

Table 7: Expert evidence for review question: What is the effectiveness of stenting compared with emergency surgery for suspected colorectal cancer causing acute large bowel obstruction?

Section A: Developer to complete	
Name:	James Hill
Role:	Principal investigator (CReST trial) Consultant Colorectal Surgeon
Institution/Organisation (where applicable):	Manchester University NHS Foundation Trust
Contact information: [REDACTED TEXT]	
Guideline title:	Colorectal cancer
Guideline Committee:	Colorectal cancer
Subject of expert testimony:	Findings from the CReST trial (UK ColoRectal Endoscopic Stenting Trial)
Evidence gaps or uncertainties:	The guideline committee reviewed the evidence for the review question “What is the effectiveness of stenting compared with emergency surgery for suspected colorectal cancer causing acute large bowel obstruction?” The CReST trial is a UK phase III randomised trial that directly answers this question and is the largest trial in the topic to date and the only one from the UK, however, the findings of the trial have not yet been published (apart from a conference abstract) and the timeline of the guideline does not allow us to wait for the paper to be published. Therefore, the guideline committee has invited James Hill, the principal investigator of the CReST trial, to present the findings of the CReST trial to the guideline committee and to answer questions they may have.

Section B: Expert to complete

Summary testimony:

NICE already advise on the use of colonic stents in acute large bowel obstruction. For palliative disease the following guidance is given.

1.2.2.4 For patients with acute left-sided large bowel obstruction caused by colorectal cancer that is not potentially curable, or for whom surgery is unsuitable: **[new 2014]**

- Resuscitate patients with acute large bowel obstruction, then consider placing a self-expanding metallic stent to initially manage a left-sided complete or near-complete colonic obstruction. **[2011]**
- A consultant colorectal surgeon should consider inserting a colonic stent in patients presenting with acute large bowel obstruction. They should do this together with an endoscopist or a radiologist (or both) who is experienced in using colonic stents. **[2011]**

I gave verbal evidence that a National Bowel Cancer Audit (NBOCA) of stenting in the palliative setting demonstrated very variable uptake of this guidance in England with some units stenting 80% of such cases and other units 0% of such cases.

NICE guidance on the use of stents in the potentially curative setting was published in 2014.

1.2.2.3 For patients with acute left-sided large bowel obstruction caused by colorectal cancer that is potentially curable, and for whom surgery is suitable:

- Resuscitate patients and explain to them and their family members or carers (as appropriate) that acute bowel obstruction can initially be managed either with emergency surgery or a colonic stent, and that there is no clear evidence that one treatment is better than the other. **[new 2014]**

At the time of publication of this guidance there was concern about the use of stents in large bowel obstruction which arose from two European randomised trials. One was stopped early as a result of poor stenting success rates and the second because of increased morbidity in the stenting group. Subsequent studies have raised concerns about the adverse oncological consequences of stenting.

The CReST (ColoRectal endoscopic Stenting Trial) was designed to evaluate in a randomised controlled trial two key questions: is there a worthwhile net benefit (in reduced operative mortality and morbidity, reduced stoma formation and better quality of life adjusted survival) from endoluminal stenting for patients presenting with an obstructing colonic cancer and if a benefit exists, is this identifiable in patients undergoing attempted curative treatment, palliative treatment, or both?

Subsequent to the commencement of CReST trial, evidence for the benefit of self-expandable metal stents (SEMS) in the palliative setting has been published and is largely accepted.

The CReST trial was the largest phase III, multi-center randomised controlled trial to determine if endoluminal stenting for obstructing colonic cancers can result in:

- Reduced perioperative morbidity as assessed by length of hospital stay
- Reduced 30-day mortality

Secondary end points were

- Stenting completion and complication rate
- Presence and duration of a stoma/anastomosis rate
- 6-month survival
- 3 year survival
- Quality of life
- Perioperative morbidity

Eligibility criteria were

- Left-sided colorectal cancer
- Radiological evidence of obstruction
- Patient fit for surgery
- No evidence of peritonitis and/or perforation
- Patient able and willing to give written informed consent
- Patients stratified by palliative or potentially curative

Patients were stratified into those with palliative and potentially curative disease at trial entry. For those with potentially curative disease these were further stratified into; curative probably yes, curative probably no and uncertain. We planned to recruit 200 patients in each group. During the conduct of the trial, evidence for the benefit of stenting in the palliative setting was published. This clearly affected the recruitment rates for this group of patients. The final recruitment number was 245 with more than 90% of cases in the potentially curative group. 122/123 patients randomised to stent received this treatment.

The stenting and emergency surgery groups were well matched for age, gender, site of tumour, APACHE score and ASA grade.

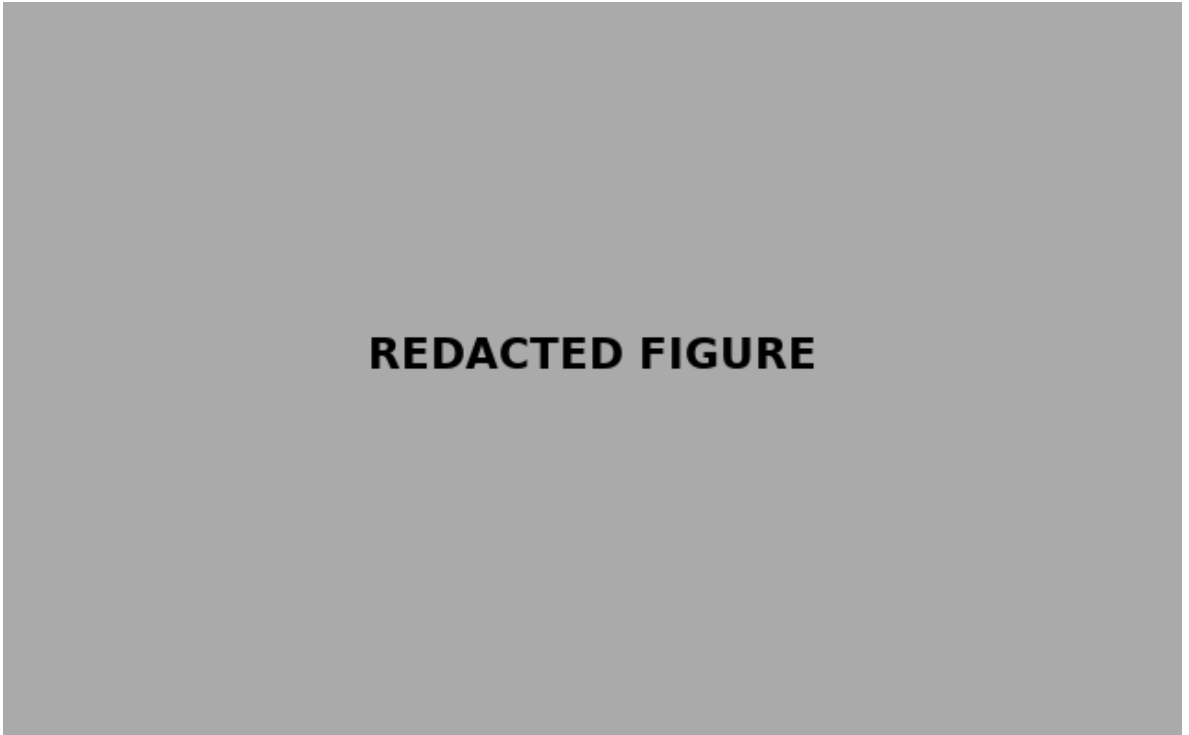
For the potentially curative group, stratification was;

	Stenting	Emergency surgery
Potentially curative	113 (92%)	113 (93%)
Likelihood of cure:		
Probably not	3 (3%)	6 (5%)
Probably yes	78 (69%)	72 (64%)
Uncertain (possibly yes)	32 (28%)	35 (31%)

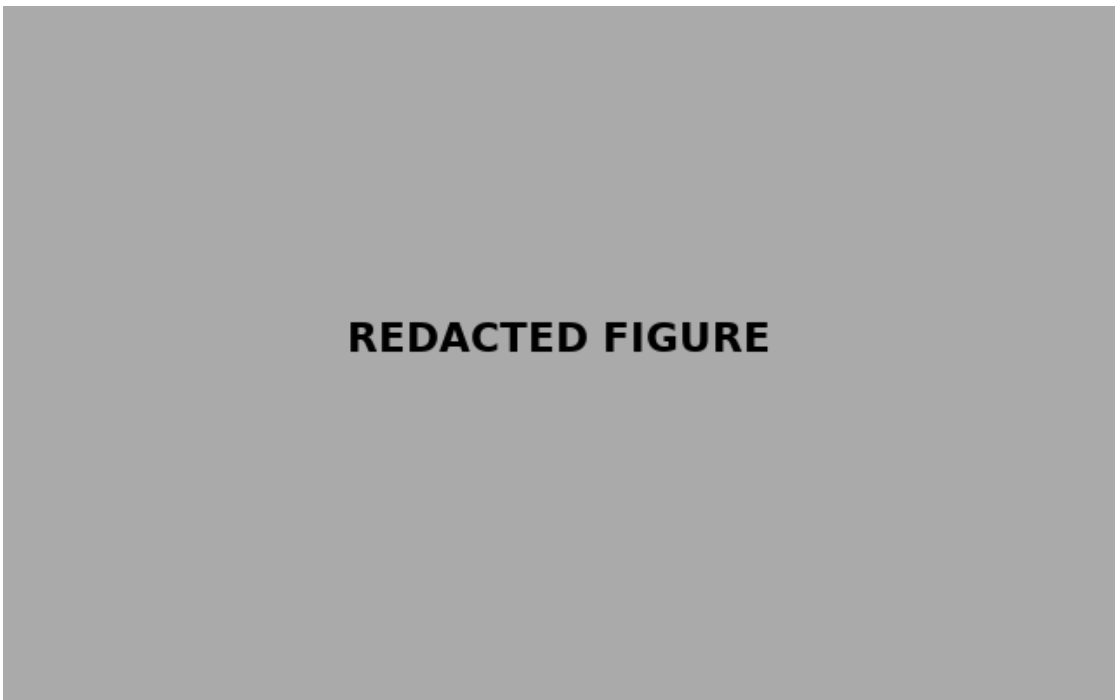
For subsequent analyses the potentially not patients (9) were grouped with the palliative patients.

Primary end points

[REDACTED TEXT]



[REDACTED TEXT]



[REDACTED TEXT]

Secondary end points

Stenting success – stenting relieved obstruction in 98 patients (82%) This was achieved across multiple hospital sites (39 recruiting hospitals).

Complications – perforation occurred in 6 patients. All required emergency surgery. There was no mortality in this group. One patient required mechanical ventilation post operatively.

Stoma rates - 46/99 (46%) in the stenting group and 82/119 (69%) $P < 0.001$

[REDACTED TEXT]



REDACTED FIGURE



REDACTED FIGURE

[REDACTED TEXT]

Summary

The CReST trial of stenting vs emergency surgery in patients with obstructing left sided colorectal cancer is the largest randomised trial in this setting. **[REDACTED TEXT]**

Stenting clinical success rates were high (82%) across multiple hospital sites.

[REDACTED TEXT]

Stenting significantly reduced stoma rates

[REDACTED TEXT]

References to other work or publications to support your testimony (if applicable):

Hill J, Kay C, Morton D et al (2016) Journal of Clinical Oncology. 34 (supplement; abstract 3507)