

Assessing motility of the gastrointestinal tract using a wireless capsule

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg502

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Recommendations

- 1.1 The evidence on assessing motility of the gastrointestinal tract using a wireless capsule raises no major safety concerns. There is evidence of efficacy in measuring gastrointestinal function but uncertainty about the clinical benefit of this, and about patient selection. Therefore, this procedure should be used only with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to assess motility of the gastrointestinal tract using a wireless capsule should take the following actions:
 - Inform the clinical governance leads in their NHS trusts.
 - Ensure that patients understand the uncertainty about the procedure's efficacy and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients having the motility of the gastrointestinal tract assessed using a wireless capsule (see section 7.1).
- 1.3 NICE encourages further research into the use of a wireless capsule to assess motility of the gastrointestinal tract. Studies should include clear details of patient selection. They should report on the diagnostic accuracy of the procedure in different parts of the gastrointestinal tract, and should provide data on the clinical benefits of the procedure for patients.

2 Indications and current treatments

- 2.1 The procedure is used to investigate gastrointestinal (GI) motility-related symptoms. Motility disorders can sometimes be difficult to diagnose. They include conditions such as gastroparesis and slow transit constipation. Gastroparesis is a chronic disorder of the stomach, characterised by delayed gastric emptying in the absence of mechanical obstruction. Treatment includes medical therapies (such as erythromycin and metoclopramide), botulinum toxin, gastric electrical stimulation, jejunostomy and parenteral nutrition. Slow transit constipation comprises a number of symptoms including straining, hard stools, sensation of incomplete evacuation and infrequent bowel movements. Management includes medical therapies such as laxatives and lifestyle advice (for example, increasing exercise, and intake of water and fibre).
- 2.2 The standard procedure used to assess upper GI motility is gastric emptying scintigraphy. It involves ingestion of a standardised radiolabelled meal. An X-ray is taken after 4 hours to determine the extent of gastric emptying.
- 2.3 Slow transit constipation is assessed using a radiopaque marker examination. The patient ingests a number of radiopaque markers and has an X-ray(s) after a predefined time period (usually 4 or 5 days) to determine whether markers have been evacuated.

3 The procedure

- 3.1 The aim of the wireless capsule procedure is to measure gastrointestinal (GI) motility (that is, gastric emptying time, small bowel transit time or colonic transit time) by assessing temperature, pressure and pH.
- 3.2 The wireless capsule system consists of a single-use, non-digestible, wireless transmitting capsule, a receiver for acquiring and storing signals from the capsule and software for displaying data on a computer. The patient fasts for several hours before the procedure and then drinks some water and eats a standardised meal replacement before swallowing the capsule. The patient then fasts for several more hours

and is advised to avoid vigorous exercise. While in the body, the capsule samples bowel contents and transmits data about pH, pressure and temperature to a portable receiver (worn by the patient) at regular intervals as it travels through the GI tract. The patient can record meals, sleep and bowel movements by pushing an event button on the receiver. The capsule is passed out of the bowel with the faeces. If not seen in the stool, loss of the recording signal or an abrupt temperature drop on the recording profile confirm exit of the capsule from the body.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 4.1 A systematic review of 745 patients (12 studies) with suspected motility problems reported sensitivity of the wireless motility capsule in comparison with clinical diagnosis of gastroparesis to be 65 to 68% and specificity to be 82 to 87% in a subset of 560 patients (reported by 7 studies included in the systematic review).
- 4.2 The systematic review of 745 patients (12 studies) with suspected motility problems reported sensitivity of the capsule in comparison with gastric emptying scintigraphy to be 59 to 86% and specificity to be 64 to 81% in a subset of 560 patients (reported by 7 studies included in the systematic review).
- 4.3 The systematic review of 745 patients (12 studies) with suspected motility problems reported sensitivity of the capsule compared with a radiopaque marker to be 37% and specificity to be 95% in a subset of 78 patients (reported by 1 study included in the systematic review) with constipation. A case series of 187 patients with constipation reported sensitivity of the capsule in comparison with radiopaque marker assessment for colonic transit time of 80% (95% confidence interval [CI] 67 to 98%, $p=0.01$) and specificity of 91% (95% CI 83 to 96%, $p=0.00001$). The same study reported sensitivity of the capsule in comparison with radiopaque marker assessment for small and large bowel transit time of 79% (95% CI 67 to 89%, $p=0.01$) and specificity of

91% (95% CI 83 to 96%, $p=0.00001$).

- 4.4 A case series of 86 patients with suspected symptoms of upper GI or lower GI dysmotility reported that using the capsule confirmed the clinical diagnosis in 58% (50/86) of patients and that radiopaque marker examination or gastric emptying scintigraphy confirmed the clinical diagnosis in 44% (38/86) of patients ($p<0.05$).
- 4.5 A case series of 83 patients with suspected gastroparesis, intestinal dysmotility or slow transit constipation reported that in 53% (44/83) of patients, using the capsule led to a new diagnosis. In a case series of 43 patients with gastroparesis comparing the capsule with gastric emptying scintigraphy, the reported overall diagnostic gain with the capsule (defined as the difference between the percentage of patients with abnormal motility detected by the capsule but normal scintigraphy, and the percentage of patients with normal capsule findings but abnormal scintigraphy) was 19% ($p=0.04$).
- 4.6 The systematic review of 745 patients (12 studies) with suspected motility problems reported data from a subset of 3 studies. In these 3 studies, using the wireless capsule altered management (medicine, diet or surgery) in 50 to 69% of patients with suspected gastroparesis.
- 4.7 The specialist advisers listed key efficacy outcomes as pan-enteric measurement of transit (units of time) and motility (units of pressure or descriptive measures) in gut regions.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [interventional procedure overview](#).

- 5.1 A case series of 187 patients with constipation reported 7 adverse events as being possibly or definitely related to the capsule: 2 cases of abdominal pain, 1 case of diarrhoea, 2 cases of dysphagia and 2 cases of nausea.

- 5.2 Device malfunction was reported in 4% (8/180) of those who ingested the wireless motility capsule in the case series of 187 patients with symptomatic constipation.
- 5.3 Software malfunction resulting in missing data was reported in 7% (12/165) of participants (group not specified) in a comparative study of 165 people (78 patients with chronic constipation versus 87 healthy subjects).
- 5.4 The specialist advisers stated theoretical adverse events included impaction of the capsule in patients with strictures, and the capsule not progressing beyond the stomach in patients with severe gastroparesis.

6 Committee comments

- 6.1 The Committee noted the difficulties of validating the accuracy of diagnostic procedures in the gastrointestinal tract, especially for patients with complex motility disorders, in whom a range of diagnostic procedures may be used. These issues contributed to the difficulty in assessing the efficacy of this procedure.
- 6.2 The Committee noted the particular difficulty of validating diagnostic procedures for motility disorders of the small bowel.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).

This guidance requires that clinicians undertaking the procedure make special arrangements for audit. [NICE has identified relevant audit criteria and has developed an audit tool](#) (which is for use at local discretion).

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with

patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).