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Research Article

Upper Gastrointestinal Tract Video Capsule as an Alternative to Oesophago-Gastro-Duodenoscopy in Clinical Practice

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Introduction. Upper gastrointestinal (UGI) video capsule endoscopy (VCE) provides a possible alternative to conventional oesophago-gastro-duodenoscopy (OGD). In Ireland, the COVID-19 pandemic led to unprecedented change in endoscopy services, accelerating the need for UGI VCE to help reduce patient exposure but allow the continuation of endoscopy services. We report on using UGI VCE as an alternative to OGD throughout all phases of COVID-related endoscopy adjustments. *Aims/Background*. Prospective observational study to assess identification of relevant UGI anatomical landmarks on UGI VCE as defined in the British Society of Gastroenterology. *Method*. Inclusion criteria were: patients with dyspepsia under 40 years of age with no alarm symptoms; known cirrhosis for variceal screening; UGI bleeds with the Blatchford score ≤ 2. A protocol for preparation and a series of positional movements were adapted for the procedure. Landmarks and pathology detection were evaluated by two independent endoscopists. *Results*. 127 UGI VCE was performed from June 2020 to December 2021, of which 22 required further evaluation with OGD. The most common indications were dyspepsia and abdominal pain, 71% and 19%, respectively. With the use of the dual-facing camera, clear views of the OGJ in 100% of cases, cardia 100%, fundus 97%, greater curve 99%, lesser curve 98%, incisura angularis 95%, antrum 95%, pylorus 94%, D1/bulb 83%, and D2 82% were obtained. The main findings at UGI VCE were reflux oesophagitis and gastritis, with normal mucosa observed in 48% of cases. Findings suggesting a neoplastic lesion at the OG junction were detected in 1 case. *Conclusion*. Since June 2020, 81% ($N = 103$) of a selected cohort of patients referred for UGI endoscopy avoided invasive traditional endoscopy and were successfully managed by VCE, thus reducing endoscopy waiting lists. UGI VCE may serve as a clinical diagnostic tool, used alongside OGD in appropriate cases, to help improve patient services and care delivery.

1. Introduction

Small-bowel (SB) video capsule endoscopy (VCE) was first developed in the year 2000 [1]. Advances in VCE, such as increased image acquisition rate, cameras at both ends of the capsule, improved field of view, and battery life [2] have allowed broader utilisation of this noninvasive endoscopic investigation to visualise the entire gastrointestinal (GI) tract.

The PillCam®ESO (Medtronic Ltd. Ireland), for example, allows endoscopic imaging of the oesophagus, stomach, and cranial SB similar to standard oesophago-gastro-duodenoscopy (OGD). This capsule has a forward and rear-view camera, delivering 35 frames per second videos with a battery life of 90 min. Several studies have investigated the use of Upper GI (UGI) capsule in detecting Barrett's oesophagus, oesophageal varices and in inpatients intolerant to conventional endoscopy, reporting high sensitivity and specificity in detecting pathology and key landmarks in the oesophagus and stomach [2–5]. For oesophageal varices, the diagnostic accuracy of UGI VCE is up to 90% (95% CI, 0.88-0.93), with a diagnostic pooled sensitivity and specificity of 83% and 85%, respectively [4], while for Barrett's diagnosis, the pooled sensitivity and specificity are 77 and 86%, respectively [5]. Two recent studies on the use of UGI VCE reported excellent views of key quality indicators of the upper GI tract. Adequate views for diagnostic assessment

of the upper GI tract were reported for the oesophagus, gastro-oesophageal junction (GOJ), cardia, fundus, gastric body, antrum, and pylorus with duodenal views between 64% and 73% [2, 6]. Adequacy of views and the diagnostic yield depends on the generation of capsule used, capsule image protocol, and reader experience [7, 8].

Similar to SB capsule endoscopy, now an established diagnostic tool for investigating occult GI bleed, anaemia and evaluating Crohn's disease [9, 10], UGI VCE provides a less invasive method of endoscopic evaluation with reduced patient contact and exposure, offering a significant advantage and opportunity in the era of Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The Coronavirus disease 2019 (COVID-19) pandemic has led to an unprecedented change in our endoscopy practice. Early in the pandemic, many routine and surveillance endoscopies were deferred, with only urgent scopes performed [11]. Although the Health Protection Surveillance Centre of Ireland does not consider OGD an aerosol-generating procedure [12], there is a viral exposure risk through small droplet particles produced by coughing, retching, and oropharyngeal suctioning during the procedure. The deferral of procedures has led to a further lengthening of patient waiting lists with the potential for delayed diagnosis of significant pathology, expediting the need for safe and effective alternatives to conventional endoscopy [13].

In our unit, a tertiary referral centre for capsule endoscopy, we developed an UGI VCE service for select patients as an alternative to OGD. We report a prospective, first Irish experience on the use of UGI VCE as a diagnostic tool in the evaluation of UGI symptoms.

2. Method

A prospective evaluation of relevant anatomical landmarks on UGI VCE as defined by the British Society of Gastroenterology (BSG) quality standards for UGI endoscopy was performed [14]. These landmarks include the oesophagus, oesophagogastric junction, gastric body, cardia, fundus, incisura angularis, lesser and greater curve, antrum, and duodenum, i.e., the duodenal bulb and second part of the duodenum (D2). In addition, our study evaluated the pathological yield of the capsule studies and the number of participants who required further evaluation or biopsy with conventional OGD.

Inclusion criteria were: patients who had not previously undergone an OGD; patients with dyspepsia < 55 years of age without alarm symptoms such as dysphagia, iron deficiency anaemia, persistent vomiting, family history of cancer or documented weight loss, and abdominal mass; patients with known cirrhosis for varices screening without any evidence of concurrent upper GI bleed; patients who presented with upper GI bleeds with the Blatchford score ≤ 2. Exclusion criteria were: patients > 70 years of age; patients with reduced mobility which would restrict them from performing the manoeuvres needed for the procedure; patients with cardiac pacemakers or other implanted electromedical devices, patients referred with dysphagia and patients with known intestinal strictures, stenosis, or chronic NSAID use.

Two experienced capsule endoscopists reviewed all images, and analysis was performed using SPSS V 26 (IBM). Continuous data are reported using median and interquartile range (IQR). Categorical data are reported as total number and/or percentage.

Ethical approval for this study was granted by the Cork University affiliated teaching hospital's clinical ethics review board, reference number ECM 4 (c) 07/07/2020 COVID and ECM 3 (a) 11/08/2020.

2.1. Delivery Protocol. Following informed consent and patient education, the data recorder (DR3) and pouch are attached to the patient with room to reposition the recorder during position changes. Before capsule ingestion, the patient drinks one litre of water with Simethicone (257.5 mg) as briskly as possible to expand the stomach. The capsule (PillCamESO3, Medtronic. Ireland), following inspection of capsule integrity and pairing with the recording device, is then swallowed in the right lateral decubitus position with some sips of water. This helps slow capsule transit through the oesophagus, thereby optimising views obtained. Once it is clear from the real-time viewer that the capsule has passed into the stomach, the head of the bed is tilted down at a 30-degree angle.

The patient is asked to lie on the flat of their back for 30 sec, lie in the left lateral position for 30 sec, and lie face down (prone) for 30 sec. The bed is then placed back horizontal, and the patient is asked to lie flat on their back for 30 sec, lie in the left lateral position for 30 sec, and lie prone for another 30 sec. The head of the bed is then tilted up at a 30-degree angle, and the patient is asked to lie flat on their back for 30 sec, lie in the left lateral position for 30 sec, and lie prone for 30 sec. Finally, the bed is adjusted to the horizontal position, and the patient is asked to lie on the right for 2 min. Next, the patient is asked to walk for 20 min to help promote capsule transit, at which time the real-time viewer is used to identify the capsule location. If the capsule remains in the stomach, intramuscular injection of Metoclopramide may be used to help stimulate gastric emptying. This helps ensure a complete test and allows visualisation of the SB's in the cranial portion. Once SB mucosa is observed or the battery expires, the test is completed.

The capsule generally passes in the stool 24-36 h postingestion. Each patient is given a written reminder to inform about any future MRI scan as they may require a plain film of the abdomen (PFA) to ensure the capsule is not retained. The patient is further advised to return to their regular diet and activities. However, they should present for medical review should they experience unexplained vomiting or abdominal pain after the procedure.

3. Results

127 UGI VCE studies have been performed in our unit from June 2020 to December 2021. Two patients were unable to swallow the capsule and were excluded from the final analysis (Figure 1). A total of 125 studies were completed as per the protocol outlined earlier. The median age was 32 years, IQR (16-68), with 58% of cases female ($N = 74$). Intramuscular

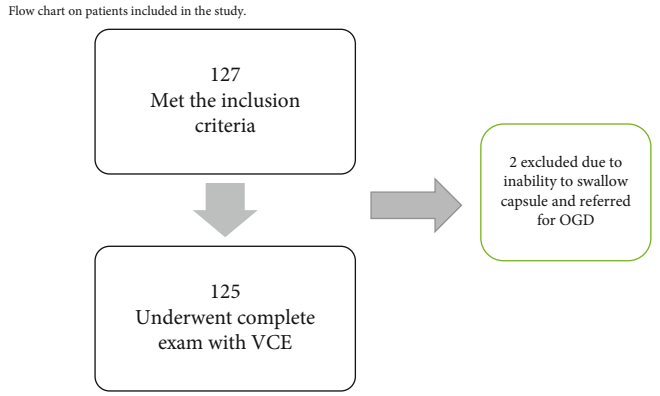

Figure 1: Flow chart on patients included in the study.

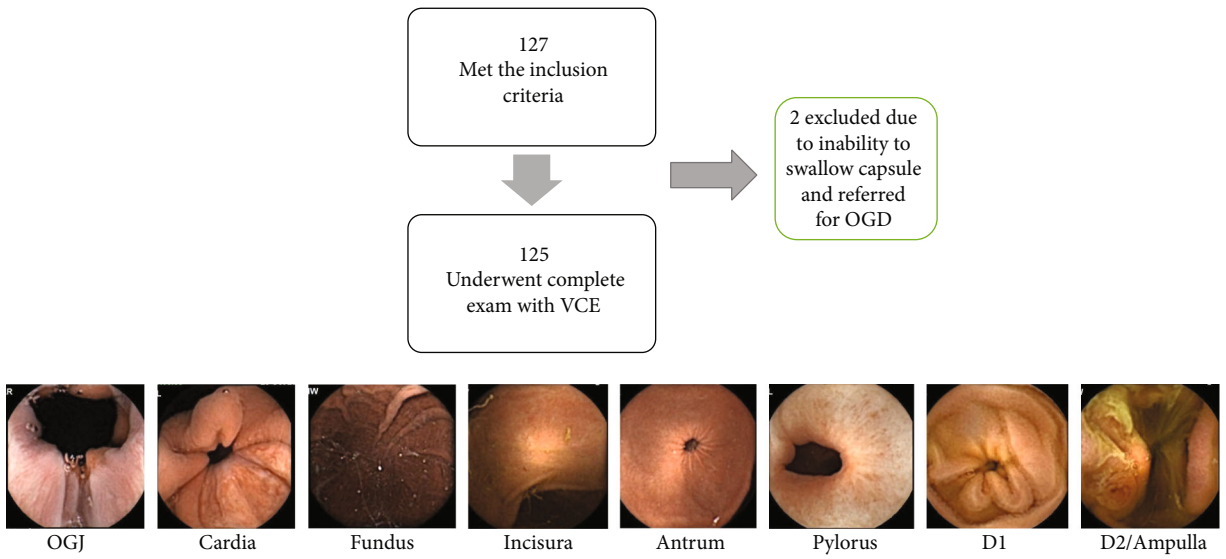

Figure 2: Demonstration of key upper GI mucosal landmarks identified using VCE.

Metoclopramide 10 mg was administered in 46% of cases to assist transit of the capsule into the SB to complete the study. There have been no reported complications.

The most frequent indications for upper GI evaluation were dyspepsia and abdominal pain at 71% and 19%, respectively. Additional indications were nausea and vomiting (7%), haematemesis (2%), and chronic cough (1%).

Clear visualisation of the oesophagus, oesophago-gastro junction, and the gastric body was achieved in 100% of cases. In all cases, the entire oesophagus, OGJ, and gastric body were completely visualised on reading the capsule images with either the front or rear-facing camera. A clear view of the cardia in 100%, fundus 97%, greater curve 99%, lesser curve 98%, incisura angularis95%, antrum 95%, pylorus 94%, duodenal bulb 83%, and D2 82% was obtained (Figure 2). Therefore, 82% of cases had a clear, complete examination with adequate views of the entire UGI tract. Patient characteristics, views of key UGI landmarks, and the outcome of the exam are reported in Tables 1 and 2. The mean capsule gastric transit time was 54 minutes.

Reflux oesophagitis and gastritis were the most common pathology detected, at 11% and 17%, respectively (Figure 3). A normal exam was reported in 48% of cases. Findings suggestive of cancer of the OG junction were observed in one patient who was referred for OGD and was diagnosed with adenocarcinoma later through biopsies. 48% ($N = 61$) were discharged after completion of the exam, 6% ($N = 8$) required a proton pump inhibitor, and 24% ($N = 30$) were scheduled to undergo the C-urea breath test. 17% ($N = 22$) of cases required subsequent OGD for further assessment and histological review (Table 2).

4. Discussion

We report the first prospective Irish experience of UGI VCE as an alternative to OGD achieving excellent mucosal views, and no adverse outcomes were reported. To date, this is the largest study examining the use of VCE in visualising the upper GI tract. Our data compares favourably with previous studies on UGI VCE, reporting excellent views of the UGI

Table 1: Patient's characteristics and key landmarks visualised % ($N = 125$).

Age, mean + SD (median)	32 ± 10.6 (32)
Gender	
Male	42% (54)
Female	58% (74)
Mucosal visualisation of key landmarks	%
Oesophagus	100
OGJ	100
Gastric	100
Cardia	100
Fundus	98
Greater curve	99
Lesser curve	98
Incisura Angularis	95
Antrum	95
Pylorus	94
Duodenal bulb	83
Second part of duodenum	82

Table 2: Outcomes following UGI capsule% ($N = 125$).

Discharged back to referral source	48% (60)
UBT to exclude *H. pylori*	24% (30)
OGD for follow up/histological assessment	17% (22)
Indications for OGD % (N = 22)	
Oesophagitis follow up	22% (5)
Gastric ulcer follow up	22% (5)
Altered blood visualised	13% (3)
Persistent symptoms	9% (2)
Antral submucosal lesion	4% (1)
OGJ lesion	4% (1)
Barrett's oesophagus for histology	5% (1)
Eosinophilic oesophagitis characteristics	9% (2)
Severe gastritis	5% (3)
Oesophageal candidiasis	4% (1)
Outpatient clinic referral for symptoms review	7% (9)
Medication prescribed	6% (8)
Barium swallow	1% (1)
Repeat UGI VCE due to assess healing	1% (1)

Urea breath test (UBT): proton pump inhibitor (PPI): oesophago-gastro-duodenoscopy (OGD).

tract and procedural tolerance [2]. Our data add to the growing literature on the safety and efficacy of UGI VCE, particularly demonstrating an essential role of UGI VCE as a clinical adjunct in diagnosing patients with UGI symptoms.

127 OGD referrals were appropriately selected prospectively from the onset of the study by a consultant gastroenterologist when a referral was received at our department. Participants who met the study's inclusion and exclusion criteria were directly referred to undergo a UGI VCE and were effectively removed from the endoscopy waiting list. Although 22 patients subsequently required an OGD, an effective reduction in UGI evaluation waiting times was achieved for these patients. The wait times for these cases to have an OGD were not negatively impacted by having prior UGI VCE examination. Instead, it hastened it because these cases were referred for further evaluation or histological assessment rather than for poor visualisation. In addition, the subsequent OGD referrals were triaged more precisely as the pathology or follow-up question was clear. The current wait time for a routine OGD at our department is three months. With an external outsourcing initiative to help reduce the waiting times for an OGD and reduce the numbers on the waiting list, the time to have a UGI VCE is much shorter at two weeks after the referral is received and reviewed by the resident gastroenterologist.

To date, 14 of the 22 OGD referrals have been performed and show a 100% correlation between the findings at UGI VCE and OGD, with no missed pathology detected. 5 of the 22 cases referred for subsequent OGD either cancelled their appointment or did not attend, and three are currently waiting with dates for the exam already scheduled. Although this number is too small to draw definitive conclusions, it is a somewhat reassuring comparison of UGI VCE and OGD. Furthermore, our selection criteria have allowed 48% of cases to be discharged following a normal UGI VCE exam. A further 32% required additional outpatient noninvasive testing with either the C-urea breath test, barium swallow, or outpatient clinic assessment which did not impact endoscopy or inpatient services. The C-urea breath test was arranged in cases when gastritis, gastric erosions, or oesophagitis was found on UGI VCE or if subjects had symptoms suggestive of *Helicobacter pylori* infection despite having a normal UGI VCE. Of the 24% ($N = 30$) cases referred for CUBT, 22 were completed, with available data demonstrating five positive and 17 negative results. Following completion of these adjunctive tests after UGI VCE and appropriate treatment, satisfactory resolution of the referral indication was achieved.

All capsules were swallowed using water with simethicone for gastric distension. A series of positional changes were implemented according to a protocol adapted from the simple positional interchange technique described by Ching et al. [2]. Our protocol was easy to follow, and the use of intramuscular Metoclopramide resulted in a D2 intubation rate of 82%. All capsules that reached the duodenum achieved excellent views of the bulb with the reverse-facing camera at that time point. The dual-facing UGI capsule offers a notable advantage over the conventional capsule typically used in small bowel capsule endoscopy. Gralnek et al. previously reported a 98% visualisation of D2 accomplished with a 90 min capsule battery life and preprocedural intravenous erythromycin [15]. The sample size in this study is, however, small at $N = 46$. In our study, IM Metoclopramide was used in 46% of cases if the capsule had not passed into the duodenum during the protocol window. Longer battery life may help achieve higher D2 intubation rates and perhaps earlier administration of Metoclopramide [16].

This study has limitations as an observational study aiming to assess if the UGI VCE could visualise all relevant

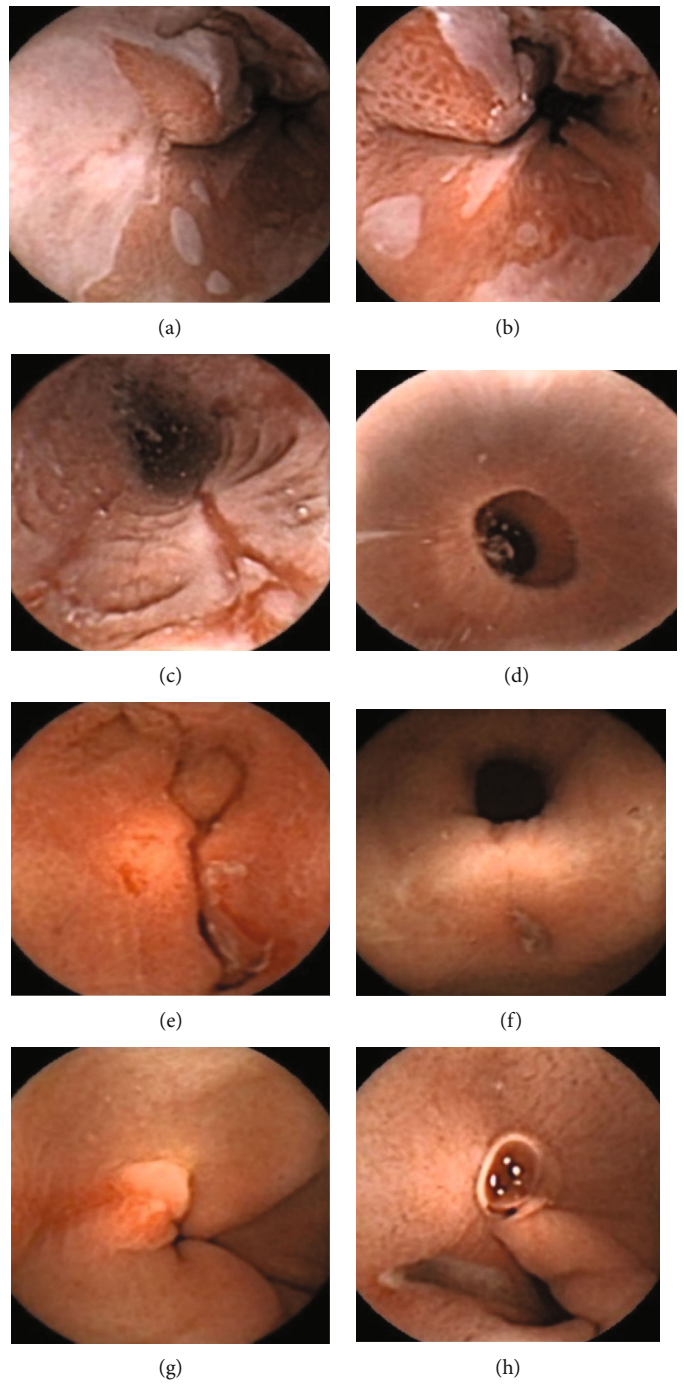

Figure 3: Pathology detected by UGI VCE. (a, b) Distal oesophageal lesion with Barrett's oesophagus. (c) Oesophagitis with oesophageal ulcer. (d) Schiatski's ring. (e, f) Gastric ulcer. (g, h) Duodenal ulcer.

landmarks typically seen at OGD without direct OGD comparison. We do, however, demonstrate comparable findings between UGI VCE and subsequent OGD, where available. An additional concern may be the time taken for analysis compared with OGD, but this reduces with experience and training. This study did not compare histological diagnosis, which will require further research. Histological assessment is unavailable using UGI VCE, adjunct breath tests and stool analysis, and Cytosponge technology for Barrett's oesophagus dysplasia detection, for example, [17, 18] may be a significant additional outpatient workup that increases clinical utility.

The technological advancements in VCE have paved the way for the broader utilisation of less-invasive endoscopic investigation. We must adopt such technology to address the challenges of the COVID-19 pandemic and the growing waiting times for diagnostic testing in many gastroenterology departments worldwide. We demonstrate the effectiveness of UGI VCE in achieving excellent mucosal views of the UGI tract in select patients that would normally be

visualised at OGD. Since the introduction of this procedure in our unit, 103 patients requiring UGI evaluation have successively been investigated without requiring a time slot in the endoscopy unit. In appropriate cases, using UGI VCE as an alternative investigative tool may reduce both waiting times and the burden on endoscopy units for evaluation of the upper GI tract.

5. Conclusion

In total, (125) patients were evaluated and treated using UGI VCE. Excellent views of key anatomical landmarks defined in the BSG quality standards for upper gastrointestinal endoscopy were achieved. 103 (81%) patients did not require invasive follow up, thus helping to reduce patient wait times for endoscopy. UGI VCE may serve as a clinical diagnostic tool, used alongside OGD in appropriate cases, to help improve patient services and care delivery. This is particularly relevant as we transition service delivery to a pandemic and postpandemic era.

Data Availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Ethical Approval

ECM 4 (c) 07/07/2020 COVID and ECM 3 (a) 11/08/2020, granted by the Cork University affiliated teaching hospital's clinical ethics review board.

Conflicts of Interest

The authors declare no conflicts of interest.

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