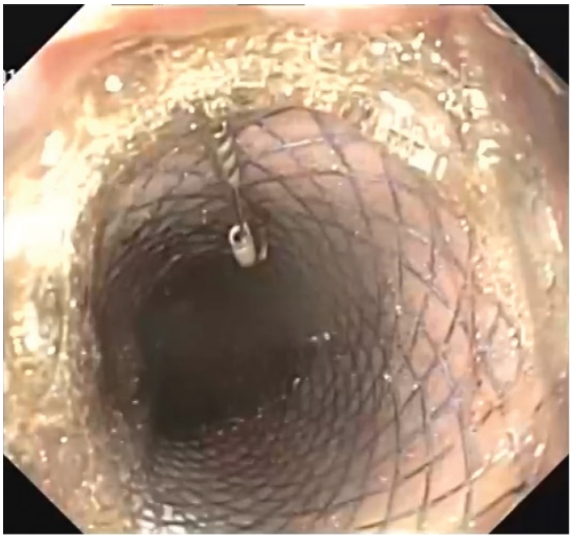

Fig. 3. Endoscopic picture. Self-expanding nitinol stent in standard position in the esophagus

Statistical processing was carried out using the SPSS program (v. 13.0). To check the distribution of indicators, the Kolmogorov–Smirnov test was used. When carrying out analysis of variance, the Student's test was used. Qualitative indicators were compared using the χ^2 test and Fisher's exact test. Differences were considered statistically significant at $p \leqslant 0.05$.

RESULTS

In the comparison group, complications occurred in 44 (100%), and in the main group complications were observed in 8 patients (53.3%) (Table 1). Reliable mechanical hemostasis in the comparison group was achieved in 33 clinical observations (75.0%). At the same time, in 11 patients (25.0%) bleeding continued with the Sengstaken–Blakemore tube. In the main group, hemostasis was achieved in 13 clinical observations (86.7%). At the same time, in 2 patients (13.3%) it was not possible to stop the bleeding using a stent.

Sengstaken–Blakemore obturator probe, trophic changes in the mucous membrane of the esophagus and stomach in the area of contact with the inflated balloons were endoscopically identified in 12 patients (27.2%). During a macroscopic examination of ten organocomplexes of the esophagus from the corpses of patients in the comparison group, multiple erosions and irregularly shaped ulcers ranging in size from 3 to 15 mm or more were found on the mucous membrane. Around the ulcers, the mucous membrane of the esophagus was swollen and hyperemic with a large amount of viscous mucus and gray and yellowish-gray films of fibrin and detritus covering the surface. The veins protruding into the lumen of the esophagus were thrombosed. Light

Table 1

Complications in the study groups of patients

No.	Nature of the complication	Number of patients				R
		Main group (n =15)		Comparison group (n =44)		
		Abs.	%	Abs.	%	
1	Difficulty breathing	–	–	44	100	0.001
2	Unpleasant sensations in the oropharynx	–	–	44	100	0.001
3	Sore throat	–	–	9	20.5	0.029
4	Bursting pain behind the sternum	2	13.3	18	41.0	0.113
5	Hypersalivation	–	–	19	43.2	0.001
6	Difficulty coughing up accumulated mucus	–	–	7	15.9	0.058
7	Vomiting	–	–	6	13.6	0.081
8	Attacks of nausea	–	–	12	27.2	0.010
9	Aspiration pneumonia	–	–	5	11.4	0.012
10	Ineffective hemostasis	2	13.3	11	25.0	0.259
11	Trophic changes in the mucous membrane of the esophagus and stomach	8	53.3	12	27.2	0.771
12	External respiration dysfunction	–	–	44	100	0.001
13	Formation of a rigid ring of the esophageal mucosa in the long term	2	13.3	–	–	0.042

microscopy revealed changes characteristic of severe ulcerative esophagitis. In the mucous membrane there are scattered eosinophils with an admixture of neutrophils, atrophy of the mucosa with flattening of the papillae and thinning of the epithelium, expansion of the interepithelial spaces and hyperplasia of cells in the basal zone of the epithelium, desquamation of mucosal cells. In the lamina propria of the esophageal mucosa there is lengthening and an increase in the number of papillae. In the submucosa, dilated vessels with homogeneous structureless walls and blood clots in the lumen were found in necrotic masses. In the veins there is local hypertrophy of the muscle layer and signs of thrombophlebitis. There were inflammatory processes in the paravascular tissue. Erosion and ulcers, both single and multiple, were characteristic. In case of erosions, the defects were limited to the mucosa up to the muscular plate, and in case of ulcers they penetrated into the submucosal and muscular layers (Fig. 4).

After removal of the self-expanding nitinol stent, changes in the esophageal mucosa at the sites of contact with the surface of the stent were endoscopically detected in 8 patients (53.3%). A macroscopic examination of four organ complexes of the esophagus from the corpses of patients in the main group showed that the mucous membrane in these places was thickened, swollen and hyperemic. The folds of the mucous membrane are thickened. Its surface is abundantly covered with mucous masses, in places with fibrin deposits of a whitish-gray or yellow-brown color. The veins protruding into the lumen of the esophagus are thrombosed. In addition, multiple small hemorrhages and erosions were found, bleeding easily on contact. Light microscopy of the walls of the esophagus revealed dystrophy, necrobiosis, hyperplasia and detachment of the superficial stratified epithelium, mainly its basal layer; elongation of epithelial papillae; inflammatory infiltration of neutrophilic granulocytes and lymphocytes. Serous, serous-mucosal or serous-leukocyte exudate. The lamina propria of the esophageal mucosa is congested and edematous, infiltrated with neutrophils, and diapedetic hemorrhages have occurred. Dilated capillaries, venules and veins of irregular shape and varying diameters contained mural or occlusive red thrombi consisting of platelets, fibrin and red blood cells, or mixed thrombi consisting of fibrin, red blood cells, leukocytes, platelets. Leukocytes, like erythrocytes, were located between the fibers of coagulated fibrin, singly or in groups (Fig. 5)

In 2 patients (13.3%), in whom the stent was in the esophagus for more than 7 days, after its removal, a circular thickening of the mucous membrane in the form of a hard whitish ring was discovered. It was located at the level of the upper edge of the stent. There is likely a risk of developing a circular stricture of the esophagus in the area of such compaction (Fig. 6).

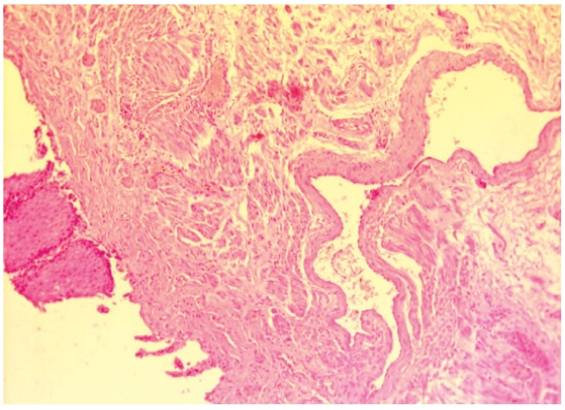

Fig. 4. Microphoto. The abdominal esophagus after mechanical hemostasis with a Sengstaken-Blakemore tube. The collection was carried out during autopsy from the corpses of patients who died during observation. Erosions and ulcers of the mucous membrane. Magnification x10. Hematoxylin and eosin staining

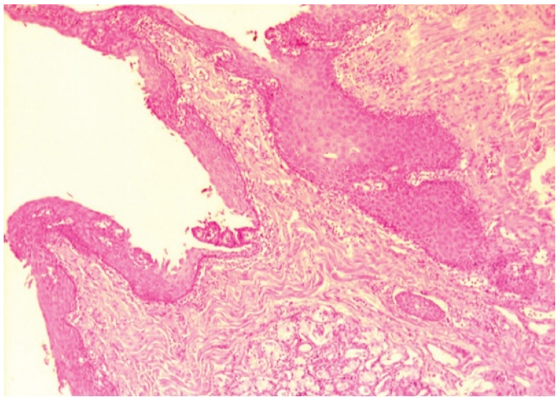

Fig. 5. Microphotography. Autopsy. Abdominal esophagus after removal of self-expanding nitinol stent. Hyperplasia and detachment of the superficial stratified epithelium, mainly its basal layer; elongation of epithelial papillae; inflammatory infiltration of neutrophilic granulocytes and lymphocytes. Magnification ×10. Hematoxylin and eosin staining

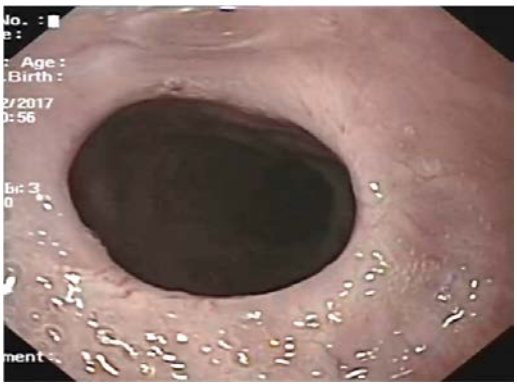

Fig. 6. Circular compaction of the mucous membrane of the esophagus at the level of the upper edge of the stent in the form of a hard whitish ring

When assessing the function of external respiration in the comparison group, a 5th degree of decrease in the ventilation capacity of the lungs and a 3rd degree of decrease in vital capacity (VC) were established, and in the main group there were grade 2 and 1, respectively (Table 2).

When studying the parameters of the blood gas composition in the comparison group against the background of metabolic acidosis with negative values of excess bases, the mechanisms of respiratory compensation did not restore the pH value to the normal initial level. The general acid-base state of the blood indicated the presence of acidemia in patients. In the main group, against the background of metabolic acidosis with statistically significant, less pronounced negative values of excess bases (p = 0.044), the blood pH level was at the lower limit of the physiological norm (Table 3). At the same time, no statistically significant difference in the acid-base properties of blood was registered in patients of the study groups (p = 0.142).

Overall (hospital) mortality in the comparison group was 56.8%. Twenty-five patients out of 44 died. In the main group, the overall (hospital) mortality rate was 26.7%. Four patients out of 15 died. The main cause of death was the progression of hepatic cellular failure, including against the background of ongoing bleeding in 11 patients in the comparison group and in 2 patients in the main group. The length of the bed-day in the comparison group in patients with liver cirrhosis of class A was 19.0±11.0 (p =0.071), class B – 10.7±2.3 (p =0.026), class C – 2.6 ±0.7 days (p =0.001). In the main group – 9.3±1.5 (p =0.007), 13.2±2.0 (p =0.013) and 9.7±2.1 days (p =0.001), respectively.

Table 2

Indicators of external respiration in the studied groups of patients

No.	External respiration indicators	Comparison group (n =9)	Main group (n =11)	R
1	vital capacity/proper vital capacity	37.3±2.7	61.7±0.9	0.001
2	FEV/pFEV	38.7±2.7	61.1±2.9	0.001
3	FEV/VC	72.3±1.1	73.7±2.2	0.062
4	The degree of decrease in the ventilation capacity of the lungs	5	2	–
5	Degree of decrease in vital capacity	3	1	–

Table 3

Blood gas parameters in the studied groups of patients

No.	Indicators of acid-base state	Comparison group (n =24)	Main group (n =12)	R
1	pH	7.312±0.029	7.377±0.029	0.142
2	PCO_2 (T), mmHg	35.33±1.62	35.91±2.74	0.848
3	PO2, mmHg	40.4±2.8	32.0±2.4	0.029
4	Hct, %	26.5±1.8	26.6±2.4	0.968
5	THb, g/L	42.9±9.8	8.9±0.8	0.021
6	TCO_2 (T), mmol/L	19.7±1.4	22.7±1.0	0.150
7	HCO_3, mmol /L	18.6±1.3	21.0±0.8	0.230
8	Beb, mmol/L	-7.1±1.6	-3.4±0.8	0.042
9	BEecf, mmol/L	-7.8±1.7	-3.6±1.0	0.044
10	SBC, mmol/L	20.2±1.6	21.2±0.6	0.547
eleven	$\%sO_2$ s, %	65.7±3.7	64.9±3.4	0.884
12	ctO2, ml/dL	8.0±0.8	7.8±0.6	0.839

DISCUSSION

Although the mortality rate from acute variceal hemorrhage has been reduced from 42 to 15%, this figure is still strikingly high [18]. In 15–20% of clinical observations, modern first-line therapy cannot cope with bleeding or is accompanied by its early relapse within the next 5 days [5]. It is recommended to include balloon tamponade with a Sengstaken–Blakemore tube in the treatment program for such patients. However, in 6–20% of cases it is associated with fatal complications: esophageal rupture [19], proximal migration of the

probe, asphyxia [20], ulceration of the esophageal or gastric mucosa, aspiration [21]. Recurrent bleeding occurs in more than 50% of cases [5]. In addition, the presence of a tube in the oropharynx is subjectively extremely unpleasant for the patient. All this prompted the search for alternative ways to save patients with refractory variceal bleeding from the esophagus. One of these promising methods, judging by the literature of recent years, is the installation of a self-expanding nitinol stent [22, 23].

Considering the above, we compared the effectiveness of a self-expanding esophageal metal stent and balloon tamponade in the treatment of refractory esophageal variceal bleeding. We have identified clinically significant complications of balloon tamponade: difficulty breathing and discomfort in the oropharynx in 100%; hypersalivation in 43.2%; chest pain in 41.0%; feeling of nausea in 27.2%; vomiting in 13.6%; trophic changes in the mucous membrane of the esophagus and stomach in 27.2%; aspiration pneumonia in 11.4%; ineffective hemostasis in 25% of cases.

Hemostasis using a self-expanding nitinol stent is characterized by: 100% low trauma; 93.5% good tolerability; 100% possibility of saliva drainage and fluid intake; 100% possibility of repeated endoscopic examination; less severe respiratory dysfunction; 100% impossibility of removing the stent by the patient in a state of agitation; 77.4% increase in time for making a decision on further treatment tactics.

On the other hand, we attributed distal migration of the stent to the disadvantages of the self-expanding nitinol stent in 19.4%; dependence of fixation on the anatomical and physiological characteristics of the cardioesophageal junction in 3.2% and previous anti-inflammatory therapy in 9.7%; high risk of bleeding from veins located distal to the lower edge of the stent in 3.2%; the possibility of tamponade of only the esophageal veins in 100%; hemorrhagic and trophic changes in the mucous membrane of the esophagus at the site of the stent in 25.8%, up to circular scarring in 6.5% of cases.

CONCLUSION

Compression hemostasis with Danis self-expanding nitinol stent as a bridge to definitive therapy versus tamponade with a Sengstaken-Blakemore tube is a promising alternative first-line treatment for patients with refractory esophageal bleeding.

The results obtained in a study conducted in two relatively representative groups of patients allow us to speak about this: fewer complications, 53.3% versus 100%; the ability to achieve reliable mechanical hemostasis in a larger number of clinical observations, 86.7% versus 75.0%; more favorable indicators of external respiration function, 2nd degree of decrease in the ventilation capacity of the lungs versus 5th and 1st degree of decrease in vital capacity of the lungs versus 3; lower overall (hospital) mortality, 26.7% versus 56.8%.

At the same time, the absence of a statistically significant difference in the acid-base properties of venous blood and trophic changes in the mucous membrane of the esophagus and stomach requires randomized controlled studies to confirm the safety and effectiveness of self-expanding nitinol stents.

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