REVIEW

Practical aspects of delivering a small bowel endoscopy service in the UK

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ABSTRACT

Capsule endoscopy remains at the forefront of small bowel investigation, offering the only non-invasive means of directly imaging the mucosa of the small bowel. Recommended for the investigation of obscure gastrointestinal bleeding, Crohn's disease, coeliac disease, small bowel tumours and hereditary polyposis syndromes, the uptake of small bowel capsule endoscopy has been widespread in the UK. However, despite a wealth of published literature supporting the utility of capsule endoscopy in clinical practice, there are limited data regarding the actual practical aspects of service delivery, training and quality assurance. In this article, we attempt to address this by considering specific factors that contribute to provision of a high-quality capsule service. The role of formal training, accreditation and quality assurance measures is also discussed.

BACKGROUND

The landscape of small bowel investigation has shifted dramatically in the last 14 years following the introduction of capsule endoscopy (CE) and device-assisted enteroscopy (DAE). Previously difficult to access due to anatomy, length and tortuosity, direct visualisation of the small bowel mucosa can now be achieved non-invasively with CE, while histological examination and therapy of abnormalities deep within the small bowel is possible using DAE. CE examination is now well established as an investigative modality for obscure gastrointestinal (GI) bleeding, iron-deficiency anaemia, Crohn's disease, coeliac disease and familial polyposis syndromes.^{1–5}

CE is relatively simple to perform, and without clear definitions of competence to practice, a CE service can be initiated with relatively little time or financial

investment. Consequently, widespread use and rising demand has meant services have developed in an organic fashion, led by local interest and initiative rather than in a planned, strategic manner. In contrast, DAE is a difficult and time-consuming procedure requiring specialised equipment, infrastructure and training and therefore remains predominantly the domain of tertiary centres.⁶ This article describes aspects of service provision, delivery and training and discusses appropriate quality service indicators.

DEMAND FOR SMALL BOWEL ENDOSCOPY

When considering development of small bowel services, it is important to think about demand both from the UK national and local perspective. In a survey published in 2012, 91% of UK gastroenterologists referred for CE with 45% referring to local services within their own trust.⁷ Despite the number of CE per centre growing year on year, only two regions performed more than the expected 45 procedures per 250 000 population per year and 22% were restricted in their use by hospital or primary care trusts.⁷ Limited access to resources (facilities, trained personnel or both) and inadequate reimbursement are potential reasons for failure of capsule services to expand. Currently (2014–2015), the Healthcare Research Group (HRG) code of FZ42Z for wireless CE attracts a tariff of £909, but Monitor and National Health Service England propose reducing this to £640 (FZ42A, 19 years and over) or £887 (FZ42B, 18 years and under) for 2015–2016.⁸ Capsule endoscopes cost between £360 and £422 plus VAT, but the CE

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procedure additionally involves bowel preparation, a day case admission, nursing time to perform the procedure and download the data, clinician time to read and report the video and the cost of renewables, printing, data storage and so on. Failure to make the procedure at least cost neutral is likely to hamper service development.

The experience of the majority of units offering CE is that demand increases with time, particularly if use is not restricted, and anticipating this may help to plan ahead.⁷ Waiting times may increase if performing CE depends on a single individual or limited trained personnel. But the commonest bottleneck arises because of inadequate time or personnel to read and report CE videos.

DAE has been slower to develop because of the complexity of the procedure and competing pressures at a time when demand for conventional upper and lower GI endoscopy continues to increase. In 2012, eight units were regularly (most weeks) performing DAE.⁷ Information provided by the UK Small Bowel Endoscopy Users' Group suggests that this has now increased to 11 centres, with 5 performing >50 procedures in the year 2014. Interestingly, there are a similar number of units in possession of the equipment but performing few if any procedures. The reasons for this are unknown but presumably relate to time or cost pressures, or inadequate training and support. There remains no specific HRG code for DAE, reimbursement for which has either been agreed locally or by assigning a 'best fit' code.

All units offering CE need to anticipate the need for DAE to obtain material for histological analysis or for therapeutic intervention. Previously, our experience was that one DAE was needed per 25 CE procedures (figure 1), but with increasing DAE experience, better organisation of DAE lists and appropriate funding,

this has increased to a ratio of 1 in 12. Therefore, a unit performing 90 CE procedures (a very conservative estimate for 0.5 m population) might anticipate referring about seven or eight patients per annum to a centre offering DAE.

ORGANISATION OF SERVICES

Our service at Sheffield Teaching Hospitals NHS Foundation Trust has expanded rapidly since 2002, undergoing frequent adaptations to cater for increasing demand and performing >800 small bowel capsule procedures in 2013–2014. The following comments are made on the basis of this experience and a straw poll of the UK Small Bowel Endoscopy Users' Group members. Central to the service must be a facility (an endoscopy or investigation unit) to house the equipment and care for the patients and where several staff (to allow for cross cover) can be trained to operate the computer software, use the data recorders, perform CE and use a 'real-time viewer'. A quiet area should be provided for reading and reporting CE videos without distraction.

More experienced units value the role of a nurse practitioner to oversee the service, most of whom are also involved in prereading CE videos and saving any still images (thumbnails) thought to be relevant in order to allow the clinician to interpret any potentially abnormal findings and produce the written report. Niv and Niv⁹ have shown that an experienced nurse 'pre-reader' was a safe, reliable and cost-effective method to reduce CE reporting time. Although not yet a widely adopted practice, Drew *et al*¹⁰ demonstrated that with appropriate experience and training an advanced endoscopy nurse can report CE procedures and provide appropriate management advice to an equivalent standard as a consultant gastroenterologist.

As patients may be referred having had varying degrees of investigation and information from many different clinicians, nurse-led telephone or preassessment clinics are regarded as helpful. Patient information leaflets and protocols for referring for CE, including when to consider prior investigation of luminal patency (using radiological methods, PillCam patency device (Given Imaging, Yoqneam, Israel), or both) and performing CE, are widely used. Networking of computer systems provides a more secure portal for data storage than detachable devices and for access by referring clinicians from neighbouring hospitals. Finally, a consultant with a specific interest in CE and dedicated time is necessary to run a service. Suggestions for starting and developing a small bowel investigation facility are presented in box 1.

Figure 1 Graph of small bowel capsule endoscopy (CE) and device-assisted enteroscopy (DAE) procedures performed per year at Sheffield Teaching Hospitals National Health Service Foundation Trust.

PRACTICAL CONSIDERATIONS

Bowel preparation

Air bubbles, pools of fluid and opaque luminal contents, particularly towards the distal small bowel, can obscure the mucosa. Early CE studies were performed

Box 1 Suggestions for starting and developing a small bowel investigation facility

- ▶ Gastroenterologist and nurse specialist interested in developing the necessary skills.
- ▶ Ensure that any business case allows for administrative time, capsule endoscopy (CE) reporting, multidisciplinary team (MDT) meetings and anticipated growth in service.
- ▶ Preparation: attend a hands-on training course and have initial readings and reports verified by an experienced colleague. Develop the necessary support network by linking up with established CE units and a device-assisted enteroscopy (DAE) centre.
- ▶ Engage local support by involving radiological and surgical colleagues. CE and radiological small bowel imaging are complementary modalities; some diagnoses require surgery as may CE complications.
- ▶ Patient information leaflets, guidelines and protocols for referrals, patient preparation, the procedure itself and the overall flow of patients through the service.
- ▶ Have a prepared strategy for dealing with complications such as inability to swallow the capsule, incomplete procedures, equipment failure and capsule retention.
- ▶ Provide detailed reports including the quality and completeness of the study (including the need for plain abdominal X-ray if the capsule has not reached the caecum), differential diagnoses and recommendations for further investigation or management.
- ▶ Perform regular audit and present results to the local department.
- ▶ Consider a regular small bowel MDT to enable discussion about complex cases, review of radiology and consideration of further investigation.

after a simple 12 h fast. However, a combination of polyethylene glycol (PEG) preprocedure and simethicone at the time of capsule ingestion has been shown to improve diagnostic yield and small bowel visualisation in two recent systematic reviews, but has no influence on examination completion rates.^{11 12} Uncertainty remains over the ideal dose and timing of bowel preparation, although 2 L of PEG seems to be at least as effective as 4 L. Sodium picosulfate or a clear liquid diet are alternatives for patients unable to tolerate a PEG purge but are associated with a lower diagnostic yield.¹³ Ultimately, decisions regarding preparation should be done in a patient-centred way, considering individual preference and the specific clinical circumstances.

Cautions and contraindications

Cautions and contraindications to CE are listed in [box 2](#). Capsule retention is reported in approximately

Box 2 Cautions and contraindications to small bowel capsule endoscopy

- ▶ Crohn's disease
- ▶ Prolonged non-steroidal anti-inflammatory drug use
- ▶ Severe abdominal pain or obstructive sounding symptoms
- ▶ Previous abdominopelvic radiotherapy
- ▶ Altered upper gastrointestinal anatomy
- ▶ Dysphagia

2% of procedures overall. The risk is primarily related to indication for the procedure. It has not been documented in normal small bowel, occurs in approximately 1% of patients with obscure GI bleeding, rising to 13% in patients with known Crohn's disease.¹⁴ Other risk factors include prolonged use of non-steroidal anti-inflammatory drugs and previous abdominopelvic irradiation.^{14 15} The World Organisation of Digestive Endoscopy–European Crohn's and Colitis Organisation consensus guidelines recommend considering CT or MR enterography as first-line modalities to evaluate the small bowel in patients with established Crohn's disease because they additionally demonstrate transmural and extramural complications.¹⁶ However, confirming functional patency using a PillCam patency device is also recommended in the event that CE is required because of unremarkable or non-diagnostic cross-sectional imaging. Small bowel radiology cannot be guaranteed to exclude short strictures,¹⁷ and our practice is to consider a preprocedure patency capsule in any high-risk patient. This is a dissolving capsule (the same size and shape as the capsule endoscope) containing a radiofrequency tag. Failure to detect the radio frequency signal using a handheld scanner 30 h after ingestion suggests functional patency of the GI tract and predicts uncomplicated excretion of the capsule.^{18 19}

A standardised CE referral form requiring information regarding the indications for the procedure and absence of contraindications allows a screening opportunity for patients at high risk of capsule retention and appropriate selection of those who would additionally benefit from luminal patency assessment.

About half of patients who swallow a patency device fail to excrete it within 30 h, in which case it needs to be located either to the small bowel (raising the possibility of a stricture) or the colon (in which case luminal patency is confirmed). This cannot be done with confidence on a plain abdominal film and conventionally has been achieved using either fluoroscopy or whole abdominal CT scan, both of which require considerable organisation, out-of-hours procedures and substantial irradiation. Our protocol includes the use of a scout film, used to target a limited abdominal CT scan (which involves minimal

radiation exposure) to localise the exact position of the patency device and determines luminal patency with a sensitivity of 99.4%.²⁰ Of 400 high-risk patients undergoing the patency protocol, only one (0.6%) retained a capsule after a limited CT scan was incorrectly reported as showing the PillCam patency in the colon. Retrospective review of this case showed the device in the terminal ileum, mistaken as the caecum because it was obstructed, dilated, contained faeces (subsequently recognised as the 'small bowel faeces sign' of obstruction) and the patient happened to have a high-lying caecum that lay outside the field of the limited slice CT scan. Collaboration with the local radiology service, a precompleted request form and predesignated CT slots allow this aspect to be entirely nurse led.

A representation of the flow pathway used within our own department is demonstrated in [figure 2](#).

A potential risk of interference with permanent implantable cardiac devices such as pacemakers and defibrillators by the radiofrequency of the capsule and data recorder has been anticipated, although several studies of many different device models have failed to demonstrate this and therefore they should not be considered as contraindications.^{21–23} However, not every model of every device has been tested and therefore it is prudent to risk-assess each patient individually. The development of a local policy in agreement with the resident cardiology department is a sensible approach to avoid confusion.

Bronchial aspiration is a rare complication, with only a small number of cases reported in the literature.^{24–27} This occurs more commonly in older patients with no prior history of swallowing disorders and may be asymptomatic. Use of a 'real-time' viewing device to determine the position of the

Figure 2 Flow chart representing the patient pathway through the capsule endoscopy service at Sheffield Teaching Hospitals NHS Foundation Trust. ABDO, abdominal; CE, capsule endoscopy; CT, computed tomography.

capsule can be reassuring if doubt exists following ingestion. Expectoration can be achieved spontaneously by coughing, or retrieval may be necessary using a bronchoscope.^{24 28}

Troubleshooting

Capsule ingestion is contraindicated in patients with known dysphagia. Similarly, patients with altered upper GI anatomy (Billroth II, Nissen fundoplication, Zenkers diverticulum), known gastroparesis or mechanical gastric outlet obstruction present technical challenges to the procedure. The AdvanCE capsule delivery device (US Endoscopy, Mentor, Ohio, USA) is a cradle fitted to the end of a standard flexible endoscope that can be used to deploy the capsule into the small bowel under direct vision. In a small series, it has shown to be safe and effective with minimal training required to operate the equipment.²⁹ This approach could also be considered for any patient with the above contraindications or if a previous CE examination failed or was incomplete due to a prolonged gastric transit time.

Delayed gastric emptying is a common contributing factor to incomplete small bowel examination.³⁰ The use of preprocedural prokinetics such as metoclopramide, domperidone and erythromycin remains contentious. Two systematic reviews and meta-analyses have attempted to resolve this issue with varying outcomes. Koulaouzidis *et al* showed an improvement in capsule endoscopy completion rate (CECR) but not diagnostic yield following preprocedural prokinetics,³¹ whereas Kotwal *et al*¹¹ found no improvement in CECR. Unselective use of prokinetics exposes all patients to the potential risks of these drugs, such as extrapyramidal side effects in the case of metoclopramide. Use of a real-time viewer to identify patients with prolonged gastric transit after capsule ingestion may allow more appropriate use of these drugs and has been shown to be useful in some smaller studies.^{32–34}

Inpatient status seems to be associated with both prolonged gastric and small bowel transit times and is an independent risk factor for incomplete CE.^{30 35 36} A combination of acute illness, comorbidities, multiple medications and the sedentary nature of a hospital admission may all play a part in reducing gut motility. However, delaying CE should be balanced against the fact that patients with suspected small bowel bleeding have higher diagnostic yields the shorter the time interval between the bleeding episode and CE.^{37 38} In such cases, an inpatient procedure may allow early diagnosis and subsequent therapy to be planned without delay.

Reporting

With each CE examination producing between 2 and 5 h of small bowel video footage³⁹ and the potential for an abnormality to be visible in only a small

number of frames,⁴⁰ CE reporting is undoubtedly a time-consuming process requiring dedicated attention. Software additions aimed at streamlining the reporting process are available, but data are limited and most can only be considered as supportive tools. However, there is good evidence to support the use of endoscopy nurse 'prereaders', and this can be an effective strategy to facilitate timely reporting as demand increases.⁴¹

An effectual reporting process relies on the accurate detection and description of abnormalities and the ability to root such findings within the clinical context and translate this into appropriate management advice. The use of a capsule endoscopy structured terminology has been suggested in order to improve interobserver agreement in CE reporting.^{42 43} However, this can be time consuming and cumbersome to perform and moderate variation is still noted even among experts.⁴⁴

The roles of device-assisted and intraoperative enteroscopy

DAE is the interventional counterpart to CE allowing histological sampling of lesions previously identified on CE and targeted therapy. The yield of DAE is significantly higher following positive CE, 75% compared with 25% after negative CE in the context of obscure GI bleeding.⁴⁵ Prior CE allows localisation of lesions prior to DAE and may influence the endoscopist's choice of route (antegrade or retrograde), potentially avoiding the need for total enteroscopy if the pathological lesion is found and treated.^{46 47}

DAE also has a role in the diagnosis of suspected small bowel Crohn's disease where conventional ileocolonoscopy and radiological imaging have proved inconclusive and histological diagnosis would influence management.¹⁶ The therapeutic potential of DAE is advantageous in this context with good short-term outcomes following dilatation of short Crohn's-related strictures in small series.^{48 49}

Intraoperative enteroscopy (IOE) allows both diagnosis and definitive surgical or endoscopic therapy but at the cost of a 17% morbidity rate and up to 20% rate of non-diagnosis.^{50–52} It provides an opportunity to examine the entire small bowel endoscopically, as well as visualising extramural lesions. Previously the 'gold standard' for investigating obscure GI bleeding, its diagnostic role has diminished since the advent of CE and DAE and great care should be taken in considering IOE if repeat CE with or without DAE have failed to identify a lesion. It should be used primarily for patients in whom CE or DAE has identified the small bowel as the site of pathology and where DAE has failed to provide histology or successful therapy.⁴ Demand for IOE is likely to reduce as small bowel capsule endoscopy and DAE techniques continue to improve and experience accumulates.

QUALITY ASSURANCE

Awareness of quality within endoscopy services has peaked over the last 10 years, prompted by patient safety initiatives and the introduction of national endoscopic screening programmes. Quality within colonoscopy practice is known to be variable and thus has been subject to major efforts to standardise practice and service delivery.^{53 54} In the UK, this has been accomplished by a central regulatory body, the Joint Advisory Group (JAG), using quality assessment tools such as the Global Rating Scale to standardise service delivery and a formal certification process for independent endoscopy practice.⁵⁵ The latter is achieved through an internet-based portfolio, the 'JAG Endoscopy Training System', which enables acquisition of skills to be documented and measured against preset criteria.⁵⁶ The identification of specific quality parameters is central to this process and should encompass the multiple steps, both clinical and non-clinical, that make up the service delivered.

Quality improvement is considered a fundamental aspect of high-quality, cost-effective healthcare. Using the principles of quality improvement may allow more efficient, patient-centred small bowel services to be developed, while facilitating audit and assessment of service provision. Since CE relies on skills of observation primarily, rather than the practical skills necessary to perform conventional endoscopy, it would require a distinct approach. Simple, reproducible outcomes that can be easily measured and audited are preferable for widespread implementation. A number of potential considerations are presented in [box 3](#).

TRAINING

With the development and growth of a new CE service comes the inherent need to develop diagnostic

skill, knowledge and certification of clinicians.⁵⁷ Unlike the technical proficiency requirements of conventional endoscopy, the CE skill set predominantly comprised observation and interpretation of findings acquired from computer images. A competent capsule endoscopist should be able to effectively optimise visualisation of the small bowel, accurately identify and diagnose pathology and apply appropriate management.⁵⁸

In the UK, CE training is not a mandatory requirement of specialist gastroenterology training and many trainees have never received any formal training.⁵⁷ A small number of structured, 1-day courses providing 'hands-on' computer-based training for beginners have been available for several years. Delegates are trained how to perform the procedure, navigate the software and apply basic interpretation to CE findings. A higher-level training course is also available for established users wishing to advance their interpretations skills. Attending a practical CE course has been shown to significantly improve lesion recognition and classification skills.⁵⁹ Web-based learning methods with demonstrable knowledge gains have also been documented; however, these have not been publicly available.⁶⁰ The value of hands-on training courses has been reflected in published training recommendations by the American Society for Gastrointestinal Endoscopy, which include completion of a hands-on course, in addition to supervised video reporting following completion of a GI fellowship.⁵⁸

There are currently no universally agreed competency frameworks for the assessment of competence in CE. Development and progression of reading skill can be assessed by supervised and double reading, correlation of findings and provision of feedback to the trainee. A recent study advocates that trainees should read a minimum of 20 CE studies before undergoing any assessment of competence, regardless of endoscopy experience.⁶¹ To formally test knowledge and skill, some units have developed in-house assessment tools comprising multiple-choice questions, case-based video clips and report completion.⁶¹ In the UK, a pathway for CE training and certification for specialist trainees is currently being developed in association with JAG and the Royal College of Physicians with expected completion in 2015. A potential model pathway for training is illustrated in [figure 3](#). A core curriculum would enable all trainees to assess patients for consideration of CE imaging. Advanced training would provide a syllabus and skills learning programme to ensure the acquisition of sufficient knowledge and skill to enable a gastroenterologist to provide a CE service in a specialist capacity.

CONCLUSION

Despite a wealth of published literature about CE, there is a lack of studies regarding organisational aspects of small bowel services or indeed any widely

Box 3 Considerations for capsule endoscopy (CE) and device-assisted enteroscopy (DAE) quality indicators

- ▶ CE
 - Time from referral to CE procedure
 - Consent
 - Quality of examination: visibility and completion rate
 - Incidence of capsule retention
 - Time from small bowel capsule endoscopy procedure to report production
- ▶ DAE
 - Patient comfort scores
 - Identification of the target lesion (abnormality seen on prior CE or other imaging modality)
 - Complications: sedation or anaesthetic related, perforation, bleeding, pancreatitis

Figure 3 Flow chart representing a potential training pathway for competence in capsule endoscopy. *Applies to medical capsule endoscopy trainees. CE, capsule endoscopy; JAG, Joint Advisory Group.

recognised quality standard indicators. Guidelines do exist to assist in the investigation of the small bowel; however, little is known about accessibility to specialist services and how these services, where available, are used. Demand for small bowel investigation is

likely to continue to increase, and thus, well-designed, patient-centred services are essential. Universally recognised quality service indicators, regular audit and a cohesive training programme are the key factors in promoting uniformity of practice and high-quality service provision.

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