Original Article

The First Egyptian Experience Using New Self-Expandable Metal Stents in Acute Esophageal Variceal Bleeding: Pilot Study

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ABSTRACT

Background/Aim: Balloon tamponade has been widely available in emergency situations of acute variceal bleeding. To lessen the complications of Balloon tamponade, a new special type of stent for exclusive use in acute variceal bleeding has been developed. This study aims to investigate the effectiveness and safety of the new self-expandable metal stents (SEMS) in the initial control of acute variceal bleeding. We also hypothesized that using SEMS can bridge the acute bleeding episode converting endoscopic management by sclerotherapy or band ligation to an elective procedure. **Patients and Methods:** Twenty patients with acute variceal bleeding were included in the study and 16 of them were allocated to receive stent treatment. **Results:** Stent deployment was successful in 15 of 16 patients (93.75%). Technical errors were reported in 3 (18.75%) patients. Initial control of variceal bleeding was reported in 14 (out of 16) (87.5%) patients. The mean duration of the procedure was 10 (±6) min. Mortality was reported in 4 (25.0%) patients. **Conclusion:** SEMS is a safe and effective mean to control acute variceal bleeding.

Key Words: Acute variceal bleeding, self-expandable metal stents, stent migration

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Esophageal varices develop in 30-60% of cirrhotics, eventually 30% of them bleed.[1,2] Survivors of a bleeding episode have a 70% risk of recurrence within 1 year.[3,4] (Acute variceal bleeding is an emergency to be managed by experienced staff).[5-8]

Initial resuscitation and endoscopy are the treatments of choice.[8-13] Balloon tamponade (Sengstaken-Blakemore tube) has been used in emergency situations yet with some disadvantages.[14] To lessen complications yet retain mechanical compression, a new type of stent has been developed.[15] Its use leads to a faster stabilization of the situation, and reduces the risk of bleeding.[16,17]

Aim of the work

This study aims to investigate the effectiveness and safety of the new self-expandable metal stents (SEMS) in the initial control of acute variceal bleeding. We also hypothesized that using SEMS can bridge the acute bleeding episode converting endoscopic management by sclerotherapy or band ligation to an elective procedure.

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PATIENTS AND METHODS

The study was approved by the Hepatogastroenterology Department and the Research Board of Cairo University. A total of 1100 patients presented to the emergency endoscopy unit from January 2008 to December 2009 with hematemsis or melena, 600 of them were due to variceal bleeding. Out of these, 20 patients fulfilled the inclusion criteria and were eligible for the study. Patients included were of either sex, aged from 18 years to 65 years, known to have chronic liver disease and presenting with acute ongoing variceal bleeding. The latter was defined as endoscopically proven ongoing (and/or spurting) active bleeding from esophageal varices. This included also the presence of cherry red spots as stigmata of variceal bleeding and or blood in the esophagus or stomach (verified by endoscopy) with exclusion of any other origin of the bleeding than from esophageal varices.[12]

Patients with end stage hepatic malignancy, non-variceal upper gastrointestinal tract (GIT) bleeding or active fundic variceal bleeding, patients participating in any other clinical trial in the preceding 3 months, pregnancy and/or breast-feeding patients were all excluded from the study. Patients with other contraindications for stent placement were excluded like patients with history of radiation therapy, esophageal strictures, tumors of the upper respiratory tract; esophagus or stomach and body weight under 40 kg. Informed and written consents were obtained for each patient after explaining the whole procedure and possible risks and complications. Four patients refused to participate in the study and therefore 16 patients were included.

All patients were exposed to the standards of care in emergency situations like vasoactive therapy (somatostatin), hemodynamic stabilization, and antibiotic treatment. Endoscopy was performed at maximum 12 h after the clinical onset of bleeding (melena and/or hematemesis).

Basic features of the stent

- Self-expandable nitinol stent, covered by polyurethane foil preloaded in a ready-to-use delivery system, delivered "sterile." The latter allows placement of the stent without radiographic or even endoscopic control.
- Nominal (relaxed) diameter of the stent body is 25 mm diameter of the stent throat is 30 mm, and the stent length is 135 mm.
- It has a European Patent Applications acceptance No. 06002107.8 submitted on February 2, 2006 and No. 06005010.1.
- There are variable pitches in the stent braiding that conform to esophageal peristalsis, reducing the risk of stent migration.
- It has a-traumatic edges and radio-opaque markers at both stent ends and at the mid-point.
- The stent has 2 loops at each end. Grasping and pulling any loop leads to elongation of the stent and narrowing of its skeleton. These loops are used in stent re-positioning and stent extraction.
- Stent insertion:
  1. Procedure is carried out under conscious sedation as with routine endoscopy
  2. The whole delivery system is introduced over a guide wire.
  3. The gastric balloon is released and inflated with 100-120 ml air.
  4. Correct positioning is accomplished when the balloon is retracted, and resistance is felt at the cardia.
  5. Should the gastric balloon inflate wrongly in the esophagus; the safety balloon at the tip of the delivery system is inflated alarming re-positioning the delivery system.
  6. The stent is deployed from distal to proximal. The gastric balloon is then deflated, and the delivery system is withdrawn [Figures 1 and 2].
  7. Three minutes are spent deployment to allow full expansion of the stent and its optimal integration with the esophageal wall, the stent is then examined endoscopically [Figures 3 and 4].
  8. The patient is given nothing orally for the following 6 hours followed by oral fluids the following 24 hours and then a semi-solid diet for the next few days.
  9. Elevating the head of the bed and avoiding recumbence within 3 hours after a meal is advised.
  10. Patients are prescribed proton pump inhibitors the duration of stening.

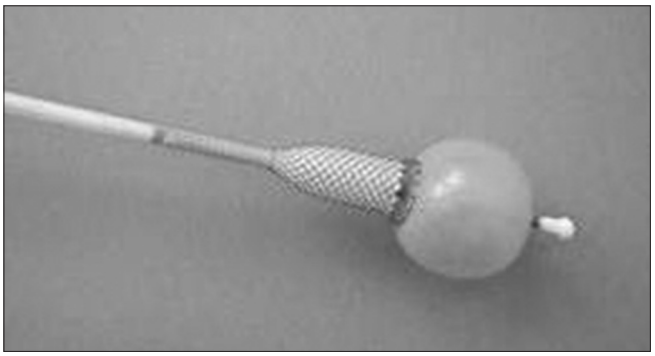

Figure 1: Inflated gastric balloon at stent deployment

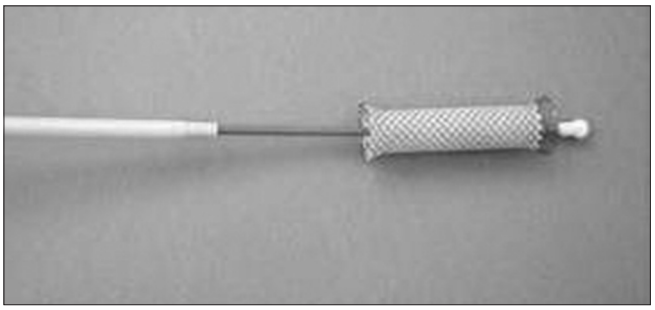

Figure 2: Deflated gastric balloon after full stent expansion

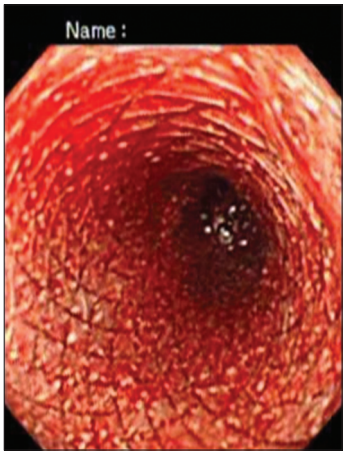

Figure 3: Self-expandable metal stent after deployment

Stent extraction

Stents are extracted using either a special extractor SX-ELLA Stent Danis extractor, or simply by grasping its upper loop using a foreign body extractor. The bare extractor is introduced through the scope and grasps the proximal stent loop, which is fixed to the extractor by means of a locking system. The scope is then removed, and an over tube (22 Fr) is slid over the extractor sheathing and removing the stent [Figures 5 and 6].

RESULTS

Out of 20 patients meeting the inclusion criteria, 16 patients were included in the study as 4 refused to participate. All patients suffered from hepatitis C virus - related liver cirrhosis. There were 14 (87.50%) males and 2 (12.50%) females. The mean age of the patients was 55.60 years (±5.62).

The clinical, laboratory and endoscopic findings of the patients are shown in Table 1, while the descriptive features related to stenting are shown in Table 2

Technical errors

Stent deployment was successful in 15 of 16 cases (93.75%) patients. Technical errors encountered during stenting were reported in 3 (18.75%) patients: In the first case, bending of the guide wire occurred and was replaced with another one. In the second case the stent slipped totally into the stomach immediately after deployment and was grasped by a foreign body extractor, pulled and positioned properly in the esophagus with proper control of bleeding. Malfunction of the delivery system causing rupture of the gastric balloon was reported in the third patient during deployment, alternatively the patient was managed by injection sclerotherapy.

Failure to control bleeding

Successful initial control of variceal bleeding was reported in 14 (out of 16) (87.50%) patients. Failure to control bleeding was seen in 2 patients (12.50%): The first was the one in whom rupture of gastric balloon occurred (managed by injection sclerotherapy). In the second patient, failure was declared as the stent, although deployed, failed to control bleeding originating from a small junctional varix (GOV-1) (managed by cyanoacrylate injection).

The number of blood units transfused during hospital stay was 2.5 packs (±2.55). Two patients (12.50%) developed hepatic encephalopathy. Mortality developed in 4 patients (25%) and was related to failure to control the initial bleeding episode in only one patient (the patient with bleeding Junctional varix). The remaining 3 cases were due to worsening of the general condition of the patients despite proper control of bleeding.

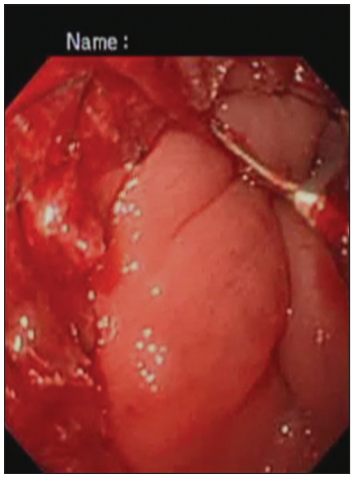

Figure 4: Compressed bleeding point

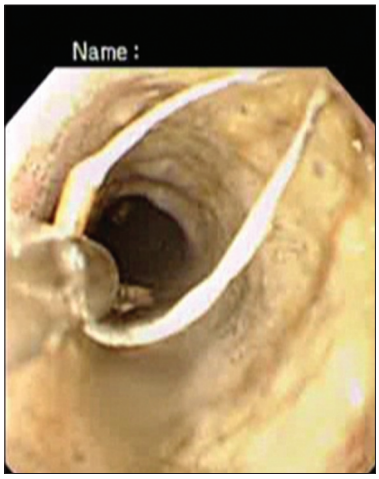

Figure 5: Stent extractor grasping the proximal loop

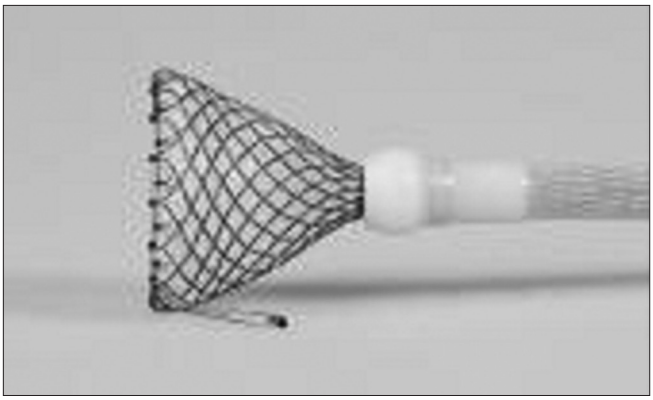

Figure 6: The overtube ensheathing the stent

The range for stent duration (n = 11) was 2-4 days. In 7 patients the stent was extracted using a standard foreign-body extractor while the remainder were extracted using the stent extractor.

Table 1: Clinical, laboratory and endosocpic parameters before intervention

Parameter	(Mean/SD or Number/%)
Mean hemoglobin (g/dl)	7.60±1.69
Mean no of past bleeding episodes	0.75±1.23
Grading of varices	
Grade I-II	5 (31.25)
Grade III-IV	11 (68.75)
Abdominal collaterals by US	2 (12.50)
Ascites by US	11 (68.75)
Child score at admission	
Child A	2 (12.50)
Child B	8 (50.0)
Child C	6 (37.50)

Table 2: Descriptive features related to stenting

Parameter	Number/mean	Percent/SD
Symptoms following stenting		
Chest pain	1	6.25
Hiccups	2	12.50
Fever	0	0
Dysphagia	1	6.25
Reflux symptoms	0	0
Deep ulcer at extraction	1	6.25
Time consumed performing the procedure (min)	10	±6
Stent migration	6	37.50
Total migration	3	18.75
Partial migration distally	2	12.50
Partial migration proximally	1	6.25
Further intervention during follow up		
Band ligation	3	18.75
Sclerotherapy	7	43.75
Drop out	4	25.00
Failure to control bleeding	2	12.50

DISCUSSION

The difficulty to perform endoscopy in the emergency situation is attributed to both a suboptimal endoscopic view and unstable condition of the patients making it challenging.[14] SEMS's are proposed as a better, and safer alternative to balloon tamponade to compress esophageal varices as the balloon in the Sengstaken-Blakemore tube is the cause for the majority of complications. This study was designed to investigate the initial Egyptian experience with the safety and efficacy of using SEMS in the initial control of acute variceal bleeding. A secondary aim was the ability to convert an emergency situation to an elective one, where the patients were managed either by band ligation or sclerotherapy. We only included patients with active ongoing bleeding (that is defined as endoscopically proven ongoing (and/or spurting) active bleeding from esophageal varices).[12] All patients were exposed to the standards of care in emergency situations and all of them underwent endoscopy within 12 hours from the onset of bleeding. Most of them exhibited poor prognosis as evidenced by ascites, advanced Child score, and low mean hemoglobin level.

The first 4 studies published about the use of SEMS in acute variceal bleeding Hubmann *et al*., Zehetner *et al*., Wright *et al*. and Dechêne *et al*. had a small sample size except for Zehetner who had a study population of 39 patients.[15-18] All of them concluded a favorable outcome regarding stent safety and efficacy. In our study, efficacy of the procedure as addressed by initial control of variceal bleeding was achieved in 87.50% patients. Failure to control bleeding was seen in 2 patients. Hubmann *et al*. and Dechêne *et al*. reported intial control of bleeding in 100% of patients,[15,18] In the largest series of 39 patients reported, initial control of bleeding was in 97% of cases.[16] On the other hand, Wright *et al*. reported initial control of bleeding in 7 (70%) of cases.[17] In that study, one patient (10%) had failure of stent deployment and in 2 (20.0%) patients, the source of bleeding originated from gastric varices. It is worth mentioning that this study protocol permitted stent deployment without index endoscopy.

All the adverse events encountered with SEMS such as dysphagia, chest pain, and hiccups were minimal and similar to those generally reported with other interventions such as band ligation and sclerotherapy. It is worth mentioning that patients were given the routine post-procedural care similar to that instructed to patients undergoing sclerotherapy or band ligation with the exception that these patients were additionally advised to maintain a semi-sitting position after meals.

Time counts in patients with acute variceal bleeding; we assume that introducing a new temporary technique as SEMS should address efficacy as well as ease and simplicity of its application. That is why we added the timing of endoscopy as an important entity to be addressed. The total time spent by the endcoscopist to put the stent was 10 (±6) mins. This time includes a standard of extra 3 mins spent after stent deployment (before the second check endoscopy) in order to allow full expansion of the stent and its optimal integration with the esophageal wall thus preventing stent migration. Furthermore, the growing experience with the stenting technique might have caused prolongation of time spent on that technique. None of the published studies reported the duration of stenting. In future, with better experience, stents may be applied in a relatively shorter time. Furthermore, the introduction of stents without the necessity of fluoroscopic guidance and without simultaneous endoscopic control adds to the simplicity of the technique.

In this study stents were removed using either a foreign body

extractor or the specialized extractor. Wright *et al*. used the extractor in all his cases.[17] Hubmann *et al*. and Zehetner *et al*. didn't use the extractor for any of their cases.[15,16] In our experience removing the stent using the foreign body forceps is easier than the extractor. The stent is flexible, elongates as it is grasped by the forceps, its upper end tapers in a purse string fashion and is therefore extracted without trauma.

In the studies by Hubmann *et al*., Zehetner *et al*., Wright *et al*. and Dechêne *et al*., they all reported small superficial ulcerations in the distal esophagus after stent extraction.[15-18] No other complications were reported. In our study, apart from indentation marks and trivial superficial ulcerations, a deep ulcer was observed in only one patient and was managed by conventional sucralfate, proton pump inhibition and oral fluids for 6 days followed by ulcer healing and with no reported ulcer bleeding.

As stated by De Franchis, bleeding related mortality is defined as bleeding within a time frame of 6 weeks after the onset of bleeding.[12] Four patients (25%) died, despite initial control of bleeding in 3 of them. Wright *et al*. 2010 reported a survival rate of 50% (5 patients out of 10), with only one related to bleeding.[17] Hubmann *et al*., Zehetner *et al*. and Dechêne *et al*. reported no bleeding related mortalities in the patients. However, they didn't clarify in these studies the time-frame for the definition of bleeding-related mortality.[15,16,18]

Gastric extension was not an exclusion criterion to study enrollment. However, in one patient bleeding from a short gastric extension was linked to failure to control bleeding and later on mortality, this lead us to discourage the use of stents in the presence of gastric extensions.

Stent migration

Stent migration was by far the most common event related to stent insertion. Trying to minimize this incidence, we proposed delaying the second endoscopy (done to verify correct position of the stent) for 3 min; this is to give time for full stent expansion. All migrations except one (with partial proximal migration) were identified during the process of stent extraction. None of them were associated with re-bleeding. Hubmann *et al*., Zehetner *et al*. and Wright *et al*. reported 25%, 15% and 70% of cases of distal stent migration in their series. Similarly, none of them was associated with bleeding.[15-17]

CONCLUSION

According to our experience, the use of SEMSs is a safe and effective means to control acute variceal bleeding. It can be used as a temporary procedure to control variceal bleeding as a bridge to the emergency situation till elective endoscopy is further arranged. Larger scale studies are recommended in the future.

REFERENCES

1. D'Amico G, Garcia-Pagan JC, Luca A, Bosch J. Hepatic vein pressure gradient reduction and prevention of variceal bleeding in cirrhosis: A systematic review. Gastroenterology 2006;131:1611-24.
2. Jalan R, Hayes PC. UK guidelines on the management of variceal haemorrhage in cirrhotic patients. British Society of Gastroenterology. Gut 2000 Jun;46 Suppl 3-4:III1-15.
3. Graham DY, Smith JL. The course of patients after variceal hemorrhage. Gastroenterology 1981;80:800-9.
4. Jamal MM, Samarasena JB, Hashemzadeh M, Vega KJ. Declining hospitalization rate of esophageal variceal bleeding in the United States. Clin Gastroenterol Hepatol 2008;6:689-95.
5. Sarin SK, Kumar A, Angus PW, Baijal SS, Chawla YK, Dhiman RK, *et al*. Primary prophylaxis of gastroesophageal variceal bleeding: Consensus recommendations of the Asian pacific association for the study of the liver. Hepatol Int 2008;2:429-39.
6. Nidegger D, Ragot S, Berthelémy P, Masliah C, Pilette C, Martin T, *et al*. Cirrhosis and bleeding: The need for very early management. J Hepatol 2003;39:509-14.
7. Augustin S, Muntaner L, Altamirano JT, González A, Saperas E, Dot J, *et al*. Predicting early mortality after acute variceal hemorrhage based on classification and regression tree analysis. Clin Gastroenterol Hepatol 2009;7:1347-54.
8. Augustin S, González A, Genescà J. Acute esophageal variceal bleeding: Current strategies and new perspectives. World J Hepatol 2010;2:261-74.
9. Ben-Ari Z, Cardin F, McCormick AP, Wannamethee G, Burroughs AK. A predictive model for failure to control bleeding during acute variceal haemorrhage. J Hepatol 1999;31:443-50.
10. Garcia-Tsao G, Bosch J. Management of varices and variceal hemorrhage in cirrhosis. N Engl J Med 2010;362:823-32.
11. Ioannou G, Doust J, Rockey DC. Terlipressin for acute esophageal variceal hemorrhage. Cochrane Database Syst Rev 2001;1:CD002147.
12. de Franchis R. Evolving consensus in portal hypertension. Report of the Baveno IV consensus workshop on methodology of diagnosis and therapy in portal hypertension. J Hepatol 2005;43:167-76.
13. Garcia-Tsao G, Sanyal AJ, Grace ND, Carey W. Practice Guidelines Committee of the American Association for the Study of Liver Diseases, Practice Parameters Committee of the American College of Gastroenterology. Prevention and management of gastroesophageal varices and variceal hemorrhage in cirrhosis. Hepatology 2007;46:922-38.
14. Agarwal R, Aggarwal AN, Gupta D. Endobronchial malposition of Sengstaken-Blakemore tube. J Emerg Med 2008;34:93-4.
15. Hubmann R, Bodlaj G, Czompo M, Benkö L, Pichler P, Al-Kathib S, *et al*. The use of self-expanding metal stents to treat acute esophageal variceal bleeding. Endoscopy 2006;38:896-901.
16. Zehetner J, Shamiyeh A, Wayand W, Hubmann R. Results of a new method to stop acute bleeding from esophageal varices: Implantation of a self-expanding stent. Surg Endosc 2008;22:2149-52.
17. Wright G, Lewis H, Hogan B, Burroughs A, Patch D, O'Beirne J. A self-expanding metal stent for complicated variceal hemorrhage: Experience at a single center. Gastrointest Endosc 2010;71:71-8.
18. Dechêne A, El Fouly AH, Bechmann LP, Jochum C, Saner FH, Gerken G, *et al*. Acute management of refractory variceal bleeding in liver cirrhosis by self-expanding metal stents. Digestion 2012;85:185-91.

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