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Dual-focus Magnification, High-Definition Endoscopy Improves Pathology Detection in Direct-to-Test Diagnostic Upper Gastrointestinal Endoscopy

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ABSTRACT

Background: In the UK, the majority of diagnostic upper gastrointestinal (UGI) endoscopies are a result of direct-to-test referral from the primary care physician. The diagnostic yield of these tests is relatively low, and the burden high on endoscopy services. Dual-focus magnification, high-definition endoscopy is expected to improve detection and classification of UGI mucosal lesions and also help minimize biopsies by allowing better targeting.

Methods: This is a retrospective study of patients attending for direct-to-test UGI endoscopy from January 2015 to June 2015. The primary outcome of interest was the identification of significant pathology. Detection of significant pathology was modelled using logistic regression.

Results: 500 procedures were included. The mean age of patients was 61.5 (±15.6) years; 60.8% of patients were female. Ninety-four gastroscopies were performed using dual-focus magnification high-definition endoscopy. Increasing age, male gender, type of endoscope, and type of operator were all identified as significant factors influencing the odds of detecting significant mucosal pathology. Use of dual-focus magnification, high-definition endoscopy was associated with an odds ratio of 1.87 (95%CI 1.11-3.12) favouring the detection of significant pathology. Subsequent analysis suggested that the increased detection of pathology during dual-focus magnification, high-definition endoscopy also influenced patient follow-up and led to a 3.0 fold (p=0.04) increase in the proportion of patients entered into an UGI endoscopic surveillance program.

Conclusion: Dual-focus magnification, high-definition endoscopy improved the diagnostic yield for significant mucosal pathology in patients referred for direct-to-test endoscopy. If this finding is recapitulated elsewhere it will have substantial impact on the provision of UGI endoscopic services.

Key words: upper gastrointestinal tract – mucosal pathology – dual-focus magnification – high definition endoscopy – diagnosis.

Abbreviations: 2WR: 2 week rule; AFI: Autofluorescence imaging; ASGE: American Society for Gastrointestinal Endoscopy; JAG: Joint Advisory Group; MDT: Multi-disciplinary team; NBI: Narrow band imaging; NICE: National Institute for Health and Care Excellence; OA: open access; UGI: Upper gastrointestinal.

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INTRODUCTION

There is increasing demand upon gastrointestinal diagnostic services, including diagnostic upper gastrointestinal (UGI) endoscopy. The majority of new referrals for UGI endoscopy originate from primary care physicians who refer via a direct-to-test pathway. In the UK, direct-to-test UGI endoscopy can be accessed through two distinct pathways: referrals are made either through a routine "open access" (OA) referral system, or through a fast tracked, cancer exclusion service in which patients receive their gastroscopy within two weeks of referral (2WR) [1]. As a result, the majority of studies assessing dual focus endoscopy are conducted using such a referral population.

These referral pathways aim to reduce unnecessary outpatient consultations and streamline the diagnostic algorithm for patients [2], and have been adopted globally [3, 4]. However, the effectiveness of direct-to-test referral has been refuted by some authors because of a perceived increase in inappropriate referrals when comparing direct-to-test endoscopy to endoscopy with a prior GI consultation [5].

Both the American Society for Gastrointestinal Endoscopy (ASGE) and the National Institute for Health and Care Excellence (NICE) have produced guidance documents which support the use of direct-to-test referral routes for diagnostic UGI endoscopy [6], and adherence to these guidelines has been shown to improve the yield of clinically relevant findings at UGI endoscopy [6–8].

These guidelines focus on appropriateness of referral, patient acceptance and preparedness for endoscopy, informed consent, and assurance of appropriate follow-up. However, in addition to these services level factors recent technical advances in endoscope design may also influence the diagnostic yield of UGI endoscopy. High-definition, high-magnification endoscopy, with or without mucosal enhancement techniques by indigo carmine chromoendoscopy or blue light endoscopy enable more detailed visualization of GI mucosa than has been achievable using earlier generation endoscopic equipment, and may allow improved detection and classification of GI mucosal lesions leading to better biopsy targeting [9].

Since January 2015, patients attending our teaching hospital for direct-to-test UGI endoscopy have been allocated either an Olympus GIF-HQ290 dual-focus magnification, high-definition gastroscope or an older generation video gastroscope (Olympus GIF-H260 or GIF-Q240). We aimed to establish whether the use of dual-focus magnification, high-definition endoscopy influenced the diagnostic yield in patients attending for OA diagnostic UGI endoscopy.

METHOD

A retrospective observational study of factors that influence identification of significant pathology during direct-to-test UGI endoscopy was performed in a University teaching hospital. Endoscopists consisted of nurses, specialist gastroenterology trainees and consultants: all were Joint Advisory Group (JAG) accredited endoscopists. Patients referred between January 2015 and June 2015, through a direct-to-test pathway and who underwent a completed UGI endoscopy were all included. Data were collected using the Unisoft endoscopy reporting software and hospital pathology database. The primary outcome of interest was the identification of significant pathology, defined as mucosal ulceration, stricture formation, biopsy proven cancer, biopsy proven Barrett's oesophagus or *Helicobacter pylori* positive gastritis. The latter two diagnoses were included due to their pre-malignant potential.

Any other findings were defined as non-significant and are summarised in supplementary Table I.

During this period an updated video-endoscopy system (EVIS LUCERA ELITE, CV-290, Olympus) was incorporated into our endoscopy department. A newly released dual-focus magnification, high-definition gastroscope (GIF-HQ290, Olympus) was used alongside existing models of video endoscopes (GIF-H260, GIF-Q260 & GIF-Q240, Olympus). Their usage was allocated based on availability post decontamination and the requirements of the lists being conducted. There was no blinded randomisation of the scope systems. The GIF-HQ290 endoscope allows for x45-fold magnification at the touch of a button on the endoscope. For the purposes of this study this endoscope was compared to all other endoscope technologies in use within the department. Recorded variables included endoscope type, age, gender, endoscopist, mode of referral (OA or 2WR) and primary symptoms prompting referral. Along with the finding of significant pathology, secondary measures were site of pathology and outcome after endoscopy.

Statistical analysis

Numerical summaries of the data were made. Categorical variables have been summarised as frequency (%) and continuous variables as mean (±SD). Univariate analysis was performed by Student's *t*-test, Fisher's exact test and χ^2 test as described in the figures. Multivariate analysis was performed by modelling significant pathology (yes/no) using nominal logistic regression and contingency table analysis incorporating the factors: age, gender, endoscope model, mode of referral and type of operator. Odds ratios were estimated from the fitted model. JMP (SAS Inc.) v11.0.0 and Prism (Graphpad Software Inc) v.6.0f were used for statistical analyses. A p value of <0.05 was considered statistically significant.

RESULTS

Patient demographics

Five hundred endoscopies were included in the study. In keeping with our known departmental practice, 77% of procedures were performed by nurse endoscopists, the remainder being performed by a mixture of training grade (16%) and non-training grade (7%) doctors.

Ninety-four gastroscopies were carried out using the dual-focus magnification, high-definition gastroscope; the remaining 406 were conducted with, for the purposes of this study, standard Olympus gastroscopes (260 series, n=343 and 240 series, n=63). Significant pathology was identified in 122 (24.4%) patients. Seventy three percent of these significant pathologies were identified by nurse endoscopists, whilst training grade and non-training grade doctors identified 23% and 4%, respectively. No other mucosal enhancement techniques were recorded as being used during any of the recorded procedures.

The mean age of patients was 61.5 (SD 15.6) years; 304 (60.8%) were female patients. There was no significant difference in age between males and females (p=0.97, Fig. 1A). The majority of patients (69.8%) were referred via open access, rather than the 2WR pathway. Mode of referral was similar for male and female patients (p=0.2, Fig.1B).

The two commonest indications for endoscopy were dyspepsia and dysphagia, accounting for 48% and 27% of referrals, respectively. Men and women were equally likely to be referred for each of these indications (Fig. 2A), and, in our dataset, individuals were at similar risk of being diagnosed with significant pathology irrespective of the indication for which the procedure was performed (Fig. 2B). Of the 8 patients found to have an UGI cancer, 5 were referred with dysphagia, 2 with weight loss and anaemia and 1 with dyspepsia.

Univariate analysis of impact on diagnostic yield

To characterise which factors influenced the diagnostic yield of direct-to-test UGI endoscopy we performed contingency

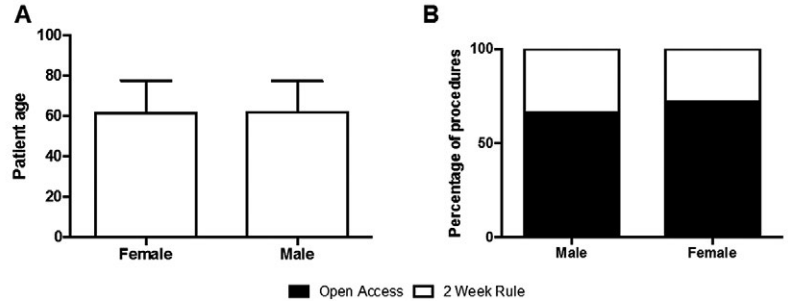

Fig. 1. A) The age of patients at endoscopy according to gender (mean ± SD). No significant differences were identified between groups by Student's *t*-test (p=0.77). B) The proportion of patients referred by gender and referral pathway. No significant differences between groups (p=0.19) by Fisher's exact test.

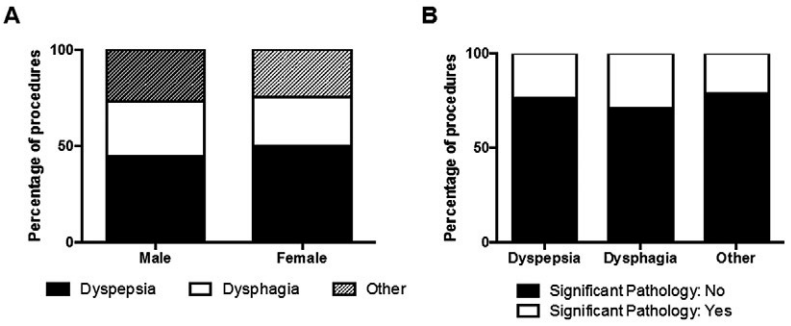

Fig. 2. A) The proportion of male and female patients referred with dyspepsia, dysphagia or other indications. No significant differences identified between proportions of men and women referred with each indication (p=0.49). B) The proportion of patients referred with dyspepsia, dysphagia or another indication who were found to have significant pathology following endoscopy. No significant differences between groups (p=0.29) by χ^2 test.

table analyses or Student *t*-tests to determine whether there were correlations between age, gender, mode of referral, operator and type of endoscope used and the identification of significant pathology (Table I). Whilst the group with significant pathology were marginally older than those without significant pathology (mean age 63.6 vs 61.0 years, p=0.12) there was no significant difference in ages. Male patients were more likely to have significant pathology than female patients (p=0.02). Mode of referral was not associated with a difference in diagnostic yield (p=0.50), whilst the type of operator was significantly associated with differences in diagnostic yield with nurse endoscopists identifying significant pathology in 23% of procedures, training grade doctors identifying pathology in 35% of procedures and consultants (who performed the fewest procedures in this cohort) identifying significant pathology at 14% of procedures (p=0.04). The use of dual-focus magnification, high-definition endoscopes was also associated with increased identification of significant pathology compared to other endoscope series (p=0.02).

Multivariate analysis

As univariate analysis identified a number of potentially confounding factors that influenced the frequency of identifying significant pathology in direct-to-test UGI endoscopy we built a logistic regression model to determine what impact specific variables had on diagnostic yield (Table II).

In this model, advancing age was identified as a statistically significant risk factor for the identification of pathology, though the effect size was extremely small: OR 1.01 (95%CI 1.00-1.02). In keeping with previous literature, male gender was also

Table I. Univariate analysis of the factors that influence diagnostic yield in primary care physician initiated UGI endoscopy.

	Complete cohort (n)	No pathology	Pathology	p value
Number of procedures	500	378	122	-
Age (mean ± SD) years	61.5 (±15.6)	61.0 (±16.1)	63.6 (±14.3)	0.12
Gender				0.02
Male	196 (39%)	137	59	
Female	304 (61%)	241	63	
Mode of referral				0.50
Open access	349 (69%)	267	82	
2 week rule	151 (31%)	111	40	
Operator				0.04
Nurse	387 (77%)	297	90	
Training grade doctor	78 (15%)	51	27	
Non-training grade doctor	35 (8%)	30	5	
Endoscope				0.02
GIF-HQ290	94	62	32	
Non GIF-HQ290	406	316	90	

UGI: upper gastrointesinal tract; SD: standard deviation

Table II. Logistic regression analysis using the measured variables and their impact upon the identification of significant upper gastrointestinal pathology.

Variable		Odds ratio	Lower CI	Upper CI	p value
Age	Increasing age	1.01	1.00	1.02	0.04
Gender	Male : Female	1.59	1.04	2.43	0.03
Mode of referral	Open access : 2 week	0.93	0.58	1.49	0.77
Operator	Nurse : Non-training grade doctor	2.14	0.85	6.59	0.1
	Nurse : Training grade doctor	0.58	0.33	1.01	0.06
	SpR : Non-training grade doctor	3.7	1.34	12.05	0.01
Endoscope	GIF-HQ290 : Non GIF-HQ290	1.87	1.11	3.12	0.01

CI: confidence interval. Increasing age of 5 yearly intervals was used for the analysis.

identified as a risk factor for the identification of significant pathology and conferred an OR of 1.59 (95%CI 1.04-2.43). As in the univariate analysis, mode of referral did not influence the risk of identifying significant pathology. The type of operator did contribute to diagnostic yield in the multivariate analysis, with training grade doctors 3.7 (1.34-12.05) times more likely to identify pathology than their non-training grade colleagues. The use of dual-focus magnification, high-definition endoscopes was also identified as an independent factor in the identification of significant UGI pathology and conferred an OR of 1.87 (95%CI 1.11-3.12) for identifying significant pathology over the use of other endoscope series.

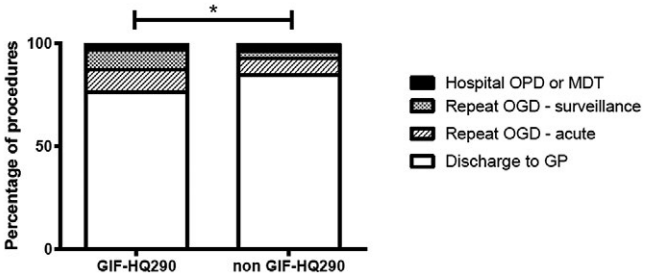

Fig. 3. Outcome of UGI endoscopies segregated by endoscope type. *p<0.05.

Dual-focus magnification, high-definition endoscopy influences outcome following endoscopy

Having established that the identification of significant pathology is influenced by the use of dual-focus magnification, high-definition endoscopy we wanted to characterise whether this endoscopy system also influenced the ongoing care provided to patients. We therefore categorised patient outcomes following endoscopy into hospital outpatient or MDT follow-up, an acute repeat UGI endoscopy, repeat endoscopy for surveillance, or discharge to the primary care physician. Acute repeat gastroscopies were defined as a further procedure within three months, and were requested either for interventional therapies including oesophageal dilatation, or to assess healing of mucosal lesions identified in the initial endoscopy.

There was a significant (p=0.04) difference in the outcome of endoscopies following dual-focus magnification, high-definition endoscopy with a 3.0-fold increase in the proportion of patients entering an endoscopic surveillance program than in the group of patients examined with conventional endoscopes (Fig. 3).

Non-trainee doctors discharged a higher percentage of patients, followed by nurse and trainee doctors (91.42, 83.72 and 78.2%, respectively). Nurses and non-trainee doctors enrolled patients into surveillance at a very similar rate, 2.84 and 2.85% respectively, with trainee doctors having the greatest rate of surveillance enrolment at 5.12%.

Dual-focus magnification, high-definition endoscopy aids diagnosis of significant oesophageal and gastric pathology

To determine whether dual-focus magnification, high-definition endoscopy might have an impact on the identification of lesions in a specific part of the UGI tract we categorised pathology by location and performed contingency table analyses. This demonstrated significant differences in distribution (p=0.01) with a 1.3 fold higher proportion of procedures identifying significant oesophageal pathology when procedures were performed with endoscopy compared to other endoscope series and a 2.7 fold increase in identification of gastric pathology (Table III and Fig. 4). Significant duodenal pathology was identified in less than 1% of procedures and was not identified during any of the 94 endoscopies performed using a high-definition, high-magnification endoscope. Hence, this site was excluded from this analysis.

Table III. The number of significant pathologies identified according to their anatomical location. No significant pathology category includes those with a non-significant abnormality and a normal endoscopy.

	GIF-HQ290 n (%)	Non GIF-HQ290 n (%)	p-value
No significant pathology	62 (65.9)	316 (77.8)	0.01
Oesophagus	20 (21.3)	67 (16.5)	
Stomach	12 (12.8)	19 (4.7)	

Comparing the standard and high definition scopes, all endoscopic findings were also subjected to univariate analysis (Table IV). This demonstrated a superior ability for the high definition scope to identify Barrett's oesophagus, gastric ulcers and gastritis. There was no difference in the identification of established oesophageal cancer. Insufficient duodenal pathology was identified to characterise statistically significant differences.

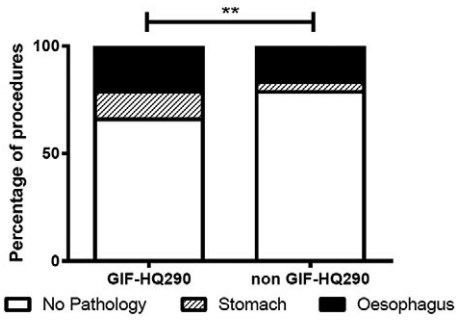

Fig. 4. Distribution of pathology in the upper gastrointestinal tract segregated by anatomical site. ** p<0.01.

DISCUSSION

This study demonstrates dual-focus magnification, high-definition endoscopy as an independent factor in the identification of significant mucosal pathology in patients attending for direct-to-test UGI endoscopy. In a multivariate analysis these endoscopes conferred a 1.87 fold increased odds of identifying pathology over the previously adopted standard endoscopes in our department. This increased ability to detect pathology also appears to have influenced the outcomes for patients included in the study. People who were examined with a dual-focus magnification, high-definition endoscope were approximately three times as likely to be entered into a Barrett's oesophagus surveillance programme as those in whom their endoscopy was performed with a standard endoscope. This is in keeping with previous data which have demonstrated the utility for this type of endoscope in the surveillance of Barrett's oesophagus [10].

In addition, an increased rate of mucosal pathology was identified in patients' stomachs when dual-focus magnification, high-definition endoscopes were used. The gastric mucosa is recognised to be a particularly challenging area to examine well, with reports of up to 7% of gastric cancers being missed when endoscopy was performed within a year of diagnosis [11]. Because of this, there has been a push amongst policy makers to try to improve UGI endoscopy service provision [12]. The data presented here suggest that there may be a role for dual-focus magnification, high-definition endoscopes in this. In our study, advanced imaging techniques, such as NBI or AFI, were not utilised. Therefore, we are unable to comment on the utility of this system to endoscopically determine the malignant potential of neoplastic lesions or significant pathology.

The retrospective design of this study accurately reflects practice in our unit, but does introduce limitations to the study. Of particular note, the distribution of dual-focus magnification, high-definition endoscopes between different users was not random, and we identified a preponderance for their use by non-training grade doctors.

This observation may reflect the fact that more experienced endoscopists are more comfortable with using new equipment, but we cannot exclude that dual-focus magnification, high-definition endoscopes were used for patients thought to have a higher pre-procedure index of suspicion for pathology. In this study, the majority of procedures were performed by nurse endoscopists, with non-training grade doctors conducting the smallest number of procedures. This is representative of the workload in the Royal Liverpool and Broadgreen University Hospitals Trust, and may well be representative across UK university hospital departments where non-training grade doctors conduct more complex therapeutic endoscopies,

Table IV. The number of each of the endoscopic findings according to anatomical location and scope generation.

Pathology	Non GIF-HQ290 cases / controls	GIF-HQ290 Cases / controls	Odds Ratio	95% CI	p-value
Reported oesophageal pathology					
Barrett's oesophagus	16/406	10/94	0.34	0.15 to 0.76	0.016
Oesophageal cancer	5/406	3/94	0.37	0.09 to 1.45	0.175
Stricture	15/406	3/94	1.16	0.34 to 3.85	>0.99
Oesophagitis	34/406	4/94	2.05	0.73 to 5.52	0.20
Hiatus hernia	59/406	16/94	0.82	0.45 to 1.51	0.52
other (non-significant)	14/406	0/94	Infinity	0.87 to Infinity	0.08
Normal oesophagus	263/406	58/94	1.14	0.71 to 1.81	0.63
Reported gastric pathology					
Gastric ulcer	18/406	10/94	0.38	0.17 to 0.85	0.02
Gastritis	96/406	33/94	0.57	0.35 to 0.92	0.02
Gastric polyp	21/406	5/94	0.97	0.37 to 2.41	>0.99
Normal stomach	271/406	46/94	2.095	1.32 to 3.32	0.001
Reported duodenal pathology					
Duodenal ulcer	2/406	0/406	Infinity	0.10 to Infinity	>0.99
Duodenitis	10/406	2/406	1.16	0.26 to 5.37	>0.99
Duodenal polyp	1/406	1/406	0.22	0.012 to 4.40	0.34
Normal duodenum	393/406	91/406	0.99	0.29 to 3.51	>0.99

CI: confidence intervals.

whilst other endoscopists perform the bulk of OA endoscopy. The logistic regression analysis, which was corrected for the type of endoscope used, demonstrated that training grade doctors identified more epithelial pathology than non-training grade doctors, but no differences were identified between the diagnostic abilities of nurse endoscopists and non-training grade doctors. This supports the logistic regression's assertion that the type of endoscope used is an independent factor for the likelihood of making a diagnosis.

One of the benefits of dual-focus magnification, high definition endoscopy over other types of image enhancement, particularly chromoendoscopy, is the limited additional training and procedural time required. This means that the adoption of this technology may have relatively little impact on the direct provision of procedures, and that endoscopists of all levels of experience are likely to derive benefits from this technology. However, the observation that more patients entered a Barrett's oesophagus surveillance programme could, if replicated, have a profound impact on the provision of UGI endoscopic services in the future.

Therefore, further research is indicated to understand what the impact of introducing dual-focus magnification, high-definition endoscopy would be on service provision in the future. In the first instance similar studies need to be replicated in other settings, preferably adopting a prospective study design and a multicentre approach.

CONCLUSION

Dual-focus magnification, high-definition endoscopy increased the yield of significant pathology in patients referred by their primary care physician for direct-to-test UGI endoscopy. This altered clinical outcomes, and if recapitulated across services would have an impact on the provision of UGI endoscopy services in general, and the provision of Barrett's oesophagus surveillance in particular.

Conflicts of interest: No conflict to declare.

Authors' contributions: A.B. was responsible for data collection, data analysis, writing and editing the manuscript. M.D.B. performed data analysis, wrote and edited the manuscript. T.C. provided statistical support and analysis. H.L.S., N.H. and S.S. devised the study and were responsible for editing the manuscript. C.P. assisted with editing manuscript prior to submission.

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Table Supplementary

Row Labels	Count of Finding- Oesophagus		
Barrett's	24	Hiatus Hernia	78
Barrett's and hiatus hernia	1	Candidiasis	7
Barrett's, hiatus hernia	1	Fundoplication	1
Cancer	8	Oesophagitis	40
Candida	7	Schatzki Ring	6
Fundoplication	1	Varices	1
Hiatus hernia	74		
Hiatus hernia and oesophagitis	2		
Normal	319		
Normal	2		
Oesophagitis	35		
Oesophagitis- grade A	1		
Oesophagitis- grade B	1		
Oesophagitis- grade D	1		
Schatzki ring	6		
Stricture	7		
Stricture- benign	4		
Stricture-benign	1		
Ulcer	4		
Varices	1		
Grand Total	**500**		

Row Labels	Count of Finding- Stomach		
Gastritis	129	Polyp	26
		Non-*H. pylori* gastritis	113
Normal	317		
Polyp	26		
Ulcer	26		
Ulcer, healing	1		
Ulcers	1		
Grand Total	**500**		

Row Labels	Count of Finding- Stomach				
	no	**no**	**yes**	**yes-o**	**yes-s**
Gastritis	113		10	1	5
Normal	239	1	57	20	
Polyp	23		2	1	
Ulcer	2		13		11
Ulcer, healing					1
Ulcers			1		
Grand Total	**377**	**1**	**83**	**22**	**17**

Row Labels	Count of Finding- Duodenum
duodenitis	11
normal	484

odematous	1
polyp	2
ulcer	1
ulcers	1
Grand Total	**500**