National Institute for Health and Clinical Excellence

690/2– Stent insertion for bleeding oesophageal varices
Consultation Comments table

IPAC date: Friday 11 February 2011

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 2 NHS Professional	**1**	As study author of the pilot study and own experience in more than 50 stent insertions for variceal bleeding I agree totally with this recommendations.	Thank you for your comment.
2	Consultee 3 UK distributor for Ella Danis Stent	**2**	Not directly related to section 1. but please note that Danis stent removal is indicated within 7 days (in IFUs) with specific Ella Extractor device to reduce potential of rebleed at extraction. Also the stent is noe silicone covered (was polyurethane)	Thank you for your comment. The description of the stent in section 2.2.2 of the guidance will be changed.
3	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2**	Specialist Societies should include BSIR and BSGAR, Advisors should be familiar with the system discussed. The guidance document is incorrect in the following points: 1, The covered design of the Danis stent is exactly like stents used for cancer	Thank you for your comment. NICE approached the British Society of Interventional Radiography and asked them to comment on the draft guidance. The description of the stent in section 2.2.2 of the guidance will be changed.
4	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2**	2, No balloon is inserted into the stent, this is a self-expanding nitinol stent, not a balloon expandable stent. The system consists of a gastric balloon that is inflated as with a Sengstaken tube to ensure accurate positioning of the delivery system in the distal oesophagus on traction. The stent is released by withdrawal of a constraining sheath	Thank you for your comment. The consultee is referring to the overview which will be changed.

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5	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2**	. 3, Literature search should exlude the term "endoscopic" as it may be done without It should be emphasised that currently only one stent system is designed and licensed for this purpose (Danis stent, Ella-CS, Hradec Kralove, Czech Republic marketed by UK Medical, Sheffield). That system can be used without image guidance in dire emergencies. It consists of a stent mounted on a Sengstaken-type balloon catheter. Fluoroscopy is advisable if available.	Thank you for your comment. The search term “endoscopic” was one of several used to identify relevant literature. Section 2.2.2 of the guidance will be changed to include fluoroscopy.
6	Consultee 5 NHS Professional	**2**	Agree but worthwhile adding that the mortality associated with the use of rescue treatments such as TIPS or Shunt surgery is very high as it can lead to a deterioration in liver function.	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
7	Consultee 3 UK distributor for Ella Danis Stent	**2**	Danis stent is recommended for acute bleeding with further treatment option (e.g. TIPSS)to follow	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
8	Consultee 2 NHS Professional	**2.1**	Up to the recent information and study results, there is very high evidence, that stent procedure is much more effective than balloon tamponade, has much lower side effects and less risks of any complications. In failure of band ligation or sclerotherapy, stent therapy should be therapy of choice. In high risk patients if avaliable early treatment with PTFE-TIPS is therapy of choice.	Thank you for your comment.
9	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2.1**	The first 4 measures cited only address the acute bleeding, not the underlying cause. The increased portal blood pressure remains with a risk of re-bleeding. This also applies to stent insertion.	Thank you for your comment.

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10	Consultee 5 NHS Professional	**2.2**	The manufacturer recommends stents should be left in place for 1 week but we have left stents in for 2 weeks without problems. The highest incidence of early rebleeding is in the first week. Theoretically there should be no need to leave stents in situ for more than 1 week. They can be removed and secondary therapy with band ligation applled at the same session. The benefit of the stent may be that it allows time for improvment of liver function and/or institution of secondary prophylaxis which may mean that TIPS etc are not required	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
11	Consultee 3 UK distributor for Ella Danis Stent	**2.2**	Plastic is Silicone Delivery system enables accurate stent placement No need for intubation	Thank you for your comment. The Committee considered this comment and decided not to change the guidance.
12	Consultee 6 Specialist Adviser	**2.2**	"TIPPS" should be "TIPSS"	Thank you for your comment. Section 2.2.4 of the guidance will be changed.
13	Consultee 2 NHS Professional	**2.2**	I also agree to that outline of the procedure. Additional remarks: The metal stent is coated inside with polyurethan (not plastic)	Thank you for your comment. Please see response to comment number 2.
14	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2.2**	Positioning is NOT confirmed by chest x-ray but with real-time x-ray fluoroscopy. Endoscopic placement is not as accurate, particularly in the case of active bleeding and this is ideally also supported by fluoroscopy. There are currently also biodegradable stents available by the same manufacturer, which dissolve over 3-4 months. These are licensed for treatment of non-cancer narrowing (stricture) of the oesophagus. Efforts are under way to get these licensed for treating variceal haemorrhage. The great benefit is that these avoid the cost and trauma of removal.	Thank you for your comment. Please see response to comment number 5.
15	Consultee 3 UK distributor for Ella Danis Stent	**2.3**	Please note that the stent (nitinol) is self expandable and not balloon expanded as described.	Thank you for your comment. Please see response to comment number 5.
16	Consultee 2 NHS Professional	**2.3**	I agree to that informations.	Thank you for your comment.

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17	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2.3**	Further case report on traumatic haemorrhage treated with a Danis stent Kaya E, Lenz P, Lebiedz P, Baumgarten K, Wessling J, Domagk D Placement of covered self-expanding metal stent to treat razor blade-induced esophageal hemorrhage. Endoscopy, 42 Suppl 2:E201-202 It should emphasised that this is a symptomatic treatment and does not address the underlying venous hypertension. Therefore late re-bleeding is to be expected if no other treatment is instigated.	Thank you for your comment. The indication in the case report mentioned by the consultee does not relate to bleeding varices, and therefore this literature has not been included in the evidence base for the guidance.
18	Consultee 2 NHS Professional	**2.4**	Usually to the anatomic situation without malformations the stent length and diameter was chosen in a way, that there shouldn`t be any complications or compressions of bronchus. It is of great interest, if there was any anatomic malformation causing the left main bronchus obstruction. Of course any reported side effect should cause further evaluation and information	Thank you for your comment
19	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**2.4**	Airway compromise from oesophageal stenting usually only occurs with mediastinal masses and is essentially unheard of in benign disease. Reference could be made to the Registry of Oesophageal Stenting of the BSIR.	Thank you for your comment. The NICE IP team has been in contact with BSIR in response to this comment..
20	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**General**	The procedure has evidence of benefit in 3 small published series. It needs to be emphasised that this is an emergency procedure to control active haemorrhage, it does not treat the underlying cause. Equally varices will re-develop/recanalise after stent removall, No references are included. The only dedicated system (Danis, UK Medical, Sheffield) licensed for this purpose and used in the studies, can be used without image guidance. It consists of a stent mounted on a Sengstaken-type balloon catheter. Endoscopy / fluoroscopy is advisable if available.	Thank you for your comment. Please see response to comment number 5. No other change will be made to the guidance.

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			Standard oesophageal stents need image guidance; even endoscopists ideally using additional fluoroscopy. No stents are currently licensed for this use – this should be emphasised. Biodegradable (BD) stents could be used instead, which have the benefit of not requiring removal, thus avoiding trauma to the source of haemorrhage. The manufacturer (Ella-CS) is in the process of getting this licensed, but I am awaiting clarification how far they have got. I have made some more detailed comments/amendments directly into the document below. [SUGGESTED CHANGES TO GUIDANCE INCLUDED BELOW] [TO FIRST PARAGRAPH] “People who drink heavily or who have hepatitis C may develop liver cirrhosis (scarring). This can cause bleeding arising from swollen veins in the gullet (oesophagus), which is potentially life threatening. This procedure involves temporary insertion of a flexible tube made out a wire ~~shaped~~ mesh covered in plastic [biodegradable stents?] (called a stent) into the oesophagus. The stent ~~is~~ expand~~ed~~s to the width of the gullet so that it presses against the veins with the aim of stopping the bleeding. The stent is removed within 2 weeks.” “2.2.2 The procedure is usually carried out following diagnostic endoscopy, but with dedicated systems can be performed as an emergency without endoscopy. A purpose-made metal stent with a plastic coating, supplied on a delivery	

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			system, is inserted with the aim of compressing the bleeding varices in the oesophageal wall. Appropriate positioning of the stent may be ~~confirmed~~ guided by endoscopic~~ally~~ or ideally by ~~chest~~ real-time x-ray control (fluoroscopy). 2.2.3 The stent maintains a patent oesophageal lumen for passage of food, saliva and other fluids. It is left in position for up to 2 weeks and is then removed endoscopically. Biodegradable stetns do not require removal, but dissolve over 3-4 months." It needs emphasising that at present stenting is an emergency measure to control active bleeding. It does not treat the underlying problem and a risk of haemorrhage remains after stent removal. "2.3.1 Case series of 34 and 20 patients reported that metal stent insertion stopped the bleeding in all patients and that no re-bleeding occurred in any patients (60-day follow-up)." Late migration of BD stents after haemostasis does not require stent removal avoiding the associated trauma.	
21	Consultee 1 Oesophageal Section of British Society of Gastroenterology	**General**	We note the evidence base is very limited - Â 2 case series. We beleive the technique should only be considered when variceal banding has failed or is not possible. A trial against balloon tamponade would be appropriate Data on Â migration rates (likely to be considerable since there is no stricture to hold the stent in place) will be important. Cost effectiveness also important	Thank you for your comment. The Committee considered this comment and decided not to change the guidance. Cost-effectiveness is not part of the remit of the IP Programme.

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22	Consultee 4 Representative of British Society of Interventional Radiology, Royal College of Radiologists and British Society of GI and Abdominal Radiology	**Conflict**	I have acted as technical consultant for Ella-CS and offer staff training to their UK manufacturer (UK Medical) and a competitor (BVM Medical)	Thank you for your comment, noted.