

## The role of capsule endoscopy in small bowel pathology: a review of 122 cases

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### Abstract

**Aim** Small bowel capsule endoscopy (CE) has been introduced in New Zealand (NZ) in all of the tertiary and some secondary centres over the last few years. We describe our experience with CE from a single centre in NZ.

**Methods** In this 2-year, retrospective, study of 122 consecutive patients, data was collected on multiple variables from the patient clinical, laboratory, and radiology records. Pillcam of Given Imaging Diagnostic System (Given Imaging Ltd, Yogneam, Israel) was used to image the small bowel. Descriptive statistics were used to analyse the data.

**Results** Good preparation was noted in 69% of the cases. The most common indication for referral was obscure GI bleeding (70%). The overall diagnostic yield for relevant findings was 52%, with angioectasia as the most common specific finding (37%). The diagnostic yield in those with overt bleeds improved with inpatient status (74%). Incomplete examinations were noted in 12% and were significantly more common in the male gender. Preliminary imaging (barium, CT/MR) was noted to have a lower diagnostic yield. Enteroscopies were considered in 25% of the patients post CE procedure.

**Conclusion** Apart from a lower diagnostic yield in patients with overt bleeds, our data is consistent with that reported in literature and support the role of CE as the minimally invasive gold standard investigation for small bowel imaging.

Capsule endoscopy (CE) was first approved as a diagnostic tool for small bowel imaging in year 2000 in the United States.<sup>1</sup> At that time the small bowel was considered a particularly difficult area to examine and the imaging modalities used included sonography, computed tomography (CT), enterography (CT/MR), enteroclysis and push enteroscopy. Apart from the potential for complications, these modalities have a low diagnostic yield.<sup>2</sup>

Subsequent studies have now established CE as the gold standard for small bowel imaging.<sup>3</sup> The procedure is painless, does not require sedation, is easy to perform and for the first time enables exploration of the entire small bowel at high magnification. Oesophageal and colonic capsule endoscopies have also been recently introduced for imaging the upper and lower gastrointestinal (GI) tracts respectively.<sup>4,5</sup>

The two main clinical areas where CE has made a significant impact are in the diagnostic workup of patients with obscure GI bleeding and those with suspected small bowel inflammation mainly due to early Crohn's disease. The former include patients with overt or occult GI bleeding with normal upper and lower endoscopies.<sup>6</sup> The latter include patients with chronic diarrhoea with a clinical and laboratory setting

suggestive of small bowel inflammation/ulceration (high inflammatory markers and high faecal calprotectin levels) rather than irritable bowel syndrome.<sup>7</sup>

The role of small bowel CE has also been explored in other clinical settings including non specific abdominal pain, unexplained weight loss, suspected celiac disease and for surveillance in patients with small bowel tumors.<sup>8-11</sup>

In New Zealand (NZ) small bowel capsule endoscopy has been introduced in all tertiary and a few of the secondary centres. To date, no data has been published from these centres apart from an abstract publication in 2009 from Waikato Hospital.<sup>12</sup> We present our 2-year experience with 122 consecutive patients from a single centre in New Zealand.

## Patients and Methods

This is a single centre, retrospective study, of 122 consecutive patients referred for small bowel capsule endoscopy to our unit from December 2009 to December 2011. All patients had previously undergone diagnostic procedures including gastroscopy, colonoscopy and CT or MRI examinations. Each patient was given a study leaflet explaining the nature of the procedure and an informed consent was signed. Routine history and physical examination was not performed on the day of the procedure.

All outpatients had a bowel preparation with 2 litres of polyethylene glycol and started on clear fluids from the afternoon before the procedure. Metoclopramide, in oral dosage of 10mg was routinely given before the study. Inpatient were not routinely given prokinetics or bowel lavage but were given at the discretion of the requesting gastroenterologist. Clear fluids were started 2 hours after the capsule ingestion and a light snack given at 4 hours. Normal dietary habits were resumed after 8 hours. The bowel preparation in the study was graded as good, fair, or poor depending upon the adequacy of the examination. Any light contamination impairing views was also recorded.

A patency capsule was administered first before the study in patients with suspected small bowel strictures. A CE placement device was used to deliver the capsule in patients with swallowing difficulties and those with gastroparesis. Contraindications to the study included patients with known intestinal strictures and those presenting with clinical and radiological evidence of small bowel obstruction.

Patients were grouped according to their main presentation. Patients with obscure GI bleeding were stratified into those with overt bleeding and those with occult bleeding, either with accompanying iron deficiency anaemia or a low ferritin/FOB positive stool test. Patients with chronic diarrhoea (including those with suspected Crohn's disease) and those with chronic non specific abdominal pain were classed separately. All other presentations including weight loss, suspected GI malignancy and suspected celiac disease were grouped together in the "Other" category.

All the studies were performed by our endoscopy nurses according to the current protocol of our unit. The Given Imaging Diagnostic System (Given Imaging Ltd, Yotneam, Israel) was used; it involves the pillcam capsule, a data recorder worn by the patient during the study, and a work-station used to process and analyse the images using the Rapid 6 Reader software.

Each study was read independently by two of the three gastroenterologists with expertise in the procedure. The CE images of the oesophagus, stomach and the colon were also read. The results were discussed and a combined report was later written. Data for the study was collected from the patient's clinical, laboratory and radiology records and the Rapid 6 Reader software.

CE findings in the study were classed as:

- Relevant – if they accounted for the patient's presentation, e.g. vascular ectasias in a patient with iron deficiency anaemia or fresh blood in the lumen in patients with overt bleeds;
- Significant – if they were not relevant to the clinical presentation but still important to be noted, e.g. ulcers, polyps or neoplasms; and
- Normal – this class included those with a normal study and also those with insignificant findings (e.g. venous lakes, prominent vessels, prominent mucosal folds, submucosal bulges, red spots etc).

Cases with relevant/significant findings in the Upper GI tract or colon but missed on prior endoscopies were also recorded. If more than one lesion was found during a study, then only the most relevant lesion was counted. In our study ‘ulcers’ and ‘aphthous ulcers’ were counted together, separate from erosions and ‘fresh blood in the lumen’ was counted as a relevant finding. The completion status of the study was classed as Complete - when the capsule reached the caecum and Incomplete when either the capsule did not leave the stomach or failed to reach the caecum. A plain abdominal X-ray was taken if the patient did not report passing out the capsule 5 days after ingestion.

A comparative analysis of CE findings was made, both with the imaging studies (barium/CT or MR Enterography) done up to a year before the CE examination for the same indication and with the faecal (calprotectin) and plasma (CRP) inflammatory markers done prior to the CE study. Procedure-related complications and post CE procedures recommended by the reporting gastroenterologist were also noted.

## Results

Table 1 shows the indications for referral according to the gender, age category and inpatient status of the examination. The status of bowel preparation in different indications is also noted.

The most common indication for referral was obscure GI bleeding (70%, N=86) which was sub-classified into overt bleeding (n=33), iron deficiency anaemia (n=39) and those with no anaemia but low ferritin (n=14).

Patients referred with predominant diarrhoea, for workup for suspected enteropathy (n=18) and patients with non-specific abdominal pain (n=10) were the other significant groups. Rare indications, including suspected celiac disease and studies in Peutz Jegher patients were grouped into the ‘other’ category.

**Table 1. Summary statistics, acuity status and bowel preparation**

Variables		Obscure GI bleed (N=86)			Predominant diarrhoea (N=18)	Abdominal pain (N=10)	Other indications (N=8)
		Overt	Occult				
			Anaemia	Low ferritin			
<b>Gender</b>	Male	25	19	6	6	5	2
	Female	8	20	8	12	5	6
<b>Age</b>	<40 years	2	4	0	3	8	2
	40–75 years	17	26	12	10	2	5
	>75 years	14	9	2	5	0	1
<b>Acuity</b>	Outpatients	14	39	14	16	7	7
	Inpatients	19	0	0	2	3	1
<b>Preparation</b>	Good	21	29	9	14	6	5
	Fair	11	9	5	4	4	2
	Poor	1	1	0	0	0	1

In our study 69% of the studies had good preparation, 29% had fair preparation while the rest had poor preparation. Light contamination, causing suboptimal views was noted in five patients (4%). No relationship was noted between the quality of preparation and the indication for the procedure.

Inpatient CE examination were carried out in 25 (20%) patients. Nineteen of them were for overt bleeds. The diagnostic yield improved with inpatient examination in only the sub-group with overt bleeds (up to 74%). In the non-GI bleed studies only

one out of the six patients with inpatient study had relevant findings. Majority of the inpatient examinations were carried out in male patients (76%). This was because presentation with overt bleeds was significantly more common in males (70%).

The overall diagnostic yield of CE studies for findings relevant to the clinical indication in our study was 52%. Relevant gastric and colonic findings, picked on CE examination but missed on prior endoscopy were 2% and 6% respectively. Table 2 shows the influence of gender, age, inpatient status and indication for referral on the diagnostic yield of the study.

Highest yield was seen in patients referred for overt bleeds (66%) and lowest yield in those referred for non-specific abdominal pain (8%). The total diagnostic yield (small bowel, stomach and colon) of relevant/significant findings was more in inpatients (75%) and the elderly (80%) but was not affected by the gender of the patient.

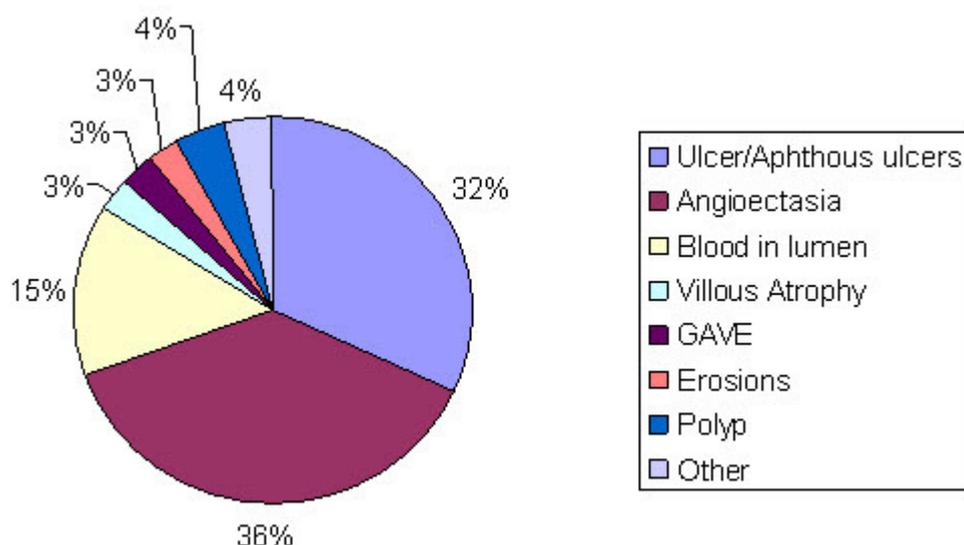
**Table 2. Diagnostic yield by gender, age, acuity and indication**

Variables		Relevant and significant findings	Normal and insignificant findings
<b>Gender</b>	Males	41	22
	Females	34	25
<b>Age category</b>	<40 years	7	12
	40–75 years	43	29
	>75 years	25	6
<b>Acuity</b>	Outpatients	56	41
	Inpatients	19	6
<b>Indication</b>	Overt bleeds	27	6
	Anaemia	27	12
	Low ferritin	7	7
	Diarrhoea	12	6
	Abdominal pain	2	8
	Others	1	7

We only calculated the frequency of specific findings in those studies where the findings were relevant/significant to the indication for the study. If more than one finding was reported, then the most relevant/significant finding was counted. Overall angioectasias (36%) and ulcers/aphthous ulcers (32%) were the most frequent specific findings (Figure 1).

For specific indications, the most frequently reported specific finding in those with overt bleed was fresh blood in the lumen (38%), and angioectasia (35%), in iron deficiency was angioectasia (52%), and in those with predominant diarrhoea was ulcer (75%).

**Figure 1. Frequency of relevant/significant findings**



GAVE= Gastric Antral Vascular Ectasias.

Barium and CT/MR studies of the small bowel were done in 19 cases (16%), mainly in those with indications other than suspected GI bleeds (Table 3). Findings were consistent with the CE findings in 12 cases (63%) and false negative in seven cases (37%). No false positive cases were reported. As shown in the Table 3 most studies were done for cases presenting with predominant diarrhoea, where both the concordance and the false negative rates were 50%.

CRP and faecal calprotectin measurements were also recorded in the subgroup of patients presenting predominantly with diarrhoea and non-specific abdominal discomfort (data not illustrated). In those with predominant diarrhoea, faecal calprotectin was raised in all but one case (when measured) compared to CRP levels which were recorded as normal in 56% (9 out of 16 measured) of the cases. However, the faecal calprotectin levels correlated correctly with CE findings in only 64% of the cases. In five cases (35%) the faecal calprotectin was falsely elevated, that is, the levels were significantly raised but the CE examination was unremarkable.

**Table 3. Preliminary imaging**

Variables		Obscure GI bleeds			Predominant diarrhoea	Abdominal pain	Other indications
		Overt	Occult				
			Anaemia	Low ferritin			
Imaging	not done	32	36	14	8	7	6
	concordant	0	3	0	5	2	2
	false negatives	1	0	0	5	1	0
	false positives	0	0	0	0	0	0

The reading gastroenterologists suggested consideration of enteroscopy in their reports (push enteroscopy, single balloon or double balloon enteroscopy) in 31 (25%) patients post CE examination. All of these patients had relevant findings on their CE examinations. Also, one patient with suspected celiac disease was referred for repeat OGD and duodenal biopsies. As shown in Figure 2, most of these patients belonged to the categories of overt bleeds (45%) and iron deficiency anaemia (39%) and none belonged to the categories of non-specific abdominal pain or the 'others' category.

**Figure 2. Patients considered for enteroscopy (n=31)**

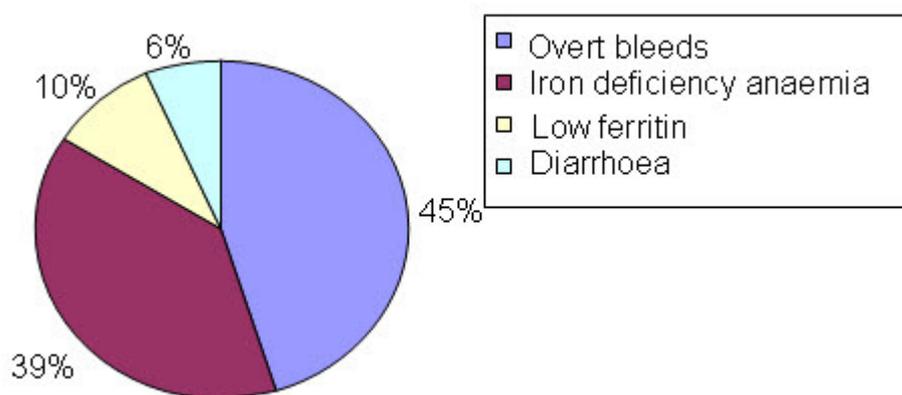


Table 4 shows the effect of different variable on the completion rate of the procedure. The overall completion rate and those with obscure GI bleeds in our study was 88%. The completion was rate was not significantly different between inpatients (84%) and outpatients (90%) and across different age categories, but was higher in females (95%) than in males (80%).

**Table 4. Factors affecting completion of the capsule endoscopy examination**

Variables		Complete	Incomplete	Total
<b>Acuity</b>	Inpatient	4	4	4
	Outpatient	86	11	97
<b>Indication</b>	Bleed – overt	28	5	33
	Iron deficiency anaemia	34	5	39
	Low ferritin	14	0	14
	Diarrhoea	16	2	18
	Abdominal pain	8	2	10
	Other indications	7	1	8
<b>Gender</b>	Males	51	12	63
	Females	56	3	59
<b>Age</b>	<40 years	17	2	19
	40–75 years	63	9	72
	>75 years	27	4	31

CE placement device was used in four cases for either a swallowing disorder or gastroparesis. Three patients, with suspected small bowel Crohn's disease with strictures had a patency capsule study prior to CE examination which was successful in all the three cases. No procedure related complications were noted in any of our cases.

## Discussion

The advent of capsule endoscopy in year 2000 dramatically changed the diagnostic evaluation of small intestinal diseases. CE is currently the minimally-invasive gold standard investigation for both obscure GI bleeding and suspected inflammatory conditions of the small bowel.<sup>13,14</sup>

Our report of an overall diagnostic yield of around 50% for relevant findings, with obscure GI bleed as the most common reason for referral (70% of the cases), and angioectasia as the most commonly reported relevant lesion (37%), is consistent with that reported in literature.<sup>15,16</sup>

Studies with sub-stratification of patients referred for overt bleeds have shown that CE studies within two weeks of an overt bleed have higher diagnostic yield than delayed studies.<sup>17</sup> Pennazio has reported a diagnostic yield of 92% in patients with ongoing bleeding compared to 29% in patients with previous overt bleeds.<sup>18</sup> Apostolopoulos has similarly found a higher yield in overt inpatient bleeds (93%).<sup>19</sup> In our study the overall diagnostic yield was 66% in patients with overt bleeds.

Inpatient CE examination were carried out in 57% of these cases. Our diagnostic yield in the subset of inpatients with overt bleeds was higher (74%) but still below the over 90% yield reported in literature.<sup>19</sup> Studies have also reported a higher overall diagnostic yield and a higher pick up of missed lesions (in the stomach and the colon) in inpatient studies.<sup>20</sup> In our study, the diagnostic yield for inpatients only improved in the subset of overt bleeds.

The 2005 consensus on obscure GI bleeding recommends careful examination of both the upper and lower GI tracts in reading small bowel CE examinations in patients with obscure GI bleeds.<sup>29</sup> This is based on the observation that small bowel CE examinations have picked up a reasonable number of missed lesions within the reach of upper and lower endoscopies.<sup>30</sup>

We report a miss rate of 2% and 6% for gastric and colonic lesions respectively. We have excluded from this category proximal small bowel lesions within the reach of upper GI endoscopy. In our study, not all patients had the localisation device during the study and it was, therefore, not always clear whether any proximal small bowel lesion noted during the CE study was within the reach of the prior endoscopic examination.

Age and gender has been reported in literature to influence the transit time, diagnostic yield and the pick up rates of missed lesions (gastric and colonic) outside the small bowel.<sup>31,32</sup> In our study, the highest percentage of presentations with overt bleeds were in those over 75 years of age (45%).

Males presented more often with overt bleeds (45% versus 14% in females) and had a significantly higher number of incomplete examinations (19%) compared to females

(5%). In our study the pick up rate of relevant findings was higher with increasing age category and the inpatient status but was not affected by gender.

There has been controversy about the use of formal preparation of small bowel for the CE examination. A recent meta-analysis has favoured formal preparation over just fasting the patient overnight.<sup>33</sup> All of our outpatients and majority of inpatients had 2 litres of polyethylene glycol on the day before the procedure. We classed the bowel preparation as good, fair and poor. Our study noted poor preparation in only three cases. Newer and more detailed scoring systems for the quality of examinations are now available in literature.<sup>34</sup>

About 15% to 30% of the CE examinations are *incomplete*.<sup>16,21</sup> It is important to identify the risk factors for incomplete examinations. Factors known to be associated with incomplete procedures include a prior history of bowel obstruction, previous bowel surgery, male gender, old age, opiate medications and inpatient status.<sup>21,22</sup>

In our series, incomplete examinations constituted 12% of the studies. Male gender was the only variable that influenced the completion rate of the examination. Age, inpatient status, and the indication for referral did not affect the completion rates in our study. Data on the comorbid status and medications, factors that could also potentially affect the transit time of a CE study, were not collected in our study.

Preliminary non-CE small bowel imaging studies have a lower diagnostic yield in the evaluation of small bowel pathologies.<sup>23,24</sup> Our results on such studies with an overall concordance of 63% with the CE examinations is consistent with the literature. A pooled meta-analysis of prospective comparative studies in 2010 has demonstrated superior diagnostic yield of CE compared to push enteroscopy, colonoscopy with retrograde ileoscopy, small bowel follow through examinations and CT/MR enterography in patients with suspected or established Crohn's disease.<sup>14</sup> In our 10 patients with suspected enteropathy and preliminary small bowel imaging, five patients had concordant findings on the subsequent CE study and five had normal (false negative) findings.

Faecal calprotectin is a non-invasive surrogate marker for intestinal inflammation and has been used in differentiating organic from functional bowel disorders.<sup>25,26</sup> It is considered a better marker of intestinal inflammation than CRP measurement and is raised in almost all types of intestinal inflammation, including the enteropathy associated with NSAID use.<sup>27,28</sup> In our patients, faecal calprotectin levels were raised in all but one cases, with a true positive rate of 64% and false positive rate of 36%. We noted poor concordance between plasma CRP levels and faecal calprotectin levels.

Our study was not designed to report on patient outcome as complete follow-up after the study was not available on all the patients. We did record the consideration for further enteroscopic intervention in 25% of the patients as suggested by the reporting gastroenterologists after the CE examinations. Predictably, those with overt bleeds constituted the highest group (45%), followed by those with occult bleeds presenting as iron deficiency anaemia (39%). However, it does not mean that the other CE examinations were not effective in influencing the outcome. Some bleeds with relevant findings were left for conservative management based on their comorbidities after discussion with the patients.

In literature, about 40% of the patients will have a change in management based on the CE findings.<sup>35</sup> In our view, also important is the ability of a negative CE examination to reassure the patients by ruling out serious pathologies like small bowel tumours and, therefore, eliminating the need for further testing.

Limitations of our study included the retrospective nature of the study, lack of data on the comorbid conditions of patients, the timing of the examination or the most recent bleeding episode of the patient and the lack of routine grading system for the quality of preparation. Data on medications that may have precipitated a GI bleed (anti-platelets, anticoagulants) or may have influenced the transit time of the procedure (opiates) were also not collected.

**Competing interests:** Nil.

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