

Appropriateness of indications for diagnostic upper gastrointestinal endoscopy in India

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ABSTRACT

Introduction: Guidelines for an upper gastrointestinal endoscopy have been outlined for the Western population, but not yet for India. The study aimed to assess the appropriateness of upper gastrointestinal endoscopy for patients with dyspepsia and to identify the cut-off age for endoscopy from an Indian perspective.

Methods: Patients referred for upper digestive endoscopy to a university clinic in India were prospectively studied between January 2004 and June 2005. Patients who presented with dyspepsia and those with isolated alarm symptoms without dyspepsia who underwent endoscopy were included. The cut-off age for the detection of upper gastrointestinal tract carcinoma in dyspepsia was derived.

Results: A total of 3,432 endoscopies were performed during the study period. There were 2,068 men and 1,364 women. The overall mean age was 41.6 +/- 15 (range 7-85) years. 18.3 percent of 284 patients with malignancy were between 25 and 45 years of age. Using the receiver operator characteristic curve, the cut-off age for malignancy was between 35 and 44 years; specifically, the optimal cut-off age was 38 years for females and 43.5 years for males.

Conclusion: In the south Indian population with dyspepsia, there were more normal and benign lesions at endoscopy. The optimal cut-off ages for detecting malignancy for both genders were also determined.

Keywords: dyspepsia, endoscopy, malignancy, upper gastrointestinal endoscopy

INTRODUCTION

The introduction of increasingly complex procedures in the health sector makes it necessary not only to evaluate the efficacy and cost of procedures, but also its appropriateness in the clinical setting in question. In the specialty of gastroenterology, the problem of appropriateness is particularly perceived with regard to the use of upper gastrointestinal (GI) endoscopy, because of the open access to its application all over the world. To deal with this problem, guidelines have been drawn by various associations to make the use of upper GI endoscopy more rational. The appropriation of the procedure in a clinical setting, though established in the USA and the UK where an early upper GI endoscopy is done for those above the age of 45 years, may not hold true for a distinct south Asian population. Guidelines are not yet available for our population.

The term, dyspepsia, encompasses a heterogeneous group of upper abdominal symptoms often referred to as discomfort, pain, bloating, fullness, burning or indigestion, which poses a diagnostic and therapeutic challenge to the clinician. Additionally, the number of upper endoscopies for dyspepsia has increased and its appropriateness needs to be all the more studied. With this background, a cross-sectional and prospective study was undertaken to devise a guideline for the Asian region, based on the outcome of endoscopy in patients with dyspepsia, viz. ulcer and dysmotility – either alone or in combination with or without alarm symptoms. The second objective was to identify the cut-off age for endoscopy among patients with dyspepsia from an Indian perspective.

METHODS

Patients with dyspepsia and attending the outpatient clinic of the medical gastroenterology department of a large tertiary care referral centre in south India, were requested for their clinical history and subjected to a systematic examination and an upper GI endoscopy. The

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Table I. Demographic characteristics in the three groups of patients.

	Gp I (n = 2,673)			Gp II (n = 222)	Gp III (n = 447)
	ULD	DD	CTD	Dyspepsia & alarm	Alarm alone
Total no. of patients	1,898 (68.7)	193 (7)	353 + 319 (24.3)	222 (6.5)	447 (13)
Mean age (years)	41	41.8	39	45.3	46.2
No. of M:F (ratio)	1,203:695 (1.7:1)	115:78 (1.4:1)	171 + 190:148 + 163 (1.1:1)	136:86 (1.58:1)	253:194 (1.3:1)
Smokers	208 (11)	17 (8.8)	34 (10)	3 (1.35)	65 (14.54)
Alcoholics	74 (4)	3 (1.5)	3 (<1)	5 (2.25)	16 (3.58)
NSAIDs	125 (6.6)	3 (1.5)	22 (6.4)	19 (8.56)	7 (1.57)

ULD: ulcer-like dyspepsia; DD: dysmotility-like dyspepsia; CTD: combination of ulcer-like and dysmotility-like dyspepsia
M: male. F: female

Table II. Duration of symptoms and outcome of endoscopy.

Symptom duration (months)	No. (%) outcome			χ^2 test	p-value
	Normal	Benign	Malignant		
< 6	746 (51.3)	1,140 (67.3)	266 (93.7)	327.6	0.001
6-9	184 (12.7)	304 (17.9)	9 (3.2)		
> 9	523 (36.0)	251 (14.8)	9 (3.2)		
Total	1,453	1,695	284		

data was recorded on a prestructured proforma. Patients were categorised into three groups: group I comprised patients presenting with dyspepsia with reflux type/ulcer/dysmotility, either alone or in combination; group II comprised patients with dyspepsia and alarm symptoms; and group III comprised patients with alarm symptoms only.

All patients were registered between January 2004 and June 2005. Patient information included demographical data, details of smoking, alcohol consumption and use of non-steroidal anti-inflammatory drugs (NSAIDs). Clinical details included the duration of symptoms and details of alarm symptoms, viz. anorexia, weight loss, dysphagia, GI bleed, mass abdomen and anaemia. Endoscopy was performed a day following the registration by BS. A prestudy evaluation to define the endoscopic lesions was done for 50 cases and interobserver variations between BS and VJ were documented. In two cases, there was a variation in the interpretation between a duodenal ulcer (DU) and duodenal erosion. The outcomes of endoscopy were categorised as normal, benign and malignant. Benign lesions included: inflammatory changes in the oesophagus, stomach and duodenum, oesophageal web, and erosive and ulcer lesions of the stomach and duodenum. A biopsy was taken whenever malignancy was suspected.

Dyspepsia was defined according to the ROME III consensus criteria as: moderate to severe pain or

discomfort centred in the upper abdomen lasting for at least four weeks. Dyspepsia subtypes were classified as reflux-like, ulcer-like and dysmotility-like as previously described in a number of studies.⁽¹⁾ The outcome of endoscopy was correlated with the duration of illness, age of the patient and clinical diagnosis. The cut-off age for carcinoma of the upper GI tract in dyspepsia was derived. The outcome of the various alarm symptoms was also studied. Exclusion criteria were individuals who had an endoscopy for indications other than dyspepsia, those with a known ulcer disease, second look endoscopy for suspected malignancy, and post-gastric surgery on follow-up. Hospital ethics committee approval and informed and written consent by the patient were obtained before undertaking the study.

Demographical variables, social habits and outcome were given in frequencies with their percentages. Mean and standard deviation were calculated, where appropriate. The duration of symptoms and outcome of endoscopy association were analysed using the Pearson chi-square test. Cut-off age for malignancy was computed using receiver operator characteristic (ROC) analysis. Diagnostic parameters such as sensitivity, specificity and area under the curve were given separately for both genders. The Statistical Package for Social Sciences version 11.5 (SPSS Inc, Chicago, IL, USA) was used for the statistical analysis. A p-value of less than 0.05 was taken as being statistically significant.

Table III. Outcome of endoscopy in the three groups.

Groups	No. (%) endoscopy outcome			Total	χ^2 test	p-value
	Normal	Benign	Malignant			
Dyspepsia without alarm	1,223 (44.3)	1,415 (51.2)	125 (4.5)	2,763	265.1	0.001
Dyspepsia with alarm	77 (34.7)	97 (43.7)	48 (21.6)	222		
Alarm alone	153 (34.2)	183 (40.9)	111 (24.9)	447		

Table IV. Multivariate analysis using logistic regression.

	No. (%) with alarm (n = 2,763)	No. (%) without alarm (n = 669)	Adjusted odds ratio	Significance
Alcohol				
Yes	80 (2.9)	21 (3.1)	1.08	0.75
No	2,683 (97.1)	648 (96.9)		
Smoking				
Yes	259 (9.4)	68 (10.2)	1.07	0.61
No	2,504 (90.6)	601 (89.8)		
NSAID				
Yes	150 (5.4)	26 (3.9)	0.71	0.11
No	2,613 (94.6)	643 (96.1)		

RESULTS

A total 3,432 endoscopies were performed during the study period. Table I summarises the demographical characteristics of the study group. There were 2,068 men and 1,364 women, with a male-to-female ratio of 1.5:1. The overall mean age was 41.6 ± 5 (range 7–85) years. Men predominated in all three groups. Smoking, alcohol and use of NSAIDs were common to all the three groups. Two-thirds of male patients presented with some type of dyspepsia between 25 and 54 years of age. Alarm symptoms with dyspepsia often manifested above the age of 55 years. Less than 15% manifested with some alarm symptoms below the age of 45 years. Among women, the majority (two-thirds) had dyspepsia in the same age range as men. Less than 10% had alarm symptoms in combination with dyspepsia below the age of 25 years. Unlike men, alarm symptoms were present in one-third of patients below the age of 35 years.

Overall, endoscopy was normal in 1,453 patients (42.3%) and benign lesions were seen in 1,695 patients (49.4%). The remaining 284 patients (8.3%) had a histology-confirmed malignant lesion. Among the alarm symptoms, 231 patients (51.7%) presented with dysphagia, anaemia in 26 (5.8%) patients, mass in epigastrium in four (< 1%) and upper GI bleed in 68 (15.2%). Combination of alarm symptoms was present in 118 patients (26.4%). There was an inverse relation between the duration of illness and malignant outcome at endoscopy (Table II). This was statistically significant ($\chi^2 = 327.6$; $p = 0.001$). Malignant lesions were common when the duration of illness was less than six months. Those between six and nine months had a normal or

benign lesion, and endoscopy was invariably normal when the duration of symptoms exceeded nine months.

The prevalence of benign lesions was: DU (10.9%), gastric ulcer (GU) (5.3%), oesophageal ulcer (< 1%), oesophagitis (5.1%), erosive gastritis (12.2%) and duodenitis (7.7%). Achalasia cardia, cricopharyngeal web, Barrett's oesophagus and benign stricture of the oesophagus were noted in < 1%. The overall prevalence of peptic ulcer disease was 16.6%. Men had ulcer disease 1.55 times higher than females. Table III shows the outcome of endoscopy in the three groups. Malignant lesions were statistically significant in patients with alarm symptoms ($p = 0.001$). In all three groups, a normal or benign lesion was significantly more common, more so in Group I compared to Groups II and III. A quarter of patients in Group II and Group III had a malignant lesion. On multivariate analysis using logistic regression, alcohol, smoking and NSAID were equally distributed between Group I vs. Groups II and III (Table IV).

A quarter of the patients with alarm symptoms had a malignant pathology. One-third of patients with dysphagia had a mitotic lesion. Univariate analysis showed that dysphagia was independently associated with oesophageal malignancy. 56% of patients with a malignant lesion at endoscopy had alarm symptoms either alone or in combination. In Group I, 3.9% of individuals had carcinoma of the stomach, more so among men. Five patients had duodenal malignancy. Carcinoma oesophagus was common in Group III (80%). Of the 284 patients with malignancy, 49 patients (18.3%) had malignant lesions between 25 and 45 years of age, with

Table V. Optimum cut-off age for detecting malignancy using the ROC curve for both genders.

Gender	Age group (years)	Sensitivity	Specificity
Male	0–14	1.000	0.000
	15–24	0.985	0.144
	25–34	0.946	0.374
	35–44*	0.866	0.624
	45–54	0.569	0.808
	55–64	0.228	0.915
	> 64	0.000	1.000
Female	0–14	1.000	0.000
	15–24	1.000	0.139
	25–34	0.841	0.375
	35–44*	0.695	0.610
	45–54	0.524	0.805
	55–64	0.280	0.931
	> 64	0.000	1.000

*Using the coordinates of curve sensitivity and specificity, the cut-off age for malignancy was between 35 and 44 years.

10% of patients between 35 and 44 years of age. Using the coordinates of curve sensitivity and specificity, the cut-off age for malignancy was between 35 and 44 years. For females, the optimal cut-off age was 38 years with sensitivity of 70%, specificity of 61%, and area under ROC (AUROC) of 0.77. For males, the optimal cut-off age was 43.5 years with sensitivity of 88%, specificity of 62%, and AUROC 0.78 (Table V; Figs. 1 & 2).

DISCUSSION

Dyspeptic symptoms, which have a high prevalence and incidence in the population, are the most frequent reason for requesting for an upper endoscopy. It is not uncommon for any young patient with simple dyspepsia to get investigated. The uncertainty regarding which patients with dyspepsia should undergo upper endoscopy is not clear. 87% of patients had dyspepsia in the present study. Overall, dyspepsia is common in the general population and it is not clear whether the incidence of malignancy in patients with uncomplicated dyspepsia is different from those without dyspepsia.⁽²⁾ Also, the guidelines for appropriate use of upper endoscopy may result in a more rational selection of patients worldwide. Clinical history and examination show a diagnostic accuracy of only 45%–50%. The accuracy increases to 70%–80% on using a predefined questionnaire. The latter is time consuming and is not practical in day-to-day practice. Performing an endoscopy for all patients is also not practical, especially with the increased workload in the endoscopy suite. Clinical diagnosis is unreliable in diagnosing the underlying cause of dyspepsia.⁽³⁾ The role of an empirical therapy has been highlighted by earlier workers.⁽⁴⁾ Several studies have examined the discriminant

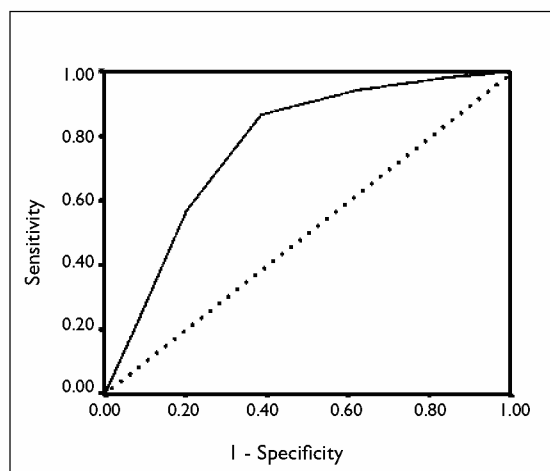


Fig. 1 Graph shows that the cut-off age for males with malignancy using the ROC curve is computed at 43.5 years. Diagonal segments are produced by ties.

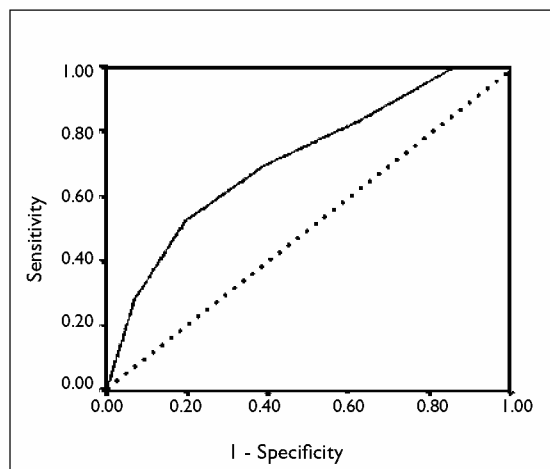


Fig. 2 Graph shows that the cut-off age for females with malignancy using the ROC curve is computed at 38 years. Diagonal segments are produced by ties.

value of various alarm symptoms for identifying the high-risk patients for early referral.^(5,6) Unlike the West, there are no set guidelines in India for clinicians to predict an appropriate outcome. The set guidelines are essential in order to enhance the quality of healthcare, reduce the cost and avoid unnecessary workload, and these need to be tailored. A number of alarm features have been suggested as indicators of high risk for a serious disease.^(7,8) These features include recent onset of dyspepsia in an older subject, occurrence at any age of the so-called alarm symptoms, viz. dysphagia, vomiting and/or weight loss.

Age is an important criterion while screening patients with dyspepsia for cancer. Among the Western population, the incidence of oesophageal and gastric cancers is very low for patients below the age of 45 years, and the Western recommendations do not justify the use of endoscopy in these patients to detect early cancer.⁽⁹⁾ As

per the American Society for Gastrointestinal Endoscopy report, only 1% of all dyspeptic patients will have an oesophageal or gastric cancer, and only six per 10,000 patients will have “early” gastric cancer at endoscopy.⁽⁹⁾ These criteria may not hold true in regions with a high prevalence of gastric and oesophageal cancers. In the present study, 5.6% of individuals with dyspepsia had a malignant lesion, more often a carcinoma of the stomach. There was a male preponderance. Also, more than 18.3% of patients with carcinoma would have been missed if the cut-off age of 45 years for endoscopy was followed as per the Western guidelines. Recommendations are empirical treatment for 4–6 weeks with antacids and H2 receptor antagonist for patients with dyspepsia and those below the age of 45 years. For our population, an empirical treatment can be recommended for those dyspeptics below the age of 35 years, provided they have no alarm symptoms, and an endoscopy can be performed after 4–6 weeks of registration. Studies have shown that serious complications seldom occur during the observation period.⁽¹⁰⁾ There is no evidence that a 4–6 week delay in diagnosis would adversely affect the natural course or the surgical cure rate of oesophageal or gastric cancer.⁽⁹⁾ In a developing country like India, this period would be warranted, considering the economic considerations of needless endoscopies. Most studies recorded normal upper endoscopy in dyspepsia varying from 30% to 40%.⁽¹¹⁾ In the present study, we found that 1,300 (43.5%) patients among the 2,985 patients with dyspepsia had a normal endoscopy. The uncertainty about the most appropriate use of upper endoscopy in the context of cost may result in underutilisation of the procedure. Froehlich et al conducted the only known study to look into the underutilisation of upper endoscopy and their rate was 11.8%.⁽¹²⁾

Symptoms of early gastric cancer are indistinguishable from a benign condition, whereas the presence of established alarm symptoms may signify the presence of an advanced inoperable lesion. A study suggested that only 7% of cancers in patients above 55 years of age present without alarm features.⁽¹³⁾ The yield of cancer in simple dyspepsia is low, and only a small proportion of those cancers identified are resectable.⁽¹⁴⁾ In the present study, 125 patients had cancer in the absence of alarm features, with a prevalence of 3.6% having dyspepsia without alarm features. Data from the UK⁽¹⁵⁾ and Europe suggest that approximately 10% of dyspeptic patients have alarm symptoms. Kapoor et al determined the predictive value of alarm symptoms in a cohort of 1,852 patients undergoing upper endoscopy. The mean age for

cancer was 54 ± 12 years. Cancer prevalence was 8.2% and gastric ulcer prevalence was 5.3%. In the same study, the predictive value as odds ratio (OR) for dysphagia was 3.1, weight loss 2.6, and 9.5 for those aged above 55 years. All these were found to have a positive predictive value for risk of cancer.⁽¹⁶⁾ In the present study, dysphagia was significantly associated with malignancy, followed by a combination of alarm symptoms (26.4%). The majority of our patients were from a low socioeconomic stratum. Hence, the higher rate of malignancy in this population was not surprising. Adang et al reported that generally-recognised alarm symptoms have been associated with demonstrable relevant endoscopy disease, i.e. ulcer disease, gastric or oesophageal malignancy.⁽¹⁷⁾ Older patients were referred for alarm symptoms and less often for dyspepsia than younger patients. Early upper GI cancer may be asymptomatic and diagnosed by chance in subjects complaining of dyspeptic symptoms that are secondary to a benign or functional cause.

The recommended age threshold for endoscopy also differs among different regions in Asia.^(18,19) In Hong Kong, 10% of patients with gastric cancer are aged less than 45 years. Sung et al reported that gastric cancer was found in three patients (0.1%), who were aged below 45 years and who did not have alarm symptoms, among 2,918 patients with dyspepsia. The investigators suggested that the “test-and-endoscopy” strategy might be a more feasible approach for dyspepsia in Hong Kong.⁽¹⁸⁾ In Singapore, the relative frequency of gastric cancer was 1.15 per 1,000 upper endoscopies in patients with simple dyspepsia and aged below 45 years. An age threshold of 45 years was therefore recommended for patients with simple dyspepsia in Singapore.⁽¹⁹⁾ A study from Taiwan considered that 40 years of age might be an appropriate age threshold for endoscopy, as 2.4 cases would be missed every year if they followed the international guidelines of 45 years.⁽²⁰⁾

The yield of endoscopy was low in patients referred for isolated dyspepsia, particularly when an individual was below the age of 45 years. A similar observation was made in the present study wherein 975 patients below 45 years of age had normal upper endoscopy. As per the British Society guidelines, 45 years is taken as cut-off for performing upper endoscopy. In an earlier retrospective audit on upper endoscopy from Coimbatore, south India, malignant lesions were uncommon below the age of 35 years. A rising incidence of oesophageal and gastric cancer was seen in the subsequent decades.⁽²¹⁾ In our study, malignancy was noted in 3.5% of the total study patients, and more than 10% of the patients diagnosed

with a malignancy belong to the age group between 35 and 44 years, with a peak around 40 years. Sensitivity and specificity tests for malignancy were found to be significant in the age group between 35 and 44 years. By ROC curve analysis, women developed malignancy five years earlier than men. As cancer was noticed at a younger age as compared to the West, we recommend the cut-off age for screening for malignancy among men should be 43.5 years and 38 years for women in a south Indian population. However, this needs to be further validated by longitudinal studies.

In Adang et al's series, the prevalence of clinically relevant endoscopic disease was 30%.⁽¹⁷⁾ This was similar to our study, which showed oesophagitis to be 5.1%, DU 10.9% and GU 5.3%. In most of the studies, age was a determinant factor for a high diagnostic yield of upper endoscopy. A delay of a few weeks in favour of an empirical therapy seems reasonable in a subset of patients with early upper GI cancer. Persistence of symptoms beyond four weeks should allow one to perform endoscopy in this subset of patients. In the present study, alarm symptoms were associated with a significant outcome at endoscopy, although 68 patients with dysphagia had normal endoscopy. Despite this, an early endoscopy within a week is desired in patients with any of the alarm symptoms either alone or in combination. Western guidelines had proposed 45 years as the cut-off age with regard to the question whether or not to investigate dyspepsia as an isolated symptom. Earlier studies have shown a high prevalence of oesophageal and gastric cancers in the south Indian population. Of the 284 patients with malignant lesions on endoscopy, 52 patients (18.3%) who had malignant lesions were between 25 and 45 years of age, with almost 10% of patients between 35 and 44 years, which would have been missed if the Western guidelines were followed.

The British Society of Gastroenterology had suggested a two-week wait period to undergo upper endoscopy and to evaluate the cause for dyspepsia. Considering the high incidence of malignant lesions in patients below 45 years of age, and based on the results of our study, we propose the following guidelines for a south Indian population that will improve the outcome of an endoscopy both in terms of diagnosis and management:

- (1) Dyspepsia with no alarm symptoms, age less than 35 years, duration of illness more than six months: empirical H2 receptor antagonist or antacid. If symptoms persist at the end of four weeks, upper endoscopy is to be done within one week.
- (2) Dyspepsia with alarm symptoms, or those with

isolated alarm symptoms: upper endoscopy within a week.

- (3) Dyspepsia above the age of 35 years, newly-acquired alarm symptoms or persistence of symptoms or recurrence during or after empiric therapy: upper endoscopy within one week.

Indications for endoscopy ultimately need to be tailored according to the clinical presentation of dyspepsia. A normal endoscopy of dyspepsia cannot be dismissed as irrelevant. Reassurance provided by normal findings may subsequently result in fewer symptoms, avoidance of unnecessary treatment and decreased consultation rate. For the future, the current guidelines laid down in this study needs extrapolation and prospective validation in different regions within and outside the country, with its economic and social implications in terms of number of lives saved and the cost factor by decreasing the cut-off age of endoscopy to 35 years.


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