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Role of self-expanding metal stents in the management of variceal haemorrhage: Hype or hope?

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Abstract

Despite the advances of medical, endoscopic and radiological therapy over recent years the mortality rates of acute variceal haemorrhage are still 16%-20% and the medium term outcome has not improved in the last 25 years. Early transjugular intrahepatic portosystemic shunt has proved to be an effective therapy for selected groups of patients with a high risk of re-bleeding and moderate liver disease. However, there is an unmet need for a therapy that can be applied in patients with a high risk of re-bleeding and advanced liver disease either as definitive therapy or as a bridge to permanent therapy. Self-expanding metal stents can be placed without the need for endoscopic or fluoroscopic control and, once in place, will provide effective haemostasis and allow a route for oral fluids and nutrition. They can remain in place whilst liver function recovers and secondary prophylaxis is initiated. We review the results of 6 case series including a total of 83 patients and the first randomised controlled trial of self-expanding metal stents *vs* balloon tamponade (BT) in the management of refractory variceal haemorrhage. We report that self-expanding metal stents provide effective haemostasis and perform better than BT in refractory bleeding, where they are associated with fewer complications. Whilst the most effective place for self-expanding metal stents in the management algorithm needs to be determined by further randomised controlled trials, currently they provide an effective alternative to BT in selected patients.

Key words: Esophageal and gastric varices; Stents; Liver cirrhosis; Gastrointestinal haemorrhage; Portal hypertension

Core tip: Failure to control bleeding in high-risk patients with variceal haemorrhage is still common, and not all patients are suitable for transjugular intrahepatic portosystemic shunts. Self-expanding metal stents can be placed without the need for endoscopic or fluoroscopic control and, once in place, provide effective haemostasis and allow a route for oral fluids and nutrition. They

can remain in place whilst liver function recovers and secondary prophylaxis is initiated or whilst definitive therapy is provided. Self-expanding metal stents provide effective haemostasis and perform better than balloon tamponade in refractory bleeding, where they are associated with fewer complications.

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INTRODUCTION

Acute variceal bleeding represents a devastating decompensating episode and occurs at a rate of 4% per year in patients with cirrhosis, increasing to 15% per year in those with medium or large varices[1].

Outcomes from a single episode of variceal bleeding have improved significantly in recent years. Better endoscopic therapy exists in the form of endoscopic variceal ligation and tissue adhesive glue[2,3] and more effective pharmacotherapy including potent vasoactive drugs[4,5] and prophylactic antibiotics[6]. However, the mortality rates of 16%-20% are still significant and medium term outcome has not improved in the last 25 years[7-10].

Failure to control bleeding, as defined by the Baveno Ⅴ criteria, is estimated at approximately 17% in the modern era[11]. Traditional factors associated with failure to control bleeding at 5 d and mortality at one month were active bleeding at endoscopy, severity of liver disease and an hepatic venous pressure gradient of > 20 mmHg[12,13]. More recently the model for end-stage liver disease (MELD) score has been shown to be useful in predicting outcome, with a MELD score < 11 being associated with < 5% mortality and a MELD score > 19 with > 20% mortality[14].

CURRENT OPTIONS FOR FAILURE OF STANDARD THERAPY

Failure to control bleeding requires salvage therapy such as balloon tamponade (BT) or insertion of transjugular intrahepatic portosystemic shunts (TIPS). These methods are effective at control of bleeding, but have important limitations. BT is a temporary therapy which most experts suggest can be used for a maximum duration of 24 h as a bridge to more definitive therapy[15]. The success of BT in controlling haemorrhage is reported to be between 88%-91% in the first 24 h[16]. BT is associated with the risks of oesophageal tear, mucosal ischaemia and aspiration pneumonia. TIPS carries a risk of worsening liver function and encephalopathy and is associated with a 30 d mortality of 30% when used as a rescue therapy[17]. In addition TIPS is not readily available in many centres that manage upper gastrointestinal haemorrhage.

The importance of early haemostasis was demonstrated in a randomised controlled trial of early TIPS insertion. Participants were randomised to either TIPS insertion within 72 h or standard medical therapy, which could include rescue TIPS. It demonstrated a reduction in uncontrolled bleeding or re-bleeding in the early TIPS group (3% *vs* 45%), a reduction in average intensive care unit stay (3.6 d *vs* 8.6 d) and a significant reduction in 1 year mortality (14% *vs* 39%, $P = 0.001$)[18]. Patients over 75 years of age, those with a Child Pugh score > 13 and those with advanced hepatocellular carcinoma were excluded from this study. Similar results have been shown using early TIPS in high-risk patients selected for a hepatic venous pressure gradient > 20 mmHg[19].

Attempts to replicate these results outside of clinical trials have been encouraging, but show that patient selection is vital and TIPS can be associated with significant complications. A United Kingdom centre began implementing an early TIPS protocol in 2010 for high-risk patients with acute variceal haemorrhage (Childs Pugh C or Childs Pugh B with active bleeding at endoscopy). The median time to TIPS was 12 h and the same exclusion criteria as reported in the above early TIPS study applied. Overall 30-d mortality was 8.6% and at 6 mo it was 14.7%. The re-bleeding rate was 11.4% and all re-bleeding occurred within the first 7 d[20]. A series from France proved similar efficacy with regards to haemostasis, with failure to control bleeding in 1/23 (4%). However, in this series there was a significant deterioration in liver function in 10/23 with 5 patients dying and 5 requiring transplantation. In addition 5/23 patients developed acute heart failure and 3 of these required mechanical ventilation[21].

Based on this data it would seem reasonable to promote TIPS as an initial treatment for high-risk patients with portal hypertensive bleeding. However, TIPS requires specialist equipment and expertise, and the logistics of providing this to all high-risk patients would be difficult for many healthcare systems internationally. There is, therefore, a need for a treatment which can be applied easily and effectively to patients at high risk of re-bleeding that could reduce early re-bleeding and promote a bridge to effective secondary prophylaxis or TIPS.

SELF-EXPANDING MESH-METAL STENT FOR VARICEAL HAEMORRHAGE

The SX-ELLA Danis stent (Ella CS, Hradec Kralove, Czech Republic) is a removable, covered, self-expanding mesh-metal stent (SEMS) that was designed for the emergency treatment of oesophageal variceal bleeding. It is 135 mm long and 25 mm in diameter giving it the ability to tamponade bleeding varices in the distal oesophagus. It is supplied with a unique insertion

system, where by a gastric balloon is inflated to anchor the distal end of the stent at the gastro-oesophageal junction when traction is applied. The Danis stent can be deployed without direct endoscopic or fluoroscopic guidance, and its' position should be confirmed by chest radiograph after insertion. Stents can be left in place for up to 14 d and can be removed endoscopically using the accompanying stent removal device. The stent provides immediate haemostasis and prevents re-bleeding for the time it is *in situ*. This allows recovery of liver function, consideration of definitive therapy and institution of secondary prophylaxis in addition to maintaining an oral route for fluids and nutrition. SEMS have also be useful in the management of BT related oesophageal rupture and for broncho-oesophageal fistula.

CURRENT EVIDENCE FOR SEMS

To date there have been 4 large case series, with ⩾ 10 patients, a number of smaller case series and reports and one randomised controlled trial assessing the safety and efficacy of SEMS in the control of variceal haemorrhage[22-24].

The first series was reported by Hubmann *et al*[25] in 20 patients with Child-Pugh B or C cirrhosis and massive ongoing bleeding. Two patients received Choo stents (140 mm × 18 mm) and three patients received a Boubela-Danis stent (95 mm × 20 mm). The next 15 patients received the purpose designed SX-ELLA Danis stent as described above. The first five were placed *via* an endoscopic guide wire and fluoroscopic control, the remainder were placed using the insertion device without a guide-wire or fluoroscopy. The stents were able to successfully control haemorrhage in all cases with no reported re-bleeding during 30 d of follow-up. In one case there was mild ulceration in the distal oesophagus after removal, no other complications were reported. Following stent extraction at a median of 5 d (1-14 d), 18 patients went on to have a definitive procedure to prevent re-bleeding (TIPS, azygoportal disconnection, liver transplant, radiological embolization or endoscopic intervention (variceal ligation or sclerotherapy). Mortality was 10% within 30 d (one at day three from hepatic failure and one at day five from multi-organ failure) and 20% at 60 d (Figure 1).

The same group of investigators published a further series of the SX-ELLA Danis stent including 15 patients previously described, with an additional 19 patients all of whom had failure to control bleeding following standard endoscopic techniques[26]. Haemostasis was achieved in all 34 cases using the SX-ELLA Danis stent without complications. All stents were deployed successfully, for a mean of 6 d (range 1-14 d). There were a total of 7 instances of stent migration, which was attributed to low stent position at insertion. Mortality was 26.5% at 30 d and 29.4% at 60 d and there was no re-bleeding reported during follow-up.

A tertiary United Kingdom centre reported SEMS use in 10 patients with on-going variceal bleeding despite standard endoscopic therapy[27]. Two patients had the added complication of BT induced oesophageal rupture. Stents were successfully deployed in 9 cases, in once case the gastric balloon failed to inflate and the procedure was abandoned. Nine/ten patients had active bleeding at the time of endoscopy and haemostasis was achieved in 7/9 (78%). The patients with continued haemorrhage were subsequently shown to be bleeding from gastric varices. The mortality rate at 6 wk was 50%.

Fierz *et al*[28] described a combined case series of 9 patients from Swiss Hospitals. They reported a total of 9 bleeding episodes in 7 cirrhotic patients (two patients had two separate bleeds). In three cases SEMS was used as first line endoscopic therapy, and in the remaining 6 cases there had been inadequate control of haemorrhage with band ligation or sclerotherapy. The majority of patients were Child-Pugh class C and the mean MELD score was 34. All stents were placed with endoscopic assistance and two cases of distal stent migration were noticed, no other complications were reported. Control of haemorrhage was achieved in all cases, except one where the stent was not deployed correctly. The reported 6 wk mortality rate of 78% is high and reflects the severity of underlying liver disease in this cohort[28].

Zakaria *et al*[29] have reported a series of 16 patients where SEMS was used for the primary therapy of variceal haemorrhage. Patients with hepatitis C related cirrhosis and evidence of on-going bleeding from varices, cherry red spots, or fresh blood in the oesophagus or stomach received a stent for between 2 and 4 d. Successful control of haemorrhage with the SEMS was reported in 14/16 patients. Of the two treatment failures one was caused by the rupture of the gastric balloon and sclerotherapy was applied to the varix and in the second the SEMS failed to control bleeding from a GOV-1 vairx which required cyanoacrylate glue.

The results of the first randomised controlled trial comparing SEMS to BT were published in abstract form in 2013[30]. This was a multicentre trial of 8 hospitals in Spain.

The study included consenting adult patients with cirrhosis and acute variceal bleeding (as defined by the Baveno Ⅱ consensus) who met either of the following inclusion criteria: (1) Failure to control bleeding (as defined by Baveno Ⅳ criteria) despite pharmacological (somatostatin 3 or 6 mg/12 h *iv* or terlipressin, 2 mg/4 h *iv*) AND endoscopic therapy (oesophageal banding ligation preferably or sclerotherapy); and (2) Massive bleeding, uncontrolled despite pharmacological therapy started at any moment, with no need of previous endoscopic therapy. Uncontrolled bleeding was defined as an upper digestive bleeding in which no hemodynamic stability (systolic arterial pressure > 70 mmHg and heart rate < 100 bpm) could be achieved.

The exclusion criteria were oesophageal rupture; oesophageal, gastric or upper respiratory tract tumor; oesophageal stenosis; recent oesophageal surgery;

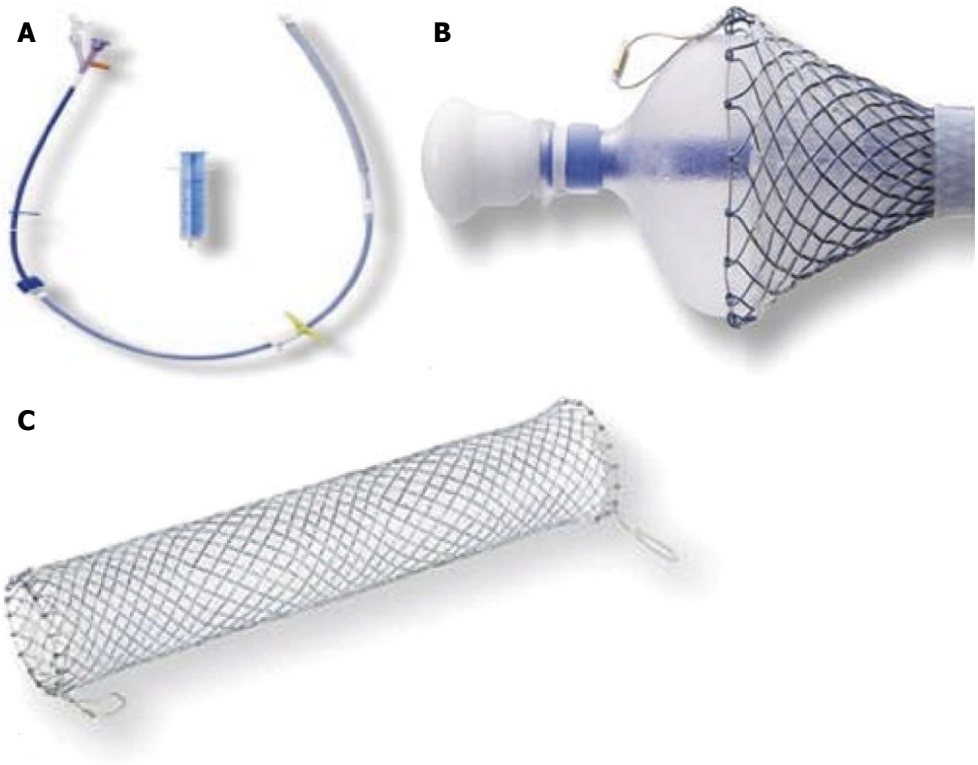

Figure 1 The Danis Stent with delivery system. A: The SX-ELLA Danis stent is supplied preloaded in an insertion device that has a 26F diameter and is 60 cm long; B: A balloon at the distal end of the insertion device (shown partially inflated) allows anchoring of the distal end of the stent at the cardia during deployment; C: The fully deployed stent is 135 mm long and 25 mm wide.

previous oesophageal tamponade to treat the index bleed; a big hiatal hernia precluding the correct placement of the oesophageal device; known hepatocellular carcinoma surpassing Milan criteria and terminal disease.

Twenty-eight patients were randomized to BT (n = 15) or SEMS (SX-Ella Danis; n = 13).

Both groups were matched for the aetiology and severity of liver disease, presence of active bleeding at endoscopy and for the initial therapy received. SEMS were placed without endoscopic or fluoroscopic guidance, but under sedation, and their position confirmed by chest radiograph. Stents remained *in situ* for a maximum of 7 d and during that time patients could undergo a TIPS. The median time to TIPS was reported as 3.5 (0-7) d in the SEMS group and 0.8 (0-1) d in the BT group. The number of patients who underwent successful TIPS placement was not reported. Unfortunately, due to difficulties with participant recruitment the study was under powered. The initial power calculation suggested that 23 patients would be required in each group (Table 1).

One patient in the SEMS group received a BT due to technical difficulties deploying the stent, however the analysis was performed using an intention to treat basis. Haemostasis was achieved in 77% of the SEMS group and 43% of the BT group (P = 0.1). The incidence of serious adverse events was lower in the SEMS group, particularly the incidence of aspiration pneumonia 2/13 *vs* 8/15 in the BT group. Survival at 15 d was 61% and 47% in the SEMS and BT groups respectively (P = 0.4).

LIMITATIONS OF SEMS IN VARICEAL HAEMORRHAGE

There have been reports of minor oesophageal ulceration several case series describing SEMS placement. However, this resolved spontaneously on removal of the stent and neither mortality nor oesophageal perforation have been observed.

Stent migration is the main issue encountered after deployment and, if occurs, impedes effective haemostasis. If adequate traction is not applied to the delivery device at the time of stent deployment, migration is more likely to occur.

There have been a number of reports of failed deployment due to balloon rupture. The insertion device is designed with a safety feature where by the balloon will rupture if more than 100 mL of air is insufflated. This is designed to prevent the complication of an over distended balloon causing an oesophageal tear, should it have been misplaced in the oesophagus (rather than the stomach) prior to inflation. Rupture of the balloon can be avoided if only 100 mL of air is insufflated.

In one case report a patient developed respiratory failure 6 d following successful control of bleeding using an SX-ELLA Danis stent[22]. Bronchoscopy revealed narrowing of the bronchus due to external compression from the proximal portion of the stent. The stent was

Table 1 Summary of case series reporting self-expanding mesh-metal stent use in the control of oesophageal variceal haemorrhage

Ref.	Stent used	*n*	Indications/severity of liver disease	Length of Insertion (d)	Initial Haemostasis with SEMS	Mortality (d)	Complications/notes
Hubmann *et al*[25], 2006	Choo in 2 Elle-Boubela in 3 SX-ELLA Danis in 15	20	FTCB in 19 FTCB and Oesophageal perforation in 1 CP A 0%/B 40%/C 60%	6 (2-14)	100%	10% 30 d 20% 60 d	Minor ulceration in 1 patient Migration in 2 patients
[1]Zehetner *et al*[26], 2008	SX-ELLA Danis	34	FTCB CP A 0%/B 38%/C 62%	5 (1-14)	97%	26.5% 30 d 29.4% 60 d	1 patient continued to bleed from a gastric ulcer Migration in 7 patients
Dechene *et al*[22], 2009	SX-ELLA Danis	1	FTCB	6	100%		Stent extracted at day 6 due to tracheal compression patient died on day 13 of hepatic failure
Mishin *et al*[24], 2010	SX-ELLA Danis	1	FTCB (EBL ulcer)	8	100%	0% 10 d	Outcomes after 10 d not reported
Wright *et al*[27], 2010	SX-ELLA Danis	10	FTCB in 8 BT induced oesophageal tear in 2 Median MELD 26 (14-39)	6 (6-14)	70%	50% 42 d	Uncontrolled bleeding from gastric varices after insertion in 2 patients Failure to place stent in 1 patient
[2]Dechêne *et al*[23], 2012	SX-ELLA Danis	9	FTCB Median MELD 32 (16-40)	11 (7-14)	100%	56% 30 d 67% 60 d	1 patient died within 5 d from liver failure (technically FTCB)
Fierz *et al*[28], 2013	SX-ELLA Danis	9	FTCB Median MELD 27 (11-37)	0.5-5	89%	78% 42 d	1 failure due to incorrect deployment
Holster *et al*[32], 2013	SX-ELLA Danis	5	FTCB Median MELD 21 (11-28)	6-214	100%	Not reported	1 re-bleed at 7 d from the GOJ
Zakaria *et al*[29], 2013	SX-ELLA Danis	16	Primary therapy in acute variceal bleed CP A 13%/B 50%/C 37%	2-4	94%	25%	Uncontrolled bleeding from GOV-1 varix after insertion in 1 patient Failure to place stent in 1 patients

[1]20 patients included in this trial were also included in the first trial by Hubmann *et al*[25]; [2]Dechene *et al*[22] previously reported 1 patient from this series in 2009. FTCB: Failure to control bleeding; BT: Balloon tamponade; EBL: Endoscopic band ligation; CP: Child-Pugh score; MELD: Model for end-stage liver disease score; GOV-1: Gastro-oesophageal varices type 1.

removed and bronchial obstruction resolved. In this case varices were secondary to hilar cholangiocarcinoma and the patient died from liver failure 7 d after the stent was removed.

CONCLUSION

Despite the recent advances in treatment of variceal bleeding there are still significant rates of treatment failure and mortality and there is still considerable variation in patient outcomes.

Current guidelines for the management of variceal haemorrhage suggest that a TIPS should be considered for high risk cases and in patients with bleeding refractory to standard medical and endoscopic therapies[15,31]. However, TIPS is not suitable for all patients and the complications of liver failure and hepatic encephalopathy limit the use of TIPS in some patients. There is, therefore, an unmet need where standard endoscopic therapy is ineffective and TIPS is not a suitable treatment.

SEMS are very effective in the control of oesophageal variceal haemorrhage, and in all of the series reported to date the only "stent failures" have either been where the stent was not deployed correctly or where the bleeding was from concomitant gastric varices. The mortality rates reported in the case series are very variable, and the main determinant is whether they are used as definitive therapy, or as a bridge to another therapy, mortality being improved with the latter.

It is not yet clear whether SEMS have a defined place in the algorithm for the management of variceal haemorrhage. The data from Escorsell *et al*[30] has not confirmed that SEMS perform better than BT in refractory bleeding, but there was a trend towards fewer complications and more effective haemostasis. This has led to a recommendation from the BAVENO Ⅵ committee for SEMS to be considered as an alternative to BT in their most recent concensus report[15]. Further data from randomised controlled trials are required to guide clinicians in their use of these devices, however they are an attractive alternative to BT and may be an effective bridge to definitive therapy.

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