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ORIGINAL ARTICLE

# Is Focused Training Adequate or is Prior Endoscopy Experience Needed for Reliable Capsule Endoscopy Reporting?

Alaa Alakkari, Omar El-Sherif, Mark Dobson, Orla Thornton, Deirdre Mc Namara

Alaa Alakkari, Omar El-Sherif, Mark Dobson, Orla Thornton, Deirdre Mc Namara, Department of Gastroenterology, Adelaide and Meath Hospital, Tallaght, Dublin 24, Ireland

Correspondence to: Alaa Alakkari, Department of Gastroenterology, Adelaide and Meath Hospital, Tallaght, Dublin 24, Ireland. alakkar@yahoo.com

Telephone: +353-1-8963844 Fax:+353-1-8962988

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## ABSTRACT

**AIM:** The aim of this study is to compare the accuracy of VCE reports by trained gastrointestinal physiologists (TP) to a consultant gastroenterologist (CG) in a tertiary referral centre.

**METHODS:** VCEs performed between November 2010 and March 2011 were prospectively reported by both CG and TP. Both were blinded to each other's results. Results were compared in terms of clinical findings, small bowel transit, and quality of preparation noted. Correlation was calculated using Cohen's κ coefficient. CG findings were considered gold standard.

**RESULTS:** Sixty dual reports were identified, 32 (52%) female, age 16 to 81 years; median 53 years. Indications were; 29 anaemia, 19 suspected or known Crohn's disease (CD), 5 overt GI bleeding, and 7 other. Complete SB transit occurred in 85% ($n$=51), TP reported as 70% ($n$=42), κ 0.58. Overall positivity was 38% ($n$=23), TP reported as 55% ($n$=33), κ 0.54. Preparation quality correlation occurred in 88% ($n$=53). Improved correlation was noted over time; caecal transit and positivity rates for the first 30 *vs* second 30 studies were 0.42, 0.39 and 0.79, 0.66 respectively. Indication did not affect correlation.

**CONCLUSION:** This study suggests that reliable VCE reporting improves with experience and reliable TP reporting is appropriate only after sufficient training. Approved Multidisciplinary CE training programs in line with recognised/established endoscopy protocols should be developed.



**Key words:** Video capsule endoscopy; Small bowel examination; Reporting; Training; Gastrointestinal physiologist; Consultant gastroenterologist

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## INTRODUCTION

Video capsule endoscopy (VCE) is a novel technology that allows direct non-invasive visualisation of the entire small bowel (SB) mucosa. Traditional methods for SB examination have several limitations. Small bowel follow through has low sensitivity, and small bowel endoscopy can be quite painful and poorly tolerated as well as its associated risk of pancreatitis and perforation[1,2]. Several studies have demonstrated the superiority of VCE over these examinations in addition to multi-slice computed tomography enteroclysis, magnetic resonance enteroclysis, and scintigraphy[3-5].

The use of VCE has grown exponentially since it was first developed in 2001. It consists of an ingestible capsule able to take video images of the intestinal tract over about 8 hours and transmits them to a data recorder attached to the outside of the body. On average 50000 images are acquired during the recording in a single patient. The average time required to accurately view these images by a physician ranges from 45 to 120 min, depending on the experience of the examiner[3,6]. It is not uncommon that significant findings may only be present in a small number of the images, and accurate identification and interpretation often requires considerable expertise.

As with all diagnostic procedures the efficacy of VCE is dependent on the accurate analysis of recordings, which can be time consuming, and requires expertise. With the rapid expansion of VCE in clinical use there is a need to address quality assurance and training. As a non-invasive procedure it can easily be performed by Allied Health Professionals, their role in analysis remains less clear. At present there are no guidelines for VCE training, and it is unclear whether a gastroenterology specialist should review all VCEs, or if they can be adequately pre-assessed or read independently by other trained medical professionals? A number of studies have compared lesion detection rates between nurses and endoscopists[7-9]. Bossa *et al* prospectively compared detection of abnormal lesions recorded by 41 capsule endoscopy examinations between an endoscopist and an endoscopy nurse and found excellent agreement for all kinds of

selected lesions (κ >0.85). They concluded that the cost effectiveness of VCE may be increased by having a nurse preview recordings to reduce the time needed for the endoscopist to make the final report without compromising final diagnosis[7].

The exact definition of adequate training is not clear. In 2005 the American Society of Gastrointestinal Endoscopy (ASGE) recommended that training in capsule endoscopy performed outside of a GI fellowship should include the completion of a hands on course with a minimum of 8 hours of continuing medical education, followed by review of the first 10 complete cases by accredited capsule endoscopists[10].

To date there are no studies comparing the accuracy of VCE reporting by trained gastrointestinal physiologist to a consultant gastroenterologist.

The aim of this study is to compare the accuracy of VCE reports read by trained gastrointestinal physiologists (TP) to those read by a consultant gastroenterologist (CG) in a tertiary referral centre.

## METHODS

All VCEs performed in a Dublin University Hospital between November 2010 and March 2011 were prospectively analysed and reported by both a consultant gastroenterologist, who has over 8 years experience and analyses in the order of 250 studies per annum and trained gastrointestinal physiologists. Our team of physiologists are experienced in other GI procedures including 24 pH and oesophageal manometry and breath testing. Prior to commencing analysis they completed an approved basic VCE training course, were both familiar with performing the procedure and with the analysis software. In addition they were encouraged to review the available image library and had reviewed at least 20 CG reports with a gastroenterology consultant prior to beginning the blinded prospective study. Neither had significant endoscopy experience.

All procedures were performed as per unit protocol. In brief patients are educated prior to undergoing small bowel examination using VCE. No laxatives are given prior to the procedure. All patients at risk of obstruction or without normal small bowel radiology within 12 months of the proposed VCE undergo a screening patency capsule. Patients are advised to eat a normal breakfast and lunch, and then cleat liquids only from 2 pm, followed by an overnight fast from 8 pm. The capsule is ingested the following morning under the supervision of the physiologist in the department. An 8 hour continuous recording is obtained using Pillcam SB2 (Given Imaging, Yonkeam, Isreal). The recording is analysed with Given Rapid Reader (Given Imaging, Yonkeam, Isreal) using the software RAPID 7. The recording is reviewed within 24 h and if the capsule had not reached the caecum it would be considered retained. In this case the patient is contacted and assessed for symptoms of obstruction or whether the capsule was known to have passed. The referring doctor is also contacted and a Plain Film of the Abdomen is advised to visualise the position of the capsule. Further management is planned depending on the outcome of the X-Ray when indicated.

Both groups of analysts were blinded to each other's results. An independent investigator reviewed the demographic data, indications of the VCE studies, and the documented reports of the examinations. The reports were then compared in terms of clinical findings, small bowel transit, and quality of preparation noted.

### Statistical analysis

The analysis of correlation of findings between the TT and CG was carried out using Cohen's κ coefficient. This was calculated for each variable with SPSS software. Kappa coefficient is used to verify that correlation exceeds chance level according to Fleiss' scale. It is scored as marginal (κ=0-0.4), good (κ>0.4-0.75), and excellent (κ>0.75). The findings of the consultant gastroenterologist were considered gold standard.

## RESULTS

A total of 60 patients underwent small bowel examination using wireless capsule endoscopy in the Adelaide and Meath Hospital in Dublin over a 5 month period. Thirty-two patients (52%) were female and 28 (48%) were male. Their age ranged from 16 to 81 years with a median age of 53 years. The indications for VCE were quite variable however the most common were anaemia (*n*=29) and suspected small bowel Crohn's disease (*n*=19). Five patients were being investigated for overt gastrointestinal bleeding, 2 for occult gastrointestinal bleeding, 3 for diarrhoea and 1 for abdominal pain. None of the patients were given medications to clear their bowel prior to the VCE.

The capsule reached the caecum allowing complete examination of the small bowel in 85% of patients (*n*=51). However, the trained gastrointestinal physiologists reported complete small bowel transit in only 70% of patients (*n*=42) with a correlation coefficient κ of 0.58. One capsule was retained during the study. The patient required surgical interventions that lead to the final diagnosis of small bowel Crohn's disease.

The GC detected an abnormality in 23 VCEs giving an overall positivity of 38%, but the TP reported findings in 33 VCEs with a positivity of 55%, correlation coefficient κ was 0.54. There was correlation between the reports of GC and TP in all the cases where there were significant positive findings detected. The positive findings reported by CG and TP in the former and latter 30 cases were 13 *vs* 20 and 10 *vs* 13, respectively. These small bowel findings were blood and /or vascular lesions, erosions, ulcers and inflammation suggestive of Crohn's disease, and small bowel polyp. TP over reported positive findings of mucosal oedema and small bowel nodules; 4 and 9, respectively which on review by CG were classified as distal ileal nodular hyperplasia and type 3 lymphangiectasias. The positive findings over reported by TP were deemed normal by CG. However no significant abnormality was missed.

The quality of video imaging was dependent on small bowel content, which was graded as satisfactory or poor. The image quality was graded as poor in 13 (22%) procedures. There was correlation regarding the reported preparation quality between the two groups of analysts in 88% of patients (*n*=53) (Table 1). Results reported by TP and GC for each variable.

During the study analysis the reports were divided into two groups; group A represents the first 30 VCEs and group B the latter 30 VCEs performed over the 5 month period. Comparison of the results between these two groups revealed improved correlation over time. The correlation coefficient κ for caecal transit for the first 30 VCEs was 0.42 compared to 0.79 for the latter 30 studies. The correlation coefficient κ for positive VCE findings was 0.39 for the first 30 studies compared to 0.66 for the latter 30 VCEs (Figure 1). [Improvement in correlation over time (Group A: first 30 VCEs v Group B: second 30 VCEs)]. The indication for the study did not affect the correlation between the two sets of reports.

Five patients went on to have Double Balloon Enteroscopy

**Table 1** Results reported by TP and GC for each variable.

| Variable | Number reported by TP | Number reported by GC |
|---|---|---|
| Caecal Transit | 42 (70%) | 51 (85%) |
| Positive VCE findings | 33 (55%) | 23 (38%) |
| Poor preparation | 9 (15%) | 13 (22%) |

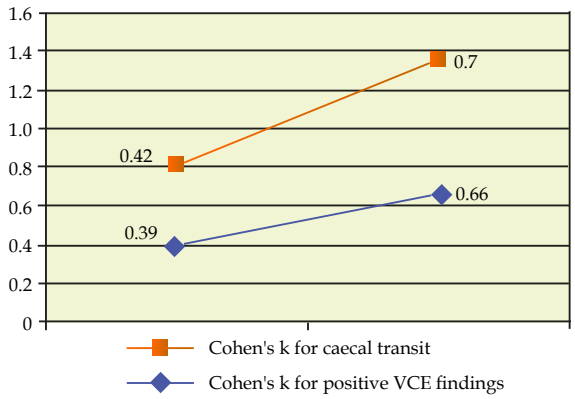


**Figure 1** Improvement in correlation over time for positive VCE findings and caecal transit.

(DBE) for further small bowel assessment and/ or therapeutic intervention. Two patients had suspected small bowel Crohn's disease; one had non-specific erosions on VCE but had a normal DBE and small bowel biopsy. The other patient had inflammation and ulcers on VCE, however DBE only showed denuded mucosa with normal small bowel biopsies. Two patients were referred for overt gastrointestinal bleeding; one had ileal ulcers on VCE confirmed on DBE, with biopsies showing non-specific focal paneth cell metaplasia. The other patient had erosions on VCE but on DBE in addition to the erosions there was an ileal diverticulum with erosions within it suspicious for Meckel's diverticulum. One patient was referred for investigation of anaemia, but on VCE had active bleeding from a focal site in the small bowel, and DBE revealed a vascular lesion which was treated with Argon Photocoagulation and marked with ink.

## DISCUSSION

VCE reporting requires appropriate expertise for the accurate diagnosis of small bowel abnormalities and is time consuming. A number of studies have looked into methods of making the reporting of VCEs more cost effective without compromising the accuracy of the study. Riphaus *et al*[8,9] showed 94% detection rate of significant lesions by the endoscopy nurse compared to the physician, and no clinically relevant findings were over looked. Therefore, they suggested the pre-evaluation of small bowel capsule recordings by trained endoscopy nurses. Iakovidis *et al*[11] proposed a novel approach to wireless capsule endoscopy reading time reduction by unsupervised mining of video frames. Comprehensive experimentation on real WCE videos revealed 85% reduction in the reading times without any loss of abnormalities.

In our prospective study we compared VCE reporting by TP to an expert GC to explore the feasibility of VCE reporting or pre-evaluation by TP as a method of cost effective reporting without affecting the accuracy of the study. There was good correlation (κ >0.4-0.75) between the two sets of analysts in terms of complete small bowel transit, and overall abnormality detection rates.

Complete small bowel transit was reported by TP in 42 of 51 cases in whom the capsule reached the caecum according to CG due to their inexperience with the appearance of caecal mucosa in the presence of liquid faeces. However, correlation did improve over time due to improved experience and training with increasing number of capsules reported.

No significant abnormalities were missed by TP throughout the study. In fact, the cases where there was no correlation in findings between TP and CG were due to TP over reporting insignificant findings deemed normal by GC, supporting the role of TP in the pre-reading of VCE recordings prior to the authorisation of final reports by GC. As a result of increasing experience over time, there was less over reporting of insignificant findings by TP.

The VCE recordings were performed without the use of laxatives for bowel preparation with 47 (78%) of recordings reported as having good image quality by both analysts.

For all parameters correlation improved over time, which highlights the importance of appropriate training in VCE for accurate reporting.

Although there are clear guidelines on clinical use, as yet there is no internationally accepted approach to VCE training in this setting, unlike training for common invasive endoscopy procedures[12]. In the UK the Joint Advisory Group (JAG) advise a minimum number of endoscopic procedures and set criteria for the trainees to undertake before they can be accredited as competent in each modality[13]. They also recommend basic skills courses as part of the training process. The TPs in our study had completed an approved basic course and reviewed at least 20 VCE images and reports prior to taking part in the study. Despite their basic training the results showed improved correlation and diagnostic accuracy over time. This highlights the need to perform a certain number of VCEs to become proficient in reporting them. Our study suggests reviewing a number in excess of what the ASGE recommended in 2005 is required[10]. There was a significant improvement in correlation after 30 VCE studies. The trainees should then undergo standardised assessment by at least two examiners such as using direct observation of procedure or skills (DOPS) assessment to insure competence and quality assurance, as advised by JAG.

A major drawback of this study and similar ones is the lack of a true gold standard with GC results being considered correct. However, when we consider the proposed role of non medical professional VCE analysts is to assist the physician in reporting VCE studies, the endpoint is valid and represents the clinical reality.

Our paper is the first to clearly demonstrate that prior endoscopy training although advantageous is not a prerequisite for adequate and safe VCE reporting opening up the potential role for Physician Assistants, Technicians and other Allied Health Care Professionals. All of whom could assist in providing a timely safe and high quality VCE service to meet the growing clinical requirement and demand.

This study suggests that reliable VCE reporting improves with increasing experience and reliable TT reporting is appropriate only after sufficient training, which improves over time. The low correlation between GC and TP reporting was due to false positives rather than false negatives and this suggests that TP pre-assessment rather than reporting maybe more appropriate initially. Approved VCE training programs should be developed for both training gastroenterologists and allied health care professionals.

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**Peer reviewers:** Hideki Iijima, MD, PhD, Assistant professor, Deparment of Gastroenterology and Hepatology, Osaka University Graduate School of Medicine, 2-2 Yamadaoka, Suita, Osaka 565-0871 Japan;Lorete Maria Da Silva Kotze, Rua Bruno Filgueira, 369, Cj 1205, Curitiba, Paraná, Brazil.