NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Danis stent for acute oesophageal variceal bleeds

1 Technology

1.1 Description of the technology

Danis stent is a self-expanding and removable silicone-covered nitinol stent. It is positioned at the gastro-oesophageal junction to compress oesophageal varices and stop acute bleeding. It comes preloaded in a balloon-style delivery system that facilitates accurate positioning without radiological or endoscopic assistance. It is claimed by the company that this allows for more rapid insertion and control of variceal bleeding in emergency situations compared with balloon tamponade. Radiopaque markers are present at the distal end and midpoint of the stent which allows its position to be confirmed on chest X-ray after the insertion, although the company state that this confirmation is not routinely required. Danis stent has retrieval loops with gold markers at both ends which facilitate stent removal under endoscopic or fluoroscopic guidance using either grasping forceps or a specifically designed removal device, Ella Extractor, which can be purchased separately from the company. The company recommends that Danis stent should remain in place for no longer than 7 days, whether or not the patient has received definitive treatment, such as trans-jugular intrahepatic portosystemic shunts (TIPS). If TIPS has been done earlier and portal hypertension is no longer a concern, the company state that the stent can be removed using grasping forceps because of a lower risk of re-bleed.

The stent is 135 mm long and 25 mm in diameter when deployed. The technology is intended to be used in secondary care by clinicians including gastroenterologists, hepatologists, endoscopy nurses, ITU or emergency

department clinicians. Endoscopy is likely to be required in the majority of cases, and so clinicians who are competent in endoscopy and with experience of managing bleeds are those most likely to insert Danis stent. Danis stent is provided in a pack which contains the stent (preloaded in the delivery system), guide wire and syringe.

Innovative aspects of this device claimed by the company are that Danis stent allows for more rapid control of bleeding because it does not need endoscopic image guidance; that it can remain in place for longer than a balloon used for tamponade (which should not be left in place for more than 24 to 36 hours); that patients' oral intake can be maintained while the stent is in place; and the stent is designed to prevent migration.

1.2 Relevant diseases and conditions

Danis stent is intended for use in acute refractory oesophageal variceal bleeding, after first line therapy, such as variceal band ligation, has failed. It is intended to be used as an alternative to balloon tamponade or early TIPS in people aged 16 years and over.

Acute variceal bleeding is a major cause of upper gastrointestinal bleeding in patients with liver cirrhosis, accounting for 70% of cases (Rudler et al. 2012). 30-50% of patients with portal hypertension will have an episode of acute variceal bleeding, and for approximately 20% of these patients the first episode of bleeding is fatal (Tripathi et al. 2015). HES data indicates that in 2018/19 there were 869 emergency admissions with a primary diagnosis of oesophageal varices with bleeding. The company estimate that approximately 500 to 1000 patients per year would be eligible for Danis stent.

1.3 Current management

The current standard care for people with acute variceal bleeding involves a combination of usual resuscitation, administration of vasoactive drugs and prophylactic antibiotics and the use of endoscopic techniques. NICE's clinical guideline on the management of acute upper gastrointestinal bleeding in over 16s recommends offering terlipressin to people with suspected variceal

bleeding at presentation. Band ligation is the recommended primary therapy for people with upper gastrointestinal bleeding from oesophageal varices, followed by TIPS if the bleeding is still not controlled. NICE's interventional procedure guidance on stent insertion for bleeding oesophageal varices states that there is enough evidence to show that stent insertion is safe and effective for people with bleeding oesophageal varices that it can be used with normal arrangements for clinical governance, consent and audit when other methods of treatment have failed to control the bleeding.

UK guidelines on the management of variceal haemorrhage in cirrhotic patients recommend upper gastrointestinal endoscopy as soon as the patient is haemodynamically stable to locate the bleeding site. Band ligation is recommended as the first-choice therapy to control bleeding varices. If banding is difficult because of continued bleeding or this technique is not available, endoscopic variceal sclerotherapy is recommended as an alternative. When bleeding is difficult to control, the guideline recommends the insertion of a temporary tamponade balloon (a Sengstaken-Blakemore tube) as a bridge to more definitive treatment such as endoscopic, TIPS, or surgical treatment. The guideline also states that, ideally, variceal bleeding should be treated in a unit where the staff are familiar with managing bleeds and where routine therapeutic interventions are available.

Baveno VI consensus report (Journal of Hepatology, 2015) states that the evidence supports the use of self-expanding oesophageal metal stents (SEMS) as being safer and more effective than balloon tamponade.

1.4 Regulatory status

Danis stent received a CE mark in June 2006 as a class IIb device for acute refractory oesophageal variceal bleeding.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Faster recovery following the procedure

- Improved quality of life
- Fewer procedural complications
- The ability to maintain oral intake
- Reduced need for patient transfer
- Better patient compliance
- Eliminated/minimised high dependency hospitalisation
- Increased possibility of stabilised bilirubin and renal function to facilitate the option of TIPS, where otherwise not possible
- Eliminated need for general anaesthetic and/or heavy sedation while achieving haemostasis

The benefits to the healthcare system claimed by the company are:

- Reduced bed use in ITU/high dependency units
- Decreased strain on fluoroscopic imaging facilities
- Reduced length of hospital stay
- Reduced hospital admissions/interventions
- Helping trusts achieve government targets relating to efficiency savings, hospital stays, positive outcomes and reduced repeated procedures
- Increased time for planning of definitive treatment (7 days vs. 24/48 hours for balloon tamponade)
- Increased possibility of successful TIPS and providing definitive treatment
- Significant cost saving compared with current treatment options

2 Decision problem

Population	People aged 16 years and over with acute refractory oesophageal variceal bleeding in whom first line therapy, such as terlipressin, prophylactic antibiotics, variceal band ligation or sclerotherapy is unsuitable or has failed
Intervention	Danis stent insertion
Comparator(s)	• Balloon tamponade • Early trans-jugular intrahepatic portosystemic shunt (TIPS)
Outcomes	The outcome measures to consider include: • Control of bleeding

	• Rebleeding rate • Blood transfusion use • Device-related adverse events, including stent migration • Mortality rate • Hepatic encephalopathy • Patient-related quality of life • Additional/further interventions including TIPS	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed. The cost analysis should allow for the expected costs of different methods of removal of the Danis stent, including the use of Ella Extractor.	
Subgroups to be considered	None identified	
Special considerations, including those related to equality	Danis stent is intended for use in people aged 16 years and over with acute refractory variceal bleeding. Oesophageal variceal bleeding is a common and life-threatening complication of cirrhosis in people with chronic liver disease. Some people with chronic liver disease may be considered disabled under the Equality Act if their condition 'has a substantial and long-term adverse effect on their ability to carry out normal day-to-day activities'. Age and disability are protected characteristics under the Equality Act 2010. Danis stent may also be an advantage to people who do not accept blood transfusions due to religious beliefs, such as Jehovah's Witnesses.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristic?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No

Any other special considerations	Not applicable

3 Related NICE guidance

Published

- Alcohol-use disorders: diagnosis and management of physical complications (2017). NICE guideline CG100.
- Acute upper gastrointestinal bleeding in over 16s: management (2016) NICE guideline CG141.
- Cirrhosis in over 16s: assessment and management (2016). NICE guideline NG50.
- Stent insertion for bleeding oesophageal varices (2011) NICE interventional procedure guidance 392.

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- British Association for the Study of the Liver
- British Liver Nurses' Association
- British Society of Gastroenterology
- Royal College of General Practitioners
- Royal College of Physicians

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Guts UK
- British Liver Trust