RESEARCH

Reassessing the value of gastroscopy for the investigation of dyspepsia

Hey-Long Ching, Melissa F Hale, Reena Sidhu, Mark E McAlindon

Department of Gastroenterology,
Royal Hallamshire Hospital,
Sheffield Teaching Hospitals,
Sheffield, UK

Correspondence to

Dr Hey-Long Ching,
Clinical Research Fellow,
Gastroenterology, Royal
Hallamshire Hospital, Sheffield
Teaching Hospitals, Sheffield,
S10 2JF, UK; hey-long.ching@
sth.nhs.uk

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ABSTRACT

Objective To evaluate the diagnostic yield of investigating dyspepsia with oesophagogastroduodenoscopy (OGD) with or without mucosal biopsy.

Design Retrospective service evaluation study.

Setting Two teaching hospitals: The Royal Hallamshire Hospital and Northern General Hospital, Sheffield Teaching Hospitals NHS Foundation Trust, UK.

Patients 500 patients, 55 years of age and over, who underwent OGD to investigate dyspepsia were included. The study period included a 3-month window. All OGDs were performed on an outpatient basis.

Interventions Data were extracted from electronic OGD records within the study period.

Main outcome measures Diagnostic yield provided by endoscopic examination and histological assessment.

Results 378 patients (75.6%) were reported to have some form of endoscopic abnormality, and 417 patients (83.4%) had biopsies taken. The most common findings at OGD were gastritis (47.2%) and oesophagitis (24.4%). Oesophagogastric malignancy was seen in 1%. Diagnoses made endoscopically or histologically that would not have been appropriately managed by empirical therapies were seen in 16.2%.

Conclusion OGD in dyspepsia influences patient management in approximately one-sixth of cases. However, the majority of patients are sufficiently managed with *Helicobacter pylori* testing and eradication and/or a trial of proton pump inhibitor therapy. Further non-invasive approaches are needed to identify patients who need endoscopy for biopsy or therapy.

INTRODUCTION

Dyspepsia is defined as a group of persistent symptoms including heartburn, upper abdominal discomfort or pain and nausea or vomiting. These symptoms are

common, affecting up to 25.9% of the European population.¹ The definitive diagnostic test is flexible upper gastrointestinal (GI) endoscopy (oesophagogastroduodenoscopy (OGD)), which is invasive, may be poorly tolerated and incurs the small risks of perforation and sedation.^{2–4}

The National Institute for Health and Care Excellence (NICE) first developed management guidelines for dyspepsia in an attempt to ensure appropriate referral for OGD in 2004, updating them in 2014.⁵ American guidelines for managing dyspepsia adopt a similar approach.⁶ For uninvestigated dyspepsia, NICE guidelines recommend a *Helicobacter pylori* 'test and treat' approach or an empirical 4-week trial of full-dose proton pump inhibitor (PPI) treatment and step down therapy to the lowest dose needed to control symptoms. This would effectively treat the majority of patients with peptic ulcer or reflux disease without recourse to invasive investigation. Urgent direct referral for OGD (the '2 week wait' pathway) is recommended for patients with suspected cancer: those over 55 years of age who have dyspepsia or reflux symptoms that are treatment resistant, associated with weight loss, nausea, vomiting or a raised platelet count.⁶ This was introduced as part of the UK Department of Health Cancer Plan to improve early cancer detection and treatment.⁷

Therefore, recent guidelines and health campaigns may have affected the nature of referral practice and the rate of diagnostic findings, particularly malignant disease. This study was performed to determine the diagnostic yield and the nature of the diagnoses made both macroscopically and microscopically (following histological analysis of mucosal biopsy) based on current referral and endoscopic practice.

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METHODS AND MATERIALS

A retrospective cohort study of consecutive patients 55 years of age and over, who underwent OGD between September 2015 and January 2016 to investigate dyspepsia, was performed at Sheffield Teaching Hospitals NHS Trust. The study was registered and approved by the Clinical Effectiveness Unit, Sheffield Teaching Hospitals NHS Foundation Trust (registration number 7073). All procedures are automatically logged and data collated by InfoFlex software (Chameleon Information Management Services).

Data on patient demographics, use of sedation, procedure indication(s), endoscopic diagnoses (including site), histological diagnoses (including site) and any rapid urease tests performed were collected. Diagnoses were considered in terms of whether endoscopy (with or without biopsy) had influenced management over and above the NICE recommendations for the management of uninvestigated dyspepsia.

Statistical analysis was performed using SPSS V.22.0 (IBM). Continuous data were expressed as mean $\pm$ SD. Categorical variables were expressed as absolute numbers $\pm$ percentages. The Fisher exact probability test was used to compare differences in categorical variables. $p < 0.05$ (two sided) was considered statistically significant.

RESULTS

Over a 4-month study period, 500 OGDs were performed for patients with dyspepsia (table 1). A small proportion of patients presented with concomitant symptoms in addition to dyspepsia: dysphagia (6%), anaemia (4%), vomiting (4.2%) and suspected GI bleeding (0.6%). A percentage of 39.8 of patients were male, and the mean age ($\pm$ SD) of patients was 58 ($\pm$ 16.1) years. One hundred forty-five (29%) patients were sedated with midazolam (mean ($\pm$ SD),

2.0 mg ($\pm$ 1.0)) and, in some cases, concurrent fentanyl (50 ± 23 mcg).

Three hundred seventy-eight patients (75.6%) underwent an OGD with some form of endoscopic abnormality reported. Patients were described as having one (26.4%), two (21.8%), three (15.8%), four (8.0%), five (2.8%), six (0.4%) or seven (0.2%) endoscopic findings. In addition, 417 patients (83.4%) had biopsies taken: 15.8% for histological assessment, 27.4% for rapid urease tests and 40.2% for both. Patients had biopsies taken from one (37.8%), two (14.6%), three (3.0%) or four (0.6%) different sites.

Findings of uncertain relevance, or which could have been managed with empirical therapy, were seen in 309 patients (61.8%). These findings (table 1) included oesophagitis (n=122), Schatzki rings (n=4), benign oesophageal plaques (n=2), oesophageal diverticulae (n=1), hiatus hernias (n=178), benign polyps (n=44), gastritis (n=269), benign gastric ulcers (n=9), gastric antral vascular ectasia (n=2), portal hypertensive gastropathy (n=2), duodenitis (n=55) and a duodenal ulcer (n=1). Conversely, diagnoses made endoscopically and from biopsies that would not have been appropriately managed by empirical therapies numbered 81 (16.2%; table 1). These included 69 (13.8%) patients with Barrett's oesophagus (n=39), oesophageal stricture (n=7), oesophageal cancer (n=1) and gastric cancer (n=4). Twelve (2.4%) patients had a diagnosis made solely by histology (without evident endoscopic abnormality), which included eosinophilic oesophagitis (n=1), eosinophilic gastritis (n=1), intestinal metaplasia (without atrophy, n=3) and coeliac disease (n=7).

Subgroup analysis by referral status according to national guidelines⁵ was performed. Patients were grouped into those referred for urgent OGD for investigation of suspected cancer (within 2 weeks as

Table 1 Diagnoses made at OGD performed to investigate dyspepsia: those in bold required OGD to obtain histology or cytology and would not have been appropriately managed by empirical *Helicobacter pylori* 'test and treat' or proton pump inhibitor therapy.

Oesophagus			Stomach			Duodenum		
	n	%		n	%		n	%
Ulcer	3	0.6	Ulcer	9	1.8	Ulcer	1	0.2
Malignant tumour	1	0.2	Malignant tumour	4	0.8			
Barrett's oesophagus	39	7.8	Gastritis	268	47.2	Duodenitis	55	11
Candidiasis	10	2	Atrophy	1	0.2			
Stricture	7	1.4	GAVE	2	0.4			
Oesophagitis	122	24.4	Hiatus hernia	178	35.6			
Benign polyps	9	1.8	Benign polyps	34	6.8	Benign polyps	1	0.2
Schatzki ring	4	0.8	PHG	2	0.4			
Benign plaques	2	0.4						
Diverticula	1	0.2						

GAVE, gastric antral vascular ectasia; OGD, oesophagogastrroduodenoscopy; PHG, portal hypertensive gastropathy.

recommended by NICE⁶) in the presence of alarm symptoms (patients with dysphagia or aged 55 years and over with weight loss and upper abdominal pain and/or reflux and/or dyspepsia) and those only requiring a routine OGD. There was no significant difference in the frequency of endoscopic findings that required management other than empirical PPI or a 'test-and-treat' approach between the two groups (urgent vs routine, 15% vs 13.1%, $p=0.61$). The number of oesophagogastric cancers in patients requiring urgent OGD was four (0.8%), while those undergoing non-urgent investigation was one (0.2%). However, this difference did not reach statistical significance ($p=0.4$). Of those referred for urgent OGD, one case of oesophageal cancer had concomitantly reported dysphagia. In the remaining three cases of gastric cancer, one had iron deficiency anaemia, another with symptoms of dysphagia (not related to the diagnosis) and one patient only had symptoms of dyspepsia. One patient with gastric cancer diagnosed under the non-urgent pathway reported unrelated symptoms of dysphagia retrospectively.

DISCUSSION

In this study, 378 (75.6%) of patients who were referred for OGD to investigate dyspepsia had endoscopic abnormalities identified. However, only 16.2% had a diagnosis that required endoscopy, of whom 13.8% had a macroscopic abnormality. Although biopsies were taken for histological analysis or rapid urease testing in 83.4% of patients, these added to the diagnostic yield in only 2.4%. Malignant tumours were diagnosed in only 1% of patients with dyspepsia.

Despite the introduction of guidelines for managing benign symptoms in the community without recourse to invasive investigation and for direct urgent referral for OGD of patients with suspected cancer, diagnostic yield, including that of cancer, remains low. In fact disease detection is largely unchanged since introduction of the guidelines: meta-analysis of studies from 1950 to 2010 demonstrated that OGD performed to investigate dyspepsia was normal in 78% of cases, identified oesophagitis in 13%, peptic ulcer disease in 8% and other diseases (including cancer) in only 1%.⁸ The NICE guidelines recommend the same management approach for reflux and other dyspeptic symptoms.⁵ This is in recognition of the fact that upper GI symptoms are not specific to one disease process.⁹ However, hiatus hernia and oesophagitis were by far the most common diagnoses in this cohort of patients, neither of which need routine endoscopic biopsy, reinforcing the importance of future research in distinguishing benign oesophageal from other gastroduodenal disease causing dyspeptic symptoms.

Peptic ulcer disease was rather less common. This would be consistent with a decline in peptic ulcer disease noted before the introduction of PPIs¹⁰ and may have been further affected by the increasing use

of PPIs since.¹¹ It may be that the NICE guidelines, along with other cancer campaigns,¹⁰ have increased awareness of symptoms among the patient population and actually reduced the threshold of referral for OGD by general practitioners, primarily to exclude malignant disease. This would account for the 30% increase in demand for OGDs in the UK in the last 5 years.¹²

The diagnostic yield of malignant disease was low, and all cancers were detected at an advanced stage. Meta-analyses demonstrate that individual alarm symptoms in isolation have limited ability to specifically identify the likelihood of malignancy^{13 14} and when they do so, disease is advanced; the value of combining symptoms to predict risk remains uncertain. The lack of specificity and low positive predictive value in current models incur a high number needed to treat in order to avoid missing cancers.^{15 16} Disappointingly, up to 14% of patients presenting with gastric cancer have had an OGD within the preceding 3 years, suggesting that early stage disease is often missed. This might be because of time pressures resulting in OGD being performed too rapidly, a lack of training in recognition of early malignant disease or poor tolerance of the procedure, resulting in inadequate insufflation or an abbreviated examination. The use of antifoaming agents and mucolytics may also improve mucosal visualisation and early lesion detection.¹⁷ Cheung *et al* showed that alarm features were significantly less likely at presentation in these patients than those identified at first OGD.¹⁸

As many as 83.4% of patients had biopsies, 56% for histological analysis and 67.6% for rapid urease testing. This practice may be driven by guidelines that recommend taking biopsies from normal looking mucosa in dyspeptic patients.^{19 20} There may also be a desire not to miss any histological diagnoses by endoscopists who may not always be familiar with the patients' symptoms and who want to avoid the risk of the patient being referred for a second invasive procedure. In our study, this practice only increased diagnostic yield by 2.4% and two-thirds of these patients were referred for OGD specifically for biopsy (five with positive endomysial antibodies and one patient with dysphagia for oesophageal biopsies to diagnose eosinophilic oesophagitis). Based on previous local costings at our institute,²¹ this approximates to a total cost of over £21 000 (£10 100 for biopsy forceps, £10 600 for histology and £1100 for rapid urease testing). These data would support the findings of Nelsen *et al*, who found that a practice of having a low threshold to take biopsies for histology had a low yield at high cost.²²

Better diagnostic capability at reduced cost might be addressed to some extent within the boundaries of current practice. Polyp detection rates at colonoscopy can be improved by increasing the examination time to allow more careful mucosal inspection. Although similar studies are yet to be conducted, it seems likely that the same will apply to OGD.^{23–26} Poor tolerance

of OGD may be associated with a reduced lesion detection rate,²⁷ and some studies suggest that sedation, particularly for anxious patients, may improve tolerance.^{28 29} Patients should have had their *H. pylori* status checked prior to referral⁵ and appropriate notification on the referral form should render rapid urease testing unnecessary for most. Malignant lesions can be differentiated from benign lesions by chromoendoscopy in the hands of experts, and studies have shown that training improves lesion recognition.^{26 30 31} As with the 'resect and discard' policy for small colonic polyps, this might lead to a reduced need for histological analysis.^{32 33}

The availability of non-invasive testing to help differentiate benign from potentially malignant disease is more relevant than ever and in the future might allow diagnosis in the community and selection of the minority of patients who need referral for OGD for biopsy. Early data suggest that breath testing for five volatile organic compounds have been shown to have a sensitivity of 80% and specificity of 81% in detecting oesophagogastric cancer, although this was in patients with mostly advanced disease.³⁴ A swallowable 'cyto-sponge' attached to a thread, from which cells are analysed following retrieval, has a 79.9% sensitivity in detecting Barrett's oesophagus and is capable of detecting a variety of other oesophageal diseases.^{35 36} A panel of serological biomarkers of gastric atrophy (pepsinogen I and II and amidated G-17) and *H. pylori* IgG antibodies identifies gastric atrophy of the

corpus and antrum with sensitivities and specificities of 70.2% and 51.6% and 93.9% and 84.1%, respectively.³⁷ Gastric capsule endoscopy involves the use of a modified small bowel capsule, adapted to allow visualisation of the upper GI tract. Standard capsule endoscopy uses a pill-like camera approximately 28×12 mm in size. Novel developments have rendered a capsule responsive to external magnetic steering using a robotic system and joysticks for operator control. It is very well tolerated and has a sensitivity of 90.4% compared with OGD in detecting focal lesions.³⁸ Further research is needed to determine the role of these exciting novel non-invasive technologies in the identification of significant upper GI disease and the selection of appropriate patients for endoscopic biopsy or therapy.

Contributors MEM designed the study, assisted with interpretation of results and critically appraised the paper. H-LC led the data collection, performed the analysis and drafted the paper. MFH and RS critically appraised the paper. All authors approved the final manuscript. H-LC is guarantor.

Competing interests None declared.

Patient consent Retrospective analysis of gastroscopy reports as part of service evaluation without human subject involvement.

Provenance and peer review Not commissioned; externally peer reviewed.

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Significance of this study

What is already known on this topic?

- ▶ Dyspepsia is common, and the demand for OGD is rising.
- ▶ Oesophagogastrroduodenoscopy (OGD) can be uncomfortable and is associated with the risk of perforation and sedation.

What this study adds?

- ▶ Only 1% of patients referred for OGD have malignancy.
- ▶ A percentage of 61.8 of patients had endoscopic findings that could have been managed empirically or were not relevant to the patients' symptoms.
- ▶ Although 83.4% of patients undergo biopsy, this increases diagnostic yield by only 2.4%

How might it impact on clinical practice in the foreseeable future?

- ▶ Although published guidelines aimed to achieve the opposite effect, the demand for OGD has increased without an obvious change in detection of important pathology. Further research into non-invasive investigation that selects appropriate patients for endoscopic biopsy or therapy is needed.

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